Records processed under FOIA request 2017-9992; Released on 1/29/2019

K111010
p. 1 of 4

OCT 2 7 2011

510(k) Summary

SpiderFX® Embolic Protection Device

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1. Submitter Information

Applicant	ev3 Inc. 3033 Campus Drive Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Brenda Johnson Principal Regulatory Affairs Specialist
Date Prepared	October 26, 2011

2. Subject Device

Device Trade Name	SpiderFX® Embolic Protection Device
Device Common Name	Embolic Protection Device
Classification Name	Temporary Carotid Catheter for Embolic Capture 21 CFR 870.1250, Product Code NTE
Classification Panel	Cardiovascular

3. Predicate Devices

Device Trade Name	SpiderFX® Embolic Protection Device; SpideRX® Embolic Protection Device Angioslide eXtra™ PTA Balloon Catheter with Embolic Capture Feature
510(k) Number	K063204; K052659; K090364
510(k) Clearance Date	November 14, 2006; February 17, 2006; March 23, 2010

4. Device Description

The SpiderFX® Embolic Protection Device is a percutaneously delivered distal embolic protection system that can be delivered over any 0.014" or 0.018" guidewire. The SpiderFX Embolic Protection Device contains a Capture Wire composed of a nitinol mesh filter mounted on a 190 cm or a convertible 320/190 cm PTFE-coated 0.014" stainless steel guidewire and a dual-ended SpiderFX Catheter for delivery and recovery. The SpiderFX® Embolic Protection Device uses the following materials: pebax, grilamid, platinum/iridium, nitinol, stainless steel, PTFE coating, gold tungsten, and hydrophilic coating.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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5. Indications for Use

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities.

6. Comparison of Technological Characteristics

The SpiderFX® Embolic Protection Device is the identical device as the currently marketed SpiderFX Embolic Protection Device (K063204). The SpiderFX Embolic Protection Device for peripheral use and the predicate SpiderFX Embolic Protection Device for carotid use share the following technological characteristics:

- Intended use
- Fundamental scientific technology and operating principle
- Design & Dimensions
- Materials
- Manufacturing site and methods
- Sterilization site, method, parameters, and sterility assurance level
- Packaging
- Shelf Life

Additionally, the Indications for Use, labeling, and Instructions For Use are similar between the proposed and marketed devices. The differences include a revised sizing matrix for use during interventions in lower extremity vessels, allowing use of the SpiderFX Device with atherectomy interventional devices, and allowing use of commercially available catheters, that are minimally 0.035" guide wire compatible, for delivery and/or recovery of the SpiderFX Capture Wire. Bench and animal testing was performed to demonstrate the proposed use of the device met pre-determined acceptance criteria.

7. Biocompatibility Testing

Device materials in the proposed SpiderFX® Embolic Protection Device are identical to the materials in the commercially available SpiderFX® and SpideRX® Embolic Protection Devices. Biocompatibility testing was leveraged from the predicate SpiderFX® and SpideRX® Embolic Protection Device submissions and included cytotoxicity, sensitization, intracutaneous injection, systemic injection, hemolysis, pyrogen, complement activation, and thrombogenicity. The SpideRX Catheter and Capture Wire from the predicate SpideRX Device (K052659) meet the requirements for biocompatibility testing outlined in ISO 10993-1 Part 1: 2003 "Biological Evaluation of Medical Devices".

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8. Performance Testing Summary

To demonstrate substantial equivalence of the subject SpiderFX® Embolic Protection Device to the predicate device, the technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Analysis procedures, the following tests were performed:

- Stent Compatibility
- Filter Efficiency
- Radial Outward Force
- Simulated Use
- Deployment/Retrieval Forces
- *In Vivo* Animal Studies

The following testing was leveraged from the predicate SpiderFX® and SpideRX® Embolic Protection Device submissions. Test results met the specified acceptance criteria and were included in K063204 or K052659:

- Embolic Capture Efficiency and Retrieval Ability
- Simulated Use
- Deployment/Retrieval Forces
- Filter Capacity
- Resistance to Filter Rupture During Removal of a Fully Loaded Filter
- Flow Characteristics
- Tip Flexibility
- Tensile Strength
- Torque Strength
- Torque Response
- Kink Resistance
- Dimensional Verification
- Package Integrity
- Sterilization
- Shelf Life

The results from these tests demonstrate that the technological characteristics and performance criteria of the SpiderFX® Embolic Protection Device are comparable to the predicate device and that the SpiderFX® Embolic Protection Device performs in a manner equivalent to the predicate device currently on the market for the same intended use.

9. Clinical Summary

DEFINITIVE Ca^{++} was a prospective, multi-center, non-randomized, single-arm study to compare the SilverHawk TurboHawk and the SpiderFX to performance goals derived from an observational multi-center registry (TALON) of subjects with lower extremity PAD who underwent revascularization with catheter-based plaque excision. The purpose of this study was to evaluate the safety and effectiveness of the SilverHawk/TurboHawk and the SpiderFX for the treatment of moderate to severely calcified peripheral arterial disease (PAD) in the superficial femoral and/or the popliteal arteries.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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P. 4 of 4

The primary safety endpoint of the DEFINITIVE Ca^{++} study was freedom from major adverse event (MAE) rate. MAE was defined as a serious adverse event that results in death, acute myocardial infarction, dissection (grade C or greater), clinical perforation, pseudo-aneurysm, thrombosis, distal embolism (clinically relevant), amputation, or clinically-driven TVR, through 30 days post-procedure, as adjudicated by the clinical events committee (CEC). The 30-day freedom from MAE rate was 93.1% (122/131). The 95% lower confidence limit was 88.3% (as calculated by the Exact method), greater than the performance goal of 85.5%. Therefore, the primary safety endpoint was met.

10. Conclusions

Based on the intended use, technological characteristics, safety and performance testing included in this submission, ev3 considers the proposed SpiderFX® Embolic Protection Device to be substantially equivalent to its predicates.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

OCT 2 7 2011

ev3, Inc.
c/o Ms. Brenda Johnson
Principal Regulatory Affairs Specialist
3033 Campus Drive
Plymouth, MN 55441

Re: K111010
Trade/Device Name: SpiderFX Embolic Protection Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: September 30, 2011
Received: October 3, 2011

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Indications for Use Statement

510(k) Number (if known): K111010

Device Name: SpiderFX® Embolic Protection Device

Indications for Use:

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111010

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 17 2011

ev3, Inc.
c/o Brenda Johnson
Principal Regulatory Affairs Specialist
3033 Campus Drive
Plymouth, MN 55441

Re: K111010
Trade Name: SpiderFX Embolic Protection Device
Dated: April 8, 2011
Received: April 11, 2011

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies.

Animal Studies

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)



Labeling

(b) (4)



The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Todd Courtney at (301) 796-6371. If you need information or assistance concerning the IDE regulations, please

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Gina Mourning
for

Lisa M. Lim, PhD
Acting Chief
Peripheral Vascular Devices Branch
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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* * * COMMUNICATION RESULT REPORT (AUG. 17. 2011 3:19PM) * * *

FAX HEADER 1:
FAX HEADER 2:

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5291 MEMORY TX	EV3 Rightfax	OK	5/5

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

FAX COVER SHEET

U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION

DIVISION OF CARDIOVASCULAR DEVICES
10903 NEW HAMPSHIRE
SILVER SPRING, MARYLAND 20993-0002

NO. OF PAGES: 5 (including cover sheet) DATE: 8/17/11

TO: MS. Johnson FAX#: 763-591-3248

COMMENTS:

Re: K111010

SENDER'S NAME: Ann Hyun

SENDER'S FAX # Room # 1201 ☐ (301) 847-8114 Room # 1217 ☐ (301) 847-8115 Room # 1303 ☐ (301) 847-8116

FROM:
- ☐ Office of the Director - (301) 796-5610
- ☐ Cardiac Electrophysiology & Monitoring Devices (CEMD) - (301) 796-5630
- ☐ Pacing, Defibrillator & Leads Branch (PDLB) - (301) 796-
- ☐ Circulatory Support & Prosthetics (CSPB) - (301) 796-
- ☐ Interventional Cardiology Devices (ICDB) - (301) 796-5570
- ☐ Peripheral Vascular Devices Branch (PVDB) - (301) 796-5610

****

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

* * * COMMUNICATION RESULT REPORT (AUG. 17. 2011 3:19PM) * * *

FAX HEADER 1:
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REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-3) NO ANSWER
E-2) BUSY
E-4) NO FACSIMILE CONNECTION

FAX COVER SHEET

U.S. FOOD AND DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION

DIVISION OF CARDIOVASCULAR DEVICES
10903 NEW HAMPSHIRE
SILVER SPRING, MARYLAND 20993-0002

NO. OF PAGES: 5 (including cover sheet) DATE: 8/17/11

TO: Ms. Johnson FAX#: 763-591-3248

COMMENTS: Re: K111010

SENDER'S NAME: Ann Hugel

SENDER'S FAX # Room # 1201 ☐ (301) 847-8114 Room # 1217 ☐ (301) 847-8115 Room # 1303 ☐ (301) 847-8116

FROM:
- ☐ Office of the Director - (301) 796-5610
- ☐ Cardiac Electrophysiology & Monitoring Devices (CEMB) - (301) 796-5630
- ☐ Pacing, Defibrillator & Leads Branch (PDLB) - (301) 796-
- ☐ Circulatory Support & Prosthetics (CSPB) - (301) 796-
- ☐ Interventional Cardiology Devices (ICDB) - (301) 796-5570
- ☐ Peripheral Vascular Devices Branch (PVDB) - (301) 796-5610

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

OCT 2 7 2011

ev3, Inc.
c/o Ms. Brenda Johnson
Principal Regulatory Affairs Specialist
3033 Campus Drive
Plymouth, MN 55441

Re: K111010
Trade/Device Name: SpiderFX Embolic Protection Device
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NTE
Dated: September 30, 2011
Received: October 3, 2011

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Indications for Use Statement

510(k) Number (if known): K111010

Device Name: SpiderFX® Embolic Protection Device

Indications for Use:

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111010

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

October 04, 2011

EV3 INC
3033 CAMPUS DRIVE
PLYMOUTH, MINNESOTA 55441
ATTN: BRENDA JOHNSON

510k Number: K111010

Product: SPIDERFX EMBOLIC PROTECTION DE

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Pleaseremember that all correspondence concerning your submission MUST be sent to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely,

510(k) Staff

54

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

September 14, 2011

EV3 INC
3033 CAMPUS DRIVE
PLYMOUTH, MINNESOTA 55441
ATTN: BRENDA JOHNSON

510k Number: K111010
Product: SPIDERFX EMBOLIC PROTECTION DE

Extended Until: 10/18/2011

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(l)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

56

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ev3 Your endovascular company.™

September 13, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA CDRH DMC
SEP 14 2011
Received K27

Contents: Two paper copies

RE: K111010, SpiderFX Embolic Protection Device
Request for 30-Day Extension

To Whom It May Concern:

ev3 Endovascular Inc., doing business as ev3, is supplying the enclosed information as an amendment to **K111010**. This amendment is provided to request a 30-day extension to respond to questions received in a letter from FDA dated August 17, 2011. ev3 will provide the response to FDA's letter prior to September 17, 2011.

If additional information is required, please contact me. My contact information is provided below.

Sincerely,

Brenda Johnson
Principal Regulatory Affairs Specialist
E-mail: brenda.johnson@ev3.net
Phone: 763-398-7238
Fax: 763-591-3248

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

ev3 Your endovascular company.™

September 13, 2011

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

August 18, 2011

EV3 INC
3033 CAMPUS DRIVE
PLYMOUTH, MINNESOTA 55441
ATTN: BRENDA JOHNSON

510k Number: K111010
Product: SPIDERFX EMBOLIC PROTECTION DE

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceProvisionsofFDAModernizationAct/ucm136685.htm.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

60

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301)796-7100 or at their toll-free number (800)638-2041, or contact the 510k staff at (301)796-5640.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

April 12, 2011

EV3 INC
3033 CAMPUS DRIVE
PLYMOUTH, MINNESOTA 55441
ATTN: BRENDA JOHNSON

510k Number: K111010
Received: 4/11/2011
Product: SPIDERFX EMBOLIC PROTECTION DE

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

On September 27, 2007, the President signed an act reauthorizing medical device user fees for fiscal years 2008 - 2012. The legislation - the Medical Device User Fee Amendments of 2007 is part of a larger bill, the Food and Drug Amendments Act of 2007. Please visit our website at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/default.htm
for more information regarding fees and FDA review goals. In addition, effective January 2, 2008, any firm that chooses to use a standard in the review of ANY new 510(k) needs to fill out the new standards form (Form 3654) and submit it with their 510(k). The form may be found at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm. According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "Interactive Review for Medical Device Submissions: 510(k)s, Original PMAs, PMA Supplements, Original BLAs and BLA Supplements". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm. Please refer to this guidance for information on a formalized interactive review process. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.html. In addition, the 510(k) Program Video is now available for viewing on line at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm070201.htm .

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have questions on the status of your submission, please contact DSMICA at (301)796-7100 or the toll-free number (800)638-2041 , or at their internet address http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm. If you have procedural questions, please contact the 510(k) Staff at (301)796-5640.

Sincerely,

510(k) Staff

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

ev3 Your endovascular company.

CV|OCD
K111010

FDA

APR 11 2011

Received

4 510(k) Cover Letter

April 8, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066 – G609
10903 New Hampshire Ave.
Silver Spring, Maryland 20993-0002

Contents: **One paper copy**
One eCopy – exact duplicate of paper copy

RE: Traditional 510(k) Submission for the ev3 SpiderFX Embolic Protection Device, Peripheral Indication

To Whom It May Concern:

Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act and in accordance with 21 CFR 807.90(e), ev3 Endovascular Inc., doing business as ev3, is submitting the attached Premarket Notification. The basis for this submission is a modified indication for a legally marketed device. The legally marketed predicate devices are the SpiderFX Embolic Protection Device (K063204) and the SpideRX Embolic Protection Device (K052659).

This Traditional 510(k) Premarket Notification is supported by clinical data from the DEFINITIVE Ca^{++} study (G080017). The DEFINITIVE Ca^{++} study included class II devices from two separate product codes (embolic protection and plaque excision). Because each device requires a separate 510(k), this submission is exclusively for the SpiderFX Embolic Protection Device for use while performing revascularization of arteries in the lower extremities. ev3 plans to submit a separate 510(k) for the plaque excision devices that were used in the study together with the SpiderFX Embolic Protection Device.

The SpiderFX Embolic Protection Device is intended for use as a percutaneously delivered distal embolic protection device. The SpiderFX Device is designed to capture and remove dislodged debris during interventional procedures. The device Capture Wire is used as the 0.014" wire for interventional device delivery. The identical SpiderFX Embolic Protection Device currently has clearance for use during interventions in carotid arteries (K063204) and saphenous vein grafts (K063785).

ev3 Corporate World Headquarters / Peripheral Vascular • 3033 Campus Drive, Plymouth, MN 55441, USA • **Ph** +1 763 398 7000
ev3 Neurovascular • 9775 Toledo Way, Irvine, CA 92618 • **Ph** +1 949 837 3700
ev3 Europe / International Headquarters • 106/108 rue La Boétie, 75008 Paris, France • **Ph** +33 156 88 59 10

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The proposed SpiderFX Device uses the identical design and materials as the legally marketed predicate SpiderFX Device. However, to support the IDE study (G080017), ev3 identified that compatibility testing needed to be completed with atherectomy, thrombectomy, and laser devices, because of their widespread use during lower extremity interventions in the United States. During the compatibility testing it was noted that it is advantageous to use a larger SpiderFX filter in a smaller vessel for two reasons: 1) to provide an increased filter capacity, and 2) to optimize filter stability during the peripheral intervention. Additionally, ev3 received feedback from physicians that in certain situations the current SpiderFX Catheter does not provide an ideal amount of support to initially cross the lesion and/or to recover the SpiderFX Capture Wire in lower extremity vessels. Preclinical bench and animal testing was completed to verify that the SpiderFX Device performed safely and as intended when used in lower extremity vessels with the revised sizing matrix, and testing verified the compatibility of commercially available catheters for delivery and/or recovery of the SpiderFX Capture Wire. This submission includes these changes in the proposed labeling and Instructions for Use.

Performance standards for Embolic Protection Devices have not been established under Section 514 of the Federal Food, Drug, and Cosmetic Act. Embolic Protection Devices are covered by the following regulations:

Trade Name	SpiderFX™ Embolic Protection Device
Common Name	Embolic Protection Device
Classification Name	Temporary Carotid Catheter for Embolic Capture
Classification Regulation	21 CFR 870.1250
Classification Panel	Cardiovascular
Device Class	II (two)
Product Code	NTE

The Address the principal factors about the design and use of your device in a tabular format, for example, by answering questions shown in the table below.

Design and Use of the Device

Question	**YES**	**NO**
Is the device intended for prescription use (21 CFR 801 Subpart D)?	**X**	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		**X**
Does the device contain components derived from a tissue or other biologic source?	**X**	
Is the device provided sterile?	**X**	
Is the device intended for single use?	**X**	
Is the device a reprocessed single use device?		**X**
If yes, does this device type require reprocessed validation data?	**n/a**	
Does the device contain a drug?		**X**
Does the device contain a biologic?		**X**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment A: Engineering Drawings

703318, Capture Wire Assy, Heparin Coated
703314, Catheter, Double Ended

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Engineering Drawings

Records processed under FOIA request 2017-9992; Released on 1/29/2019



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Engineering Drawings

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment B: Proposed Product Labeling

SpiderFX Device box and pouch label (peripheral use)
SpiderFX Device Instructions for Use (peripheral use)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

ev3™

SpiderFX is a trademark of ev3 and may be registered in the US and other countries.
Protected under one or more of the following: US Patent 7,717,934; 7,637,920; 7,556,636; 7,556,635; 7,410,492; 7,404,820; 7,371,250; 7,367,986; 7,166,080; 6,979,343; 6,843,798; 6,712,835; 6,325,815. Non-US patents issued & pending.

500687-003 Rev C

7.0 mm ⊘	320/190 cm ↔	.014" 0.36mm ⊖

SpiderFX™

Embolic Protection Device

REF Model モデル	SPD2-US-070-320
LOT Lot. No. ロット番号	1234567
Use By 使用期限	2020-12-31

(1) Capture Wire
(1) SpiderFX Catheter
(1) Flushing Needle
Product Literature

Recommended Peripheral Vessel Size	4.5 - 6.0mm
Recommended Carotid Vessel Size	5.5 - 7.0mm
Recommended SVG Vessel Size	5.5 - 6.0mm
Guide Compatibility	6F (min ID .066")

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Manufactured in the U.S.A.

ev3™ SpiderFX™ 7.0mm
REF: SPD2-US-070-320
LOT 1234567
2020-12-31
(01) 0 0821684 04037 9 (17) 201231 (10) 1234567

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REF: SPD2-US-070-320
LOT 1234567
2020-12-31
(01) 0 0821684 04037 9 (17) 201231 (10) 1234567

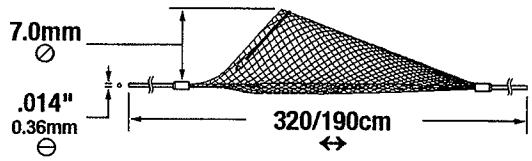
ev3™ SpiderFX™ 7.0mm
REF: SPD2-US-070-320
LOT 1234567
2020-12-31
(01) 0 0821684 04037 9 (17) 201231 (10) 1234567

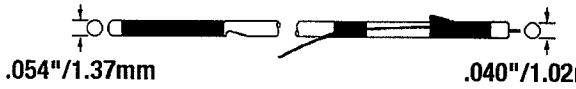
MANUFACTURER
ev3 Inc.
4600 Nathan Lane North
Plymouth, MN
55442-2920 USA

Phone 763.398.7000
800.716.6700
FAX 763.398.7200

Single Use | Keep Dry | Do Not Store in Direct Sunlight | STERILE EO Sterilized Using Ethylene Gas

CAUTION, CONSULT ACCOMPANYING DOCUMENTS





(01) 0 0821684 04037 9
(17) 201231 (10) 1234567

℞ only

500762-300 Rev. H

SpiderFX™
(01) 0 0821684 04037 9 (17) 201231 (10) 1234567

ev3™

7.0 mm ⊘	320/190 cm ↔	.014" 0.36mm ⊖	REF SPD2-US-070-320
			LOT 1234567
			2020-12-31

SpiderFX™
(01) 0 0821684 04037 9 (17) 201231 (10) 1234567

ev3™

7.0 mm ⊘ | 320/190 cm ↔ | .014" 0.36mm ⊖
REF SPD2-US-070-320
LOT 1234567
2020-12-31

(01) 0 0821684 04037 9 (17) 201231 (10) 1234567
SpiderFX™
ev3™
7.0 mm ⊘ | 320/190 cm ↔ | .014" 0.36mm ⊖
REF SPD2-US-070-320
LOT 1234567
2020-12-31

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

500400-003 Rev C

ev3™

SpiderFX is a trademark of ev3 and may be registered in the US and other countries.
Protected under one or more of the following: US Patent 7,717,934; 7,637,920; 7,556,636; 7,556,635; 7,410,492; 7,404,820; 7,371,250; 7,367,986; 7,166,080; 6,979,343; 6,843,798; 6,712,835; 6,325,815. Non-US patents issued & pending.

SpiderFX™

Embolic Protection Device

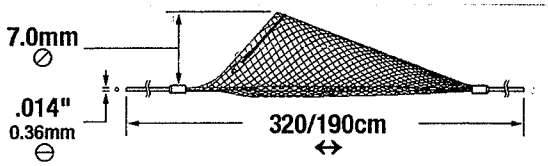
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REF Model モデル	SPD2-US-070-320
LOT Lot. No. ロット番号	1234567
Use By 使用期限	2020-12-31
(1) Capture Wire (1) SpiderFX Catheter (1) Flushing Needle	
Recommended Peripheral Vessel Size	4.5 - 6.0mm
Recommended Carotid Vessel Size	5.5 - 7.0mm
Recommended SVG Vessel Size	5.5 - 6.0mm
Guide Compatibility	6F (min ID .066")
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ev3™ SpiderFX™ 7.0mm LOT 1234567
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(01) 0 0821684 04037 9 (17) 201231 (10) 1234567





MANUFACTURER
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Phone 763.398.7000
800.716.6700
FAX 763.398.7200

Single Use | Keep Dry | Do Not Store in Direct Sunlight

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(17) 201231 (10) 1234567

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500762-200 Rev. H

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ev3®

SpiderFX™

Embolic Protection Device

Instructions for Use

PRODUCT DESCRIPTION

The SpiderFX™ Embolic Protection Device is a percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The SpiderFX Device Capture Wire is used as the 0.014 in. wire for interventional device delivery. The SpiderFX Device can be delivered over any 0.014 in. or 0.018 in. primary wire used to gain access to the lesion site.

The SpiderFX Embolic Protection Device package contains the following components:

- One **Capture Wire** composed of a nitinol mesh Filter with a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter features a heparin-coating designed to maintain patency during Filter deployment[1]. This Capture Wire acts as the primary guidewire for other interventional devices compatible with a 0.014 in. wire. The convertible 320/190 cm Capture Wire is scored, allowing the wire to be snapped to a 190 cm usable length for use with rapid exchange systems, if desired. The distal portion of the Capture Wire for rapid exchange use is gold. The proximal portion for standard over-the-wire use is black.

  [1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.

- One dual-ended **SpiderFX Catheter** used to exchange the primary access guidewire with the Capture Wire, deploy the Capture Wire at the desired location, and recover the Capture Wire at the end of the procedure.
- One 23 gauge Blunt Needle for attachment to a syringe with Luer connector for priming and flushing the Catheter.

Components are delivered sterile, for use within a single vessel only. Do not re-sterilize or reuse.

NOTE: *Commercially available catheters may also be used for delivery/recovery of the SpiderFX Capture Wire. Confirm that the Catheter of Choice is 0.035" guidewire compatible and is compatible with the Capture Wire length, guide catheter/sheath, and primary guidewire prior to use.*

INDICATIONS FOR USE

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material during revascularization procedures of arteries in the lower extremities. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 6.0mm.

CONTRAINDICATIONS

Use of the SpiderFX Embolic Protection Device is contraindicated under these circumstances:

- Do not use with patients in whom anticoagulant and antiplatelet therapy is contraindicated
- Do not use in vessels with excessive tortuosity
- Do not use in patients with uncorrected bleeding disorders
- Do not use in the renal arteries

WARNINGS

The SpiderFX Embolic Protection Device should be used only by physicians who are trained in the proper use of the device.

- This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilizing could increase the risk of patient infection and risk of compromised device performance.
- Refer to the instructions supplied with all interventional devices to be used in conjunction with the SpiderFX Embolic Protection Device for their intended uses, contraindications and potential complications.
- The safety and effectiveness of this device as an embolic protection system have not been established in the renal or iliac arteries.
- The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure in accordance with standard medical practice.
- Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 2 Sizing Guide).
- Do not grip the Catheter at the distal white tips of either end. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.
- Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.
- Maintain the Capture Wire exit port of the SpiderFX Delivery Catheter within Guide Catheter/Sheath. This results in a 38 cm maximum distance from distal tip of Guide Catheter/Sheath to distal tip of Delivery Catheter. Failure to maintain this port within the Guide Catheter/Sheath may result in increased Filter advancement/deployment forces and vessel and/or device damage.
- Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.
- Do not apply excessive force to the Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.
- Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.
- Do not place the SpiderFX Capture Wire tip in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.
- Do not deploy the Filter within a previously implanted stent.
- Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX (or comparable) Catheter. This may lead to embolization of debris, and vessel and/or device damage.
- Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow. If slow/no flow should occur, the Filter should be recovered (See *Recovery and Removal*).
- Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.
- Do not use mechanical rotational thrombectomy with the Capture Wire.
- Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow flow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).
- After recovering the Filter, do not attempt to flush the Filter and/or reintroduce the Filter into the patient. The Filter must be discarded and a new Filter used if embolic protection is still needed.
- Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the SpiderFX (or comparable) Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

PRECAUTIONS

- Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.
- Do not use the product if the packaging sterile barriers have been damaged or compromised.
- If using the SpiderFX Delivery Catheter for filter delivery, the Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.
- Improper bending of the SpiderFX Catheter at the Primary Wire Exit Port could result in damage to the Catheter.
- If using the SpiderFX Catheter for filter delivery, DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.
- Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the catheter.
- Do not advance the Filter while the primary wire is still within the catheter lumen.
- Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without coming within 2 cm of the Filter proximal end.

Summary of DEFINTIVE Ca++ Study

DEFINITIVE Ca++ was a prospective, multi-center, non-randomized, single-arm study to compare the SilverHawk TurboHawk and the SpiderFX to performance goals derived from an observational multi-center registry (TALON) of subjects with lower extremity PAD who underwent revascularization with catheter-based plaque excision. The purpose of this study was to evaluate the safety and effectiveness of the SilverHawk/TurboHawk and the SpiderFX for the treatment of moderate to severely calcified peripheral arterial disease (PAD) in the superficial femoral and/or the popliteal arteries.

A total of 133 subjects were enrolled. Subject demographics are provided in Table1.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-811

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Table 1: Subject Demographics and Baseline Clinical Characteristics

Subject Characteristics	N=133
Age (yrs.)	
Mean ± SD (N)	69.7 ± 9.8 (133)
Range (min, max)	(41.0, 95.0)
Male	71.4% (95/133)
Diabetes	47.4% (63/133)
History of hypertension requiring medication	91.7% (122/133)
History of MI	30.8% (41/133)
Hyperlipidemia	88.0% (117/133)
History of CABG or PCI	52.6% (70/133)
History of major amputation	0.8% (1/133)
Family history of CAD	49.6% (66/133)
History of peripheral intervention	57.1% (76/133)
History of smoking	78.9% (105/133)
CVA/TIA	15.8% (21/133)
Renal insufficiency	24.8% (33/133)
Rutherford clinical category score	
2	31.6% (42/133)
3	52.6% (70/133)
4	15.8% (21/133)

MI- myocardial infarction, CABG- coronary artery bypass graft, PCI- percutaneous coronary intervention, CAD- coronary artery disease, CVA- cerebrovascular accident, TIA - transient ischemic attack

The primary safety endpoint of the DEFINITIVE Ca++ study was freedom from major adverse event (MAE) rate. MAE was defined as a serious adverse event that results in death, acute myocardial infarction, dissection (grade C or greater), clinical perforation, pseudo-aneurysm, thrombosis, distal embolism (clinically relevant), amputation, or clinically-driven TVR, through 30 days post-procedure, as adjudicated by the clinical events committee (CEC). The 30-day freedom from MAE rate was 93.1% (122/131). The 95% lower confidence limit was 88.3% (as calculated by the Exact method), greater than the performance goal of 85.5%. Therefore, the primary safety endpoint was met. A summary of the MAEs is provided in Table 2.

Table 2: Summary of Major Adverse Events

Major Adverse Event	
Total	6.8% (9/133) [9]
Death	0.0% (0/133) [0]
Acute myocardial infarction	0.8% (1/133) [1]
Dissection, target vessel (C)	0.0% (0/133) [0]
Dissection, target vessel (grade D or greater)	0.8% (1/133) [1]
Vessel clinical perforation, target vessel	2.3% (3/133) [3]
Pseudoaneurysm, target vessel	0.0% (0/133) [0]
Thrombosis, target vessel	0.8% (1/133) [1]
Distal embolism	2.3% (3/133) [3]
Amputation, above metatarsal line	0.0% (0/133) [0]
Clinically Driven TVR	0.0% (0/133) [0]

Presence of debris in the SilverHawk/TurboHawk and SpiderFX by visual inspection at time of procedure was assessed. Debris (excised plaque) was present in the nosecone of the SilverHawk/TurboHawk devices in 97.0% (129/133) of cases. Debris was present in 88.4% (122/138) of deployed SpiderFX filters upon recovery. Preservation of run-off distal to SpiderFX was determined by angiography of run-off vessels at the end of the procedure, as adjudicated by the angiographic core laboratory. Preservation of run-off was verified by the angiographic core laboratory in 98.3% (113/115) of subjects with available data. The proportion of asymptomatic subjects increased from 0% at baseline to 52.3% at the 30-day follow-up visit. Likewise, the proportion of subjects with severe claudication decreased from 52.6% at baseline to 6.2% at 30 days

Adverse Events

A summary of device- and procedure-related adverse events is provided in Table 3. There were no Unanticipated Adverse Device Effects or deaths.

Table 3: Summary of Device and Procedure-Related Adverse Events and Serious Adverse Events

Adverse Event	Procedure-Related	Study Requirement-Related	SilverHawk-Related	TurboHawk-Related	SpiderFX-Related	% of subjects [# of events]
All Related Events	38.3% (51/133) [64]	1.5% (2/133) [2]	18.4% (14/76) [14]	19.3% (11/57) [11]	3.8% (5/133) [5]	39.8% (53/133) [66]
Access site adverse event	6.0% (8/133) [9]					6.0% (8/133) [9]
AV fistula, target vessel	0.8% (1/133) [1]					0.8% (1/133) [1]
Dissection, grade A or B; non-target vessel	0.8% (1/133) [1]					0.8% (1/133) [1]
Dissection, grade A or B; target vessel	19.5% (26/133) [26]		13.2% (10/76) [10]	10.5% (6/57) [6]		19.5% (26/133) [26]
Dissection, grade D or greater; target vessel	1.5% (2/133) [2]			3.5% (2/57) [2]		1.5% (2/133) [2]
Distal embolism; plaque, thrombus (blood clot) or debris distal to the filter, clinically relevant	2.3% (3/133) [3]		2.6% (2/76) [2]	1.8% (1/57) [1]	2.3% (3/133) [3]	2.3% (3/133) [3]
GI bleeding due to antico-agulation		0.8% (1/133) [1]				0.8% (1/133) [1]
Hypotension or hypertension	1.5% (2/133) [2]	0.8% (1/133) [1]				2.3% (3/133) [3]
Myocardial infarction, acute	0.8% (1/133) [1]					0.8% (1/133) [1]

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Table 3: Summary of Device and Procedure-Related Adverse Events and Serious Adverse Events

Adverse Event	Procedure-Related	Study Requirement-Related	SilverHawk-Related	TurboHawk-Related	SpiderFX-Related	% of subjects [# of events]
Pseudoaneurysm, non-target vessel	0.8% (1/133) [1]					0.8% (1/133) [1]
Renal insufficiency	1.5% (2/133) [2]					1.5% (2/133) [2]
Thrombosis (acute and subacute); target vessel	0.8% (1/133) [1]		1.3% (1/76) [1]			0.8% (1/133) [1]
Vasospasm	1.5% (2/133) [2]				1.5% (2/133) [2]	1.5% (2/133) [2]
Vessel clinical perforation, target vessel	2.3% (3/133) [3]		1.3% (1/76) [1]	3.5% (2/57) [2]		2.3% (3/133) [3]
Other, respiratory	0.8% (1/133) [1]					0.8% (1/133) [1]
Other	5.3% (7/133) [9]					5.3% (7/133) [9]

The results of the DEFINITIVE Ca++ study demonstrate that the SilverHawk/TurboHawk device is safe and effective in the endovascular treatment of moderate to severely calcified lesions in the superficial femoral and/or popliteal arteries when used with the SpiderFX embolic protection device. The data also showed that utilizing the SpiderFX embolic protection device resulted in preservation of run-off in 98.3% of subjects, further supporting that the use of the SpiderFX device is a safe and effective means of embolic protection in subjects undergoing endovascular treatment for peripheral arterial disease.

POTENTIAL COMPLICATIONS

Complications associated with the use of the SpiderFX Embolic Protection Device may include, but are not limited to:

- Access site adverse event (e.g., av fistula, hematoma, hemorrhage, pseudoaneurysm, puncture site infection)
- Adjunct device entanglement
- Adverse reaction to antiplatelet/anticoagulation agents or contrast media
- Allergic reaction to device materials
- Amputation
- Aneurysm
- Arterial dissection
- Death
- Device(s) deformation, collapse, fracture, or rupture
- Device(s) thrombosis (acute and subacute)
- Dissection
- Embolization of air, debris, plaque or thrombus (evidenced by slow or no-flow) from mechanical disruption by the intervention
- Embolization or migration of the interventional device(s)
- Emergency surgery
- GI bleeding due to anticoagulation
- Hemodynamic compromise (e.g., prolonged hypotension requiring treatment with intravenous medications)
- Hypotension or hypertension
- Infection
- Ischemia
- Myocardial infarction
- Renal insufficiency
- Renal failure requiring dialysis
- Repeat intervention to treatment site
- Sepsis
- Significant cardiac arrhythmia requiring treatment with medications and/or transvenous pacing
- Stent entanglement
- Stroke
- Thrombosis (acute and subacute)
- Transient Ischemia Attack (TIA)
- Vasospasm
- Vessel dissection, perforation, rupture or intimal flap
- Vessel/filter occlusion

DEVICE COMPONENTS

The SpiderFX Embolic Protection Device package contains one each of the following components:

NOTE: *See Table 4 for Device product specifications.*

Capture Wire — The Capture Wire has a Nitinol mesh Filter with a Proximal Mouth Indicator and a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter has a heparin coating designed to maintain patency[1]. The Capture Wire is pre-loaded through the Delivery End of the SpiderFX Catheter with the Filter extending from the Catheter distal tip. The SpiderFX Capture Wire and Catheter are provided in a single hoop.

[1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.

TABLE 4 — SpiderFX Embolic Protection Device Specifications*

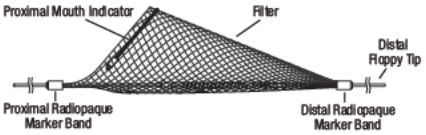
SpiderFX Capture Wire			
Filter Diameter (mm)	5.0	6.0	7.0
Filter Length (mm)**	23	23	24
Capture Wire Length RX (cm)	190	190	190
Capture Wire Length OTW/RX (cm)	320/190	320/190	320/190
Wire Diameter (in /mm)	0.014/0.36	0.014/0.36	0.014/0.36
Distal Wire Tip Coil Length (cm)	1.2	1.2	1.2
SpiderFX Catheter - Delivery End (green)			
Nominal Diameter (in./mm)	0.040/1.02	0.040/1.02	0.040/1.02
Functional Length (cm)	140	140	140
SpiderFX Catheter - Recovery End (blue)			
Diameter (F)	4.2	4.2	4.2
Functional Length (cm)	140	140	140
Total Catheter Length (cm)	180	180	180

*Nominal

**When delivered at maximum recommended vessel size.

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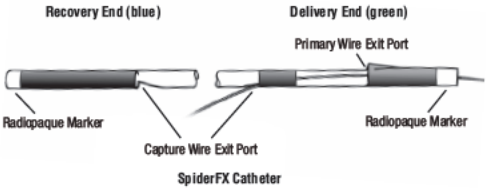
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Capture Wire

CAUTION: *Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.*

SpiderFX Catheter — The SpiderFX Catheter is dual-ended, with a Delivery End (green), and a Recovery End (blue) at the opposite end of the catheter



SpiderFX Catheter

- The **Delivery End** (green) of the SpiderFX Catheter has an embedded radiopaque marker at the distal tip, a primary wire exit port (indicated by a white stripe), a Clear Segment, and a Capture Wire Exit Port. The Capture Wire is pre-loaded into the Delivery End of the Catheter, with the Filter portion extending from the distal tip.
- The center **White Shaft** is used to manipulate the SpiderFX Catheter during delivery and recovery of the SpiderFX Capture Wire.
- The **Recovery End** (blue) of the SpiderFX Catheter has an embedded radiopaque marker at its distal tip, and a Capture Wire Exit Port.

Latex is not a component of the SpiderFX Embolic Protection Device.

INSTRUCTIONS FOR USE – SpiderFX Catheter

NOTE: *If using alternate catheter for delivery/recovery of the SpiderFX Capture Wire refer to instructions starting on page 4.*

Preparing the SpiderFX Embolic Protection Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the anticipated distal tip of interventional device to be used to treat the lesion. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the anticipated distal tip of interventional device, to allow for adequate Filter deployment.

WARNING: Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 2 Sizing Guide).

4. Ensure the guide catheter/sheath size will accommodate the SpiderFX Catheter. (Table 5).

TABLE 5 — Sizing Guide[1]

Target Vessel Size (mm)	Filter Size (mm)	Primary Guidewire Size (in)	Guide Catheter/ Sheath Min I.D.[2] (in)
3 0 - 4.0	5 0	0.014-0.018	0 066
3 5 - 5.0	6 0	0.014-0.018	0 066
4 5 - 6.0	7 0	0.014-0.018	0 066

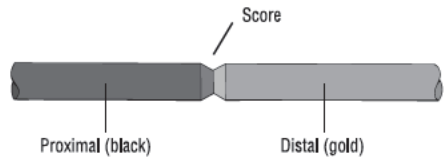
[1] Nominal
[2] Select a guide catheter that provides coaxial alignment and stable backup support.

5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the Catheter near the Primary Wire Exit Port and gently pull to expose the Catheter. The remaining Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the Catheter.

NOTE: *If using the 320/190 cm convertible version of the SpiderFX Device, it may be snapped at any point during the intervention if no over-the-wire devices are intended to be used. To do this, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*

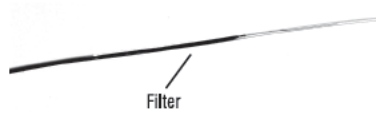


Capture Wire

8. Hold the Catheter at the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the Catheter at the distal white tips of either end. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.

9. Continue holding the Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter portion stops in the proximal end of the Clear Segment of the Catheter.



Filter in Proper Position in Clear Segment

CAUTION: *The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.*

10. Flush through the distal tip with heparinized saline until all air is removed and fluid passes from the Primary Wire Exit Port (22.5 cm proximal to the distal tip of the Catheter). A 23 gauge blunt needle included in the packaging may be used, if desired. Do not apply excessive force to the Capture Wire.
11. Gently apply pressure to the Primary Wire Exit Port. Flush until all air is removed and fluid passes from the Capture Wire Exit Port (40 cm proximal to Catheter distal tip).

WARNING: Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.

Delivery and Deployment

12. Access the vessel being treated using standard technique, and advance the primary guidewire at least 5 cm beyond the anticipated distal end of interventional device used to treat the lesion.
13. Observe the Primary Wire Exit Port indicated by a white stripe on the Catheter, to ensure the Port hole is visible.

NOTE: *When loading the primary guidewire, gently bend the Catheter placing the Primary Wire Exit Port at the apex of the curve*

CAUTION: *Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.*

14. Load the distal tip of the SpiderFX Device Delivery End (green) onto the proximal end of the primary guidewire and advance, so the primary wire exits at the Primary Wire Exit Port.

CAUTION: *DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.*

15. Gently advance the SpiderFX Delivery End carrying the Capture Wire over the primary wire and into the guide catheter/sheath. Continue advancing until the radiopaque marker at the distal tip of the Delivery End is at least 4-5 cm distal to the anticipated distal end of the interventional device used.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-811

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***CAUTION**: Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the Catheter.*

WARNING: Maintain the Capture Wire exit port of the SpiderFX Delivery Catheter within Guide Catheter/Sheath. This results in a 38 cm maximum distance from distal tip of Guide Catheter/Sheath to distal tip of Delivery Catheter. Failure to maintain this port within the Guide Catheter/Sheath may result in increased Filter advancement/deployment forces and vessel and/or device damage.

WARNING: Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.

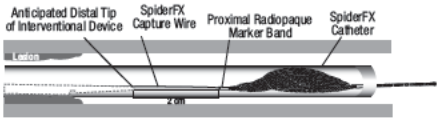
WARNING: Do not apply excessive force to Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

16. Hold the Catheter stationary, and withdraw the primary guidewire, leaving the Delivery Catheter and Capture Wire in place.
17. Hold the Catheter stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.

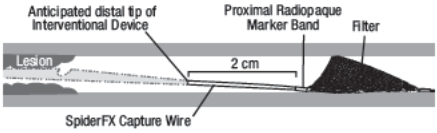
18. Observe and adjust the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the anticipated distal end of the interventional device used to treat the lesion.



Position of SpiderFX Catheter Relative to Interventional Device.

***CAUTION**: Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.*

WARNING: Do not deploy the Filter within a previously implanted stent



Position of Filter Relative to Interventional Device

19. Hold the Capture Wire stationary, and gently pull back on the Catheter to expose and deploy the Filter in the vessel. To reposition the Filter (if required),advance the Catheter back over the Filter, adjust the position of the Catheter and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter.

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX (or comparable) Catheter. This may lead to embolization of debris, and vessel and/or device damage.

20. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Delivery Catheter together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
21. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
22. Once the Filter is deployed in the desired location, carefully remove the SpiderFX Catheter from the patient. Keep the Catheter in the sterile field. **DO NOT DISCARD THE CATHETER.** The Recovery End (blue) is required for Capture Wire recovery.
23. Place the SpiderFX Catheter in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter.
24. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow. If slow/no flow should occur, the Filter should be recovered (See *Recovery and Removal*).

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use mechanical rotational thrombectomy with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).

WARNING: After recovering the Filter, do not attempt to flush the Filter and/or reintroduce the Filter into the patient. The Filter must be discarded and a new Filter used if embolic protection is still needed.

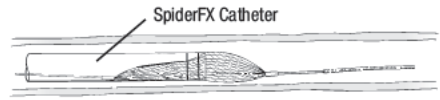
Recovery and Removal

25. After completion of the interventional procedure, wet the distal 20 cm of the Recovery End (blue) of the Catheter with heparinized saline. Flush the distal tip of the Recovery End to remove all air, until fluid passes from the Capture Wire Exit Port (25 cm from the tip).

WARNING: Do not grip the Catheter at the distal white tips of either end. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

26. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.
27. Advance the Catheter under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
28. There are two methods for Filter Recovery:

A — Partial Enclosure Recovery: Gently advance the Recovery End over the Filter, until the proximal portion of the Filter is inside the Catheter, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the radiopaque marker of the Recovery Catheter.



A. Partial Enclosure Recovery

WARNING: Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

B — Full Enclosure Recovery: Gently advance the Recovery End over the Filter until all radiopaque markers on the Filter are within the Catheter, proximal to the Catheter distal marker. The Distal Floppy Tip may remain outside the Catheter.



B. Full Enclosure Recovery

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

29. Carefully remove the Catheter and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the SpiderFX Catheter to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

***CAUTION**: Do not re-sterilize or reuse this device.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-811

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INSTRUCTIONS FOR USE –
Alternate Catheter of Choice

NOTE: *Commercially available catheters can be used for delivery/recovery of the SpiderFX Capture Wire. Confirm that the Catheter of Choice is 0.035" guidewire compatible and is compatible with the Capture Wire length, guide catheter/sheath, and primary wire prior to use.*

Preparing the SpiderFX Embolic Protection Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the anticipated distal tip of interventional device to be used to treat the lesion. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the anticipated distal tip of interventional device, to allow for adequate Filter deployment.

WARNING: Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 6 Sizing Guide).

TABLE 6 — Filter Sizing Guide

Target Vessel Size (mm)	Filter Size (mm)
3.0 - 4.0	5.0
3.5 - 5.0	6.0
4.5 - 6.0	7.0

NOTE: *Ensure that the length of the Catheter of Choice is such that it accommodates the Capture Wire length.*

4. Ensure the guide catheter/sheath size will accommodate the Catheter of Choice according to its instructions for use.
5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the SpiderFX Catheter near the Primary Wire Exit Port and gently pull to expose the SpiderFX Catheter. The remaining SpiderFX Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the SpiderFX Catheter.
8. Hold the SpiderFX Catheter near the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the SpiderFX Catheter at the distal white tips of either end. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the SpiderFX Catheter.

9. Continue holding the SpiderFX Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter and Distal Floppy Tip are fully contained within the distal tip of the SpiderFX Catheter.

WARNING: Failure to fully contain the Distal Floppy Tip within the distal end of the SpiderFX Catheter Delivery End during loading could result in kinking of the Distal Floppy Tip.

Delivery and Deployment

10. Access the vessel being treated using standard technique, and advance the primary guidewire and/or Catheter of Choice at least 5cm beyond the anticipated distal end of interventional device used to treat the lesion.
11. Hold the Catheter of Choice stationary and withdraw the primary guidewire.
12. Following removal of primary guidewire, flush the Catheter of Choice lumen with sterile heparinized saline.
13. Gently guide the tip of the SpiderFX Device Delivery End (green) into the proximal end of the Catheter of Choice or until the tip of the SpiderFX Catheter aligns with the lumen of the Catheter of Choice.

WARNING: Do not advance the SpiderFX Catheter against resistance. This may result in deformation of the embedded Radiopaque Marker Band contained within the SpiderFX Catheter tip.

14. Hold the SpiderFX Catheter and Catheter of Choice stationary, and gently advance the Capture Wire until the Filter enters the lumen of the Catheter of Choice.

NOTE: *The user should feel a reduction in force when the Filter has exited the SpiderFX Catheter and is fully contained within the Catheter of Choice.*

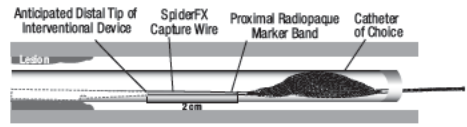
15. Continue to advance the Capture Wire through the SpiderFX Catheter and Catheter of Choice approximately 5 to 7 inches to ensure the Capture Wire's tapered section is fully supported within the Catheter of Choice.

CAUTION: *Failure to support the distal tapered section of the Capture Wire within the Catheter of Choice while advancing the Filter could result in kinking of the Capture Wire.*

16. Hold the Capture Wire stationary, and pull back on the SpiderFX Catheter to offload the SpiderFX Catheter from the Capture Wire. Keep the SpiderFX Catheter in the sterile field. **DO NOT DISCARD THE SPIDERFX CATHETER** in the event that the SpiderFX Catheter Recovery End (blue) may be needed for Filter recovery.
17. Place the SpiderFX Catheter in sterile heparinized saline or sterile field. Do not bend or kink the SpiderFX Catheter.
18. Hold the Catheter of Choice stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter of Choice distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.

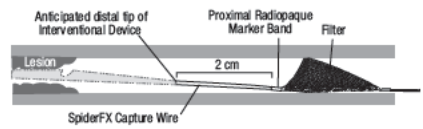
19. Observe and adjust the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the anticipated distal end of the interventional device used to treat the lesion.



Position of Catheter of Choice Relative to Interventional Device.

CAUTION: *Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without coming within 2 cm of the Filter proximal end.*

WARNING: Do not deploy the Filter within a previously implanted stent.



Position of Filter Relative to Interventional Device

20. Hold the Capture Wire stationary, and gently pull back on the Catheter of Choice to expose and deploy the Filter in the vessel. To reposition the Filter (if required), advance the Catheter of Choice back over the Filter, adjust the position of the Catheter of Choice and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter of Choice.

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the Catheter of Choice or SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.

21. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Catheter of Choice together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
22. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
23. Once the Filter is deployed in the desired location, carefully remove the Catheter of Choice from the patient. Keep the Catheter of Choice in the sterile field. DO NOT DISCARD THE CATHETER OF CHOICE. The Catheter of Choice may be used for Capture Wire recovery.
24. Place the Catheter of Choice in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter of Choice.

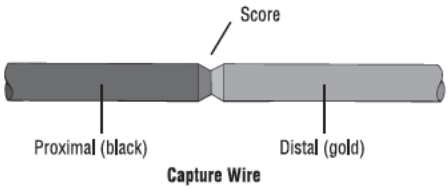
NOTE: *The SpiderFX Catheter Recovery End (blue) may also be used for Capture Wire recovery.*

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25. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

NOTE: *If using the 320/190 cm convertible version of the SpiderFX Device, it may be snapped at any point during the intervention if no over-the-wire devices are intended to be used. To do this, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*



Capture Wire

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow. If slow/no flow should occur, the Filter should be recovered (See *Recovery and Removal*).

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use mechanical rotational thrombectomy with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).

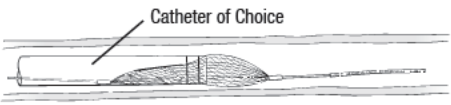
WARNING: After recovering the Filter, do not attempt to flush the Filter and/or reintroduce the Filter into the patient. The Filter must be discarded and a new Filter used if embolic protection is still needed.

Recovery and Removal

26. After completion of the interventional procedure, flush the Catheter of Choice from the proximal end to remove all air, until fluid passes through the distal tip.

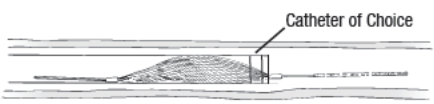
NOTE: *The SpiderFX Catheter Recovery End (blue) may also be used for Capture Wire recovery. See instructions for 'Recovery and Removal' with SpiderFX starting on page 4, step 25.*

27. Load the Catheter of Choice onto the Capture Wire and through the guide catheter/sheath.
28. Advance the Catheter of Choice under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
29. Gently advance the Catheter of Choice over the Filter, until the proximal portion of the Filter is inside the Catheter of Choice, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the distal radiopaque marker of the Catheter of Choice.



Recovery of SpiderFX Capture Wire with Catheter of Choice.

WARNING: Exercise caution when withdrawing a full Filter through a deployed stent. If resistance is felt, advance the Filter and Catheter of Choice distally and draw the Filter more fully into the Catheter of Choice before re-attempting withdrawal as illustrated below.



30. Carefully remove the Catheter of Choice and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the Catheter of Choice to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

CAUTION: *Do not re-sterilize or reuse this device.*

STORAGE

- Do not store in direct sunlight
- Keep dry

WARRANTY DISCLAIMER

Although the product has been manufactured under carefully controlled conditions, ev3 Inc. has no control over the conditions under which this product is used. ev3 Inc., therefore disclaims all warranties, both express and implied, with respect to the product including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ev3 Inc. shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind ev3 Inc. to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

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Protected under one or more of the following: US Patent 7,717,934; 7,637,920; 7,556,636; 7,556,635; 7,410,492; 7,404,820; 7,371,250; 7,367,986; 6,979,343; 6,843,798; 6,712,835; 6,325,815. Non-US patents issued & pending.

500769-001 (B) APR/11 US

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Attachment C: Predicate Product Labeling

SpiderFX Device box and pouch label (carotid use)
SpiderFX Device Instructions for Use (carotid use)

SpideRX Device box and pouch label (carotid use)
SpideRX Device Instructions for Use (carotid use)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Plymouth, MN
55442-2920 USA

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800.716.6700
FAX FX 763.398.7200

STERILE EO

SpiderFX™

Embolic Protection Device

7.0 mm	190 cm	.014" 0.36mm

REF Model モデル	SPD2-US-070-190
LOT Lot. No. ロット番号	1234567
Use By 使用期限	2012-05-06

(1) Capture Wire
(1) SpiderFX Catheter
(1) Flushing Needle
Product Literature

Recommended Carotid Vessel Size	5.5 - 7.0mm
Recommended SVG Vessel Size	5.5 - 6.0mm
Guide Compatibility	6F (min ID .066")

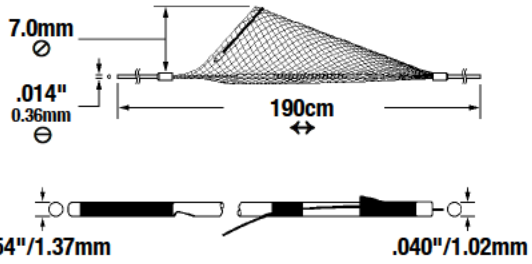
Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Manufactured in the U.S.A.

ev3™ SpiderFX™ 7.0mm LOT 1234567
REF: SPD2-US-070-190 2012-05-06
(01) 0 0821684 04052 2 (17) 120506 (10) 1234567

ev3™ SpiderFX™ 7.0mm LOT 1234567
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(01) 0 0821684 04052 2
(17) 120506 (10) 1234567

℞ only

500762-300 Rev. H

SpiderFX™
(01) 0 0821684 04052 2 (17) 120506 (10) 1234567
ev3™
7.0 mm | 190 cm | .014" 0.36mm | REF SPD2-US-070-190 | LOT 1234567 | 2012-05-06

SpiderFX™
(01) 0 0821684 04052 2 (17) 120506 (10) 1234567
ev3™
7.0 mm | 190 cm | .014" 0.36mm | REF SPD2-US-070-190 | LOT 1234567 | 2012-05-06

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STERILE EO

SpiderFX™

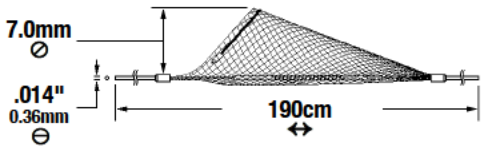
Embolic Protection Device

7.0 mm ⊘	190 cm ↔	.014" 0.36mm ⊖
REF Model モデル	SPD2-US-070-190	
LOT Lot. No. ロット番号	1234567	
Use By 使用期限	2012-05-06	
(1) Capture Wire (1) SpiderFX Catheter (1) Flushing Needle		
Recommended Carotid Vessel Size	5.5 - 7.0mm	
Recommended SVG Vessel Size	5.5 - 6.0mm	
Guide Compatibility	6F (min ID .066")	
Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.		
Manufactured in the U.S.A.		

ev3™ SpiderFX™ 7.0mm
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(01) 0 0821684 04052 2
(17) 120506 (10) 1234567

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SpiderFX™

Embolic Protection Device

PRODUCT DESCRIPTION

The SpiderFX™ Embolic Protection Device is a percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The SpiderFX Device Capture Wire is used as the 0.014 in. wire for interventional device delivery. The SpiderFX Device can be delivered over any 0.014 in. or 0.018 in. primary wire used to gain access to the lesion site.

The SpiderFX Embolic Protection Device package contains the following components:

- One **Capture Wire** composed of a nitinol mesh Filter with a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter features a heparin-coating designed to maintain patency during Filter deployment[1]. This Capture Wire acts as the primary guidewire for other interventional devices compatible with a 0.014 in. wire. The convertible 320/190 cm Capture Wire is scored, allowing the wire to be snapped to a 190 cm usable length for use with rapid exchange systems, if desired. The distal portion of the Capture Wire for rapid exchange use is gold. The proximal portion for standard over-the-wire use is black.

  [1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.
- One dual-ended **SpiderFX Catheter** used to exchange the primary access guidewire with the Capture Wire, deploy the Capture Wire at the desired location, and recover the Capture Wire at the end of the procedure.
- One 23 gauge Blunt Needle for attachment to a syringe with Luer connector for priming and flushing the Catheter.

Components are delivered sterile, for use within a single vessel only. Do not re-sterilize or reuse.

INDICATIONS FOR USE

The SpiderFX Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.

CONTRAINDICATIONS

Use of the SpiderFX Embolic Protection Device is contraindicated under these circumstances:

- Do not use with patients in whom anticoagulant and antiplatelet therapy is contraindicated
- Do not use in vessels with excessive tortuosity
- Do not use in patients with uncorrected bleeding disorders

WARNINGS

Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.

- This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilizing could increase the risk of patient infection and risk of compromised device performance.
- Refer to the instructions supplied with all interventional devices to be used in conjunction with the SpiderFX Embolic Protection Device for their intended uses, contraindications and potential complications.
- The safety and effectiveness of this device as an embolic protection system have not been established in vasculatures outside the carotid arteries (coronary, cerebral or peripheral).
- The safety and efficacy of the SpideRX Embolic Protection Device have not been demonstrated with carotid stent systems other than the over-the-wire or RX ACCULINK™ Carotid Stent System.
- The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure in accordance with standard medical practice.
- Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.
- Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.
- Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.
- Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 7 Sizing Guide).
- Do not apply excessive force to the Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.
- Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.
- Do not place the SpiderFX Capture Wire tip in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.
- Do not deploy the Filter within a previously implanted stent.
- Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.
- Do not use thrombectomy, atherectomy, or laser devices with the Capture Wire.
- Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.
- Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow flow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See Recovery and Removal).
- Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow.
- Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

PRECAUTIONS

- U.S. Federal law restricts this device to sale by or on the order of a physician.
- Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.
- Do not use the product if the packaging sterile barriers have been damaged or compromised.
- The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.
- Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.
- DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.
- Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the catheter.
- Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.
- Do not re-sterilize or reuse this device.

OBSERVED ADVERSE EVENTS - CLINICAL STUDY

The SpideRX® Embolic Protection Device was evaluated for the treatment of internal and/or common carotid artery stenoses in high-risk patients via the Carotid Revascularization with ev3 Arterial Technology Evolution (CREATE) Trial Clinical series. A total of 609 patients were enrolled in the trial as follows:

- CREATE Feasibility evaluated the ev3 over-the-wire (OTW) SPIDER™ Embolic Protection Device and PROTÉGÉ® Self-expanding Nitinol Stent and included 30 patients. The primary objective of the study was to evaluate the safety of the PROTÉGÉ Stent and SPIDER Embolic Protection Device in the treatment of common and/or internal carotid artery stenoses for subjects that are at high-risk for carotid endarterectomy.
- CREATE Pivotal also evaluated the ev3 over-the-wire (OTW) SPIDER Embolic Protection Device and PROTÉGÉ Self-expanding Nitinol Stent and included 419 patients. The primary objective of the study was to evaluate the safety and efficacy of the PROTÉGÉ Stent and SPIDER Embolic Protection Device in the treatment of common and/or internal carotid artery stenoses for subjects that are at high-risk for carotid endarterectomy.
- The SpideRX Arm of the CREATE Trial evaluated the ev3 rapid exchange SpideRX Embolic Protection Device and the commercially available ACCULINK™ Carotid Stent and included 160 patients. The primary objective of the study was to evaluate the safety and performance of the SpideRX Device in the treatment of common and/or internal carotid artery stenoses for patients at high-risk for carotid endarterectomy.

  The SpideRX Embolic Protection Device is used in an acute manner and, therefore, peri-procedural adverse events are the most relevant evaluation of device safety. Table 1, below, presents the serious adverse events (defined as any event that may be either life-threatening or involve permanent long term injuries) that were reported through the 30-day follow-up visit in the SpideRX Arm and the CREATE Pivotal (SPIDER) Trial.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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TABLE 1 – Serious Adverse Events Summary ≤ 30 Days

Description of Event[1]	SpideRX (N=160)	SPIDER (N=417)	Difference (95% C.I.)	p-value
Death	4/160 (2.5%)	8/417 (1.9%)	-0.6% (-3.3%, 2.2%)	0.7453
Ipsilateral Stroke				
Major	2/160 (1.3%)	14/417 (3.4%)	2.1% (-0.3%, 4.5%)	0.2569
Minor	2/160 (1.3%)	3/417 (0.7%)	-0.5% (-2.4%, 1.4%)	0.6207
Non-Ipsilateral Stroke	0/160 (0.0%)	3/417 (0.7%)	0.70%	0.5643
Total patients with complications	37/160 (23.1%)	130/417 (31.2%)	8.1% (0.2%, 16.0%)	0.0648
Access site complications:				
Hemorrhage	0/160 (0.0%)	4/417 (1.0%)	1.00%	0.0058
Pseudoaneurysm	2/160 (1.3%)	6/417 (1.4%)	0.2% (-1.9%, 2.3%)	1.0000
Puncture site infection	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Amaurosis Fugax	1/160 (0.6%)	1/417 (0.2%)	-0.4% (-3.1%, 0.5%)	0.0478
Angina	2/160 (1.3%)	0/417 (0.0%)	-1.30%	0.0765
Arrhythmia	5/160 (3.1%)	12/417 (2.9%)	-0.3% (-3.4%, 2.9%)	1.0000
Artery perforation:				
Contained	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Non-contained	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Congestive Heart Failure	3/160 (1.9%)	0/417 (0.0%)	-1.90%	0.0021
Dissection	1/160 (0.6%)	5/417 (1.2%)	0.6% (-1.0%, 2.2%)	1.0000
Emergent surgery	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
GI bleeding	1/160 (0.6%)	7/417 (1.7%)	0.8% (-0.9%, 2.5%)	0.6797
Hypotension	21/160 (13.1%)	73/417 (17.5%)	4.4% (-2.0%, 10.8%)	0.2568
Intracerebral bleed	1/160 (0.6%)	0/417 (0.0%)	-0.60%	0.2773
MI	1/160 (0.6%)	4/417 (1.0%)	0.3% (-1.2%, 1.9%)	1.0000
Renal failure requiring dialysis	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Renal insufficiency	2/160 (1.3%)	5/417 (1.2%)	-0.1% (-2.1%, 2.0%)	1.0000
Seizure	0/160 (0.0%)	3/417 (0.7%)	0.70%	0.5643
Stent / Vessel thrombosis	1/160 (0.6%)	0/417 (0.0%)	-0.60%	0.2773
Stent misplacement	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Stent or filter failure to deploy	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
TIA	0/160 (0.0%)	4/417 (1.0%)	1.00%	0.0058
Other	9/160 (5.6%)	40/417 (9.6%)	4.0% (-0.6%, 8.5%)	0.1365

[1] Patients may have had multiple events. Counts represent the number of events reported.

Table 2 indicates the number of deaths that were considered to be related to a stroke or myocardial infarction.

TABLE 2 – Cause of Death, 30 Days

Events	SpideRX (N=160)	SPIDER (N=417)
Stroke	2	5
Cardiac	2	3

TABLE 3 – Adverse Events Summary ≤ 30 Days

Description of Event[1]	SpideRX (N=160)	SPIDER (N=417)	Difference (95% C.I.)	p-value
Total patients with complications	12/160 (7.5%)	30/417 (7.2%)	- 0.3% (-5.1%, 4.5%)	0.8598
Access site complication:				
Hematoma	5/160 (3.1%)	2/417 (0.5%)	-2.6% (-5.4%, 0.1%)	0.0198
Puncture site infection	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
Allergic reaction to contrast dye	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Allergic reaction to procedure meds	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Arrhythmia	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
GI bleeding	0/160 (0.0%)	0/417 (0.0%)	NA	NA
Hypotension	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
Renal insufficiency	2/160 (1.3%)	3/417 (0.7%)	-0.5% (-2.4%, 1.4%)	0.6207
Restenosis	0/160 (0.0%)	0/417 (0.0%)	NA	NA
Stent or filter collapse or fracture	0/160 (0.0%)	0/417 (0.0%)	NA	NA
Stroke - Minor	2/160 (1.3%)	0/417 (0.0%)	-1.30%	0.0765
Ipsilateral stroke - Minor	2/160 (1.3%)	0/417 (0.0%)	-1.30%	0.0765
TIA	1/160 (0.6%)	6/417 (1.4%)	0.8% (-0.9%, 2.5%)	0.6797
Vasospasm	1/160 (0.6%)	0/417 (0.0%)	-0.60%	0.2773
Other	1/160 (0.6%)	11/417 (2.6%)	2.0% (0.0%, 4.0%)	0.1942

[1] Patients may have had multiple events. Counts represent the number of events reported.

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POTENTIAL COMPLICATIONS

Complications associated with the use of the SpiderFX Embolic Protection Device may include, but are not limited to:

- Access site adverse event (e.g., av fistula, hematoma, hemorrhage, pseudoaneurysm, puncture site infection)
- Adverse reaction to antiplatelet/anticoagulation agents or contrast media
- Allergic reaction to device materials
- Amaurosis Fugax
- Angina (unstable)
- Arterial dissection
- Cerebral hemorrhage
- Congestive heart failure
- Death
- Device(s) deformation, collapse, fracture, or rupture
- Device(s) thrombosis (acute and subacute)
- Dissection
- Embolization of air, debris, plaque or thrombus (evidenced by slow or no-flow) from mechanical disruption by the intervention, resulting in TIA or stroke
- Embolization or migration of the interventional device(s)
- Emergency surgery
- GI bleeding due to anticoagulation
- Hemodynamic compromise (e.g., prolonged hypotension requiring treatment with intravenous medications)
- Hyperperfusion syndrome
- Hypotension or hypertension
- Infection
- Intracerebral bleed
- Myocardial infarction
- Renal insufficiency
- Renal failure requiring dialysis
- Seizure
- Sepsis
- Significant cardiac arrhythmia requiring treatment with medications and/or transvenous pacing
- Stent entanglement
- Stroke
- Thrombosis (acute and subacute)
- Transient Ischemia Attack (TIA)
- Vasospasm
- Vessel dissection, perforation, rupture or intimal flap
- Vessel/filter occlusion

CLINICAL STUDIES

The Carotid Revascularization with ev3 Arterial Technology Evolution (CREATE) Clinical Trials were a series of prospective, non-randomized, multi-center, single-arm clinical trials. A total of 609 patients were enrolled at 35 clinical sites in the United States in three trials designed to demonstrate the safety and efficacy of the ev3 SPIDER over-the-wire and SpideRX Embolic Protection Devices as well as the PROTÉGÉ Self-Expanding Nitinol Stent when used to treat high-risk symptomatic and asymptomatic patients with internal and/or common carotid artery stenoses.

ELIGIBILITY CRITERIA

Male and female patients who presented for percutaneous treatment of an internal and/or common carotid artery intervention were considered for enrollment. To be included, the patients were required to be at least 18 years old and considered to be at high risk for carotid endarterectomy. The general and angiographic inclusion and exclusion criteria for the three trials were identical with the exception of vessel size in the SpideRX Arm of the CREATE Trial. Vessel size was changed in this trial to accommodate the limitations of the commercially available carotid stent.

Patients were considered symptomatic if their target stenosis was associated with ipsilateral transient or visual TIA evidenced by amaurosis fugax, ipsilateral hemispheric TIAs or ipsilateral ischemic stroke within 6 months prior to enrollment. Patients who were characterized as symptomatic were also required to have a target lesion stenosis (as defined in the NASCET trial) $\geq$ 50%. Asymptomatic patients were required to have a target lesion stenosis $\geq$ 70%.

High risk criteria are included in Table 4.

TABLE 4 – High Surgical Risk Criteria

Clinical Criteria[1]	Anatomical Criteria[1]
1. Age >75	1. Contralateral occlusion
2. CCS angina class 3-4 or unstable angina	2. High cervical lesion (above the angle of the jaw)
3. CHF class III-IV	3. Infraclavicular lesion
4. LVEF <35%	4. Tandem lesions >70%
5. MI <6 weeks	5. Hostile neck (cervical radiation treatment, tracheostomy/stoma, or radical neck dissection)
6. Coronary artery disease with >2 vessel disease in major vessel & history of angina	6. CEA restenosis
7. Severe pulmonary disease – home oxygen, resting p02 <60 or FEV1 <50%	7. Cervical immobility due to fusion or arthritis
8. Permanent contralateral cranial nerve injury	8. Bilateral carotid stenoses, both requiring treatment*

[1] The subjects were required to meet at least ONE or more high-risk criterion in EITHER the clinical or anatomical section.

* Only the most severe lesion meeting the angiographic inclusion criteria could be treated in the SpideRX Arm of the CREATE Trial.

Baseline demographic characteristics are included in Table 5, on the following page. They were evaluated to determine if subjects enrolled in the SpideRX Arm of the CREATE Trial and the CREATE Pivotal Trial are homogeneous. The differences reported, along with the associated p-values, correspond to the differences between the populations in the SpideRX Arm of the CREATE Trial and those enrolled in the CREATE Pivotal Trial. The only characteristics indicated to be significantly different were history of other treatment to the target artery (3.8% for RX, 0.7% for Pivotal), history of TIA (15.0% for SpideRX 23.2% for Pivotal), and lesion location in both the common and internal carotid artery (11.3% for SpideRX, 19.1% for Pivotal).

CLINICAL RESULTS SUMMARY

The primary endpoint of the SpideRX Arm of the CREATE Trial is a composite endpoint of MI, ipsilateral CVA, procedure-related contralateral CVA or death within 30 days of implantation (MACCE Table 5, following page). There are no significant differences between the SpideRX Arm and the CREATE Pivotal Trial with respect to the primary endpoint.

The relationship of patient or baseline lesion characteristics to outcomes through 30-days was considered in a multivariate analysis. This analysis did not result in any statistically significant predictor of outcomes (all $p < 0.05$).

CLINICAL USE INFORMATION

Pre-procedure anticoagulant and antiplatelet requirements were specified in the clinical trial. A baseline dose of acetylsalicylic acid (ASA) of 325 mg was required the day prior and the day of the procedure. For patients on regular Coumadin® therapy, the dose could be reduced to 81 mg.

Several options were given with respect to the loading dose of antiplatelet medication:

- Clopidogrel 75 mg for three days prior to the procedure and the day of the procedure **or**
- Clopidogrel 450 mg the day before the procedure and 75 mg the day of the procedure **or**
- Ticlopidine 1000 mg the day before the procedure and two 250 mg doses the day of the procedure.

Patients were required to take 325 mg ASA **and** either 75 mg of clopidogrel each day or 250 mg of ticlopidine twice a day for three months following the procedure. For patients on regular Coumadin® therapy, the post-procedure ASA dose could be reduced to 81 mg.

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TABLE 5 – Primary and Secondary Endpoints

Efficacy Measures	SpideRX (N=160)	SPIDER (N=417)	Difference (95% C.I.)	p-value
Primary Endpoint	9/160 (5.6%)	29/370 (7.8%)	N/A	N/A
30-Day MACCE	9/160 (5.6%)	26/414 (6.3%)	0.7% (-3.6%, 4.9%)	0.8480
Myocardial Infarction	1/160 (0.6%)	4/414 (1.0%)	0.3% (-1.2%, 1.9%)	0.6933
Ipsilateral CVA	7/160 (4.4%)	16/414 (3.9%)	-0.5% (-4.1%, 3.1%)	0.8133
Major	2/160 (1.3%)	14/414 (3.4%)	2.1% (-0.3%, 4.6%)	0.2570
Minor	4/160 (2.5%)	3/414 (0.7%)	-1.8% (-4.3%, 0.8%)	0.0988
Intracerebral Bleed	1/160 (0.6%)	0/414 (0.0%)	-0.60%	0.2800
Procedure-Related Contralateral CVA	0/160 (0.0%)	3/414 (0.7%)	0.70%	0.5638
Death	4/160 (2.6%)	8/414 (1.9%)	-0.6% (-3.4% , 2.2%)	0.7460
1 year Ipsilateral CVA	N/A	3/370 (0.8%)	N/A	N/A
Secondary Endpoints				
MANE	N/A	26/370 (7.0%)	N/A	N/A
TLR at 1 year	N/A	1/370 (0.2%)	N/A	N/A
TVR at 1 year	N/A	1/370 (0.2%)	N/A	N/A
Primary Patency at 1 year	N/A	286/304 (94.1%)	N/A	N/A
Technical Success	156/160 (97.5%)	408/419 (97.4%)	-0.13% (-3.01%, 2.76%)	0.9317
Acute Procedure Success (QCA)	147/148 (99.3%)	397/397 (100.0%)	0.68% (-0.65%, 2.01%)	0.3172
Acute Procedure Success (Site)	158/160 (98.8%)	437/444 (98.4%)	-0.3% (-2.4%, 1.8%)	1.0000

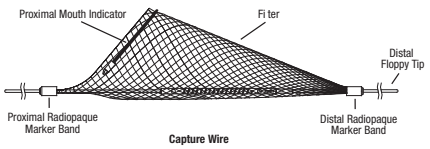
DEVICE COMPONENTS

The SpiderFX Embolic Protection Device package contains one each of the following components:

NOTE: *See* ***Table 6*** *for Device product specifications.*

Capture Wire– The Capture Wire has a Nitinol mesh Filter with a Proximal Mouth Indicator and a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter has a heparin coating designed to maintain patency[1]. The Capture Wire is pre-loaded through the Delivery End of the SpiderFX Catheter with the Filter extending from the Catheter distal tip. The SpiderFX Capture Wire and Catheter are provided in a single hoop.

[1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.

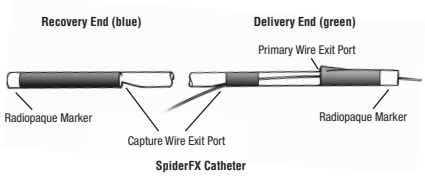


Capture Wire

CAUTION: *Do not bend or shape the Distal Floppy Tip of the Capture Wire.*

This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.

SpiderFX Catheter – The SpiderFX Catheter is dual-ended, with a Delivery End (green), and a Recovery End (blue) at the opposite end of the catheter



SpiderFX Catheter

- The **Delivery End** (green) of the SpiderFX Catheter has an embedded radiopaque marker at the distal tip, a primary wire exit port (indicated by a white stripe), a Clear Segment, and a Capture Wire Exit Port. The Capture Wire is pre-loaded into the Delivery End of the Catheter, with the Filter portion extending from the distal tip.
- The center **White Shaft** is used to manipulate the SpiderFX Catheter during delivery and recovery of the SpiderFX Capture Wire.
- The **Recovery End** (blue) of the SpiderFX Catheter has an embedded radiopaque marker at its distal tip, and a Capture Wire Exit Port.

Latex is not a component of the SpiderFX Embolic Protection Device.

TABLE 6 – SpiderFX Embolic Protection Device Specifications*

SpiderFX Capture Wire					
Filter Diameter (mm)	3.0	4.0	5.0	6.0	7.0
Capture Wire Length RX (cm)	190	190	190	190	190
Capture Wire Length OTW/RX (cm)	320/190	320/190	320/190	320/190	320/190
Wire Diameter (in./mm)	0.014/0.36	0.014/0.36	0.014/0.36	0.014/0.36	0.014/0.36
Distal Wire Tip Coil Length (cm)	1.2	1.2	1.2	1.2	1.2
SpiderFX Catheter - Delivery End (green)					
Nominal Diameter (in./mm)	0.040/1.02	0.040/1.02	0.040/1.02	0.040/1.02	0.040/1.02
Functional Length (cm)	140	140	140	140	140
SpiderFX Catheter - Recovery End (blue)					
Diameter (Fr)	4.2	4.2	4.2	4.2	4.2
Functional Length (cm)	140	140	140	140	140

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Total Catheter Length (cm)	180
180	180
180	180

*Nominal

INSTRUCTIONS FOR USE

Preparing the SpiderFX Embolic Protection Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the lesion site being treated. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the lesion, to allow for adequate Filter deployment.

WARNING: Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 7 Sizing Guide).

4. Ensure the guide catheter/sheath size will accommodate the SpiderFX Catheter. **(Table 7).**

TABLE 7 – Sizing Guide[1]

Target Vessel Size (mm)	Filter Size (mm)	Primary Guidewire Size (inches)	Guide Catheter/Sheath M n I.D.[2] (inches)
3.0	3.0	0.014-0.018	0.066
3.1-4.0	4.0	0.014-0.018	0.066
4.1-5.0	5.0	0.014-0.018	0.066
4.5-6.0	6.0	0.014-0.018	0.066
5.5-7.0	7.0	0.014-0.018	0.066

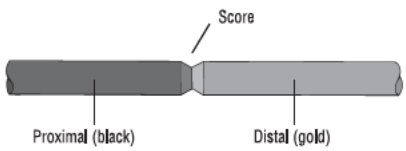
[1] Nominal
[2] Select a guide catheter that provides coaxial alignment and stable backup support.

5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the Catheter near the Primary Wire Exit Port and gently pull to expose the Catheter. The remaining Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the Catheter.

NOTE: *If using the 320/190 cm convertible version of the SpiderFX Device, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*



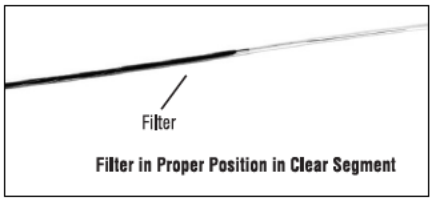
Capture Wire

8. Hold the Catheter at the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

9. Continue holding the Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter portion stops in the Clear Segment of the Catheter.

CAUTION: *The Filter and Distal FloppyTip should be visible within the Clear Segment of the Catheter.*



Filter in Proper Position in Clear Segment

10. Flush through the distal tip with heparinized saline until all air is removed and fluid passes from the Primary Wire Exit Port (22.5 cm proximal to the distal tip of the Catheter). A 23 gauge blunt needle included in the packaging may be used, if desired. Do not apply excessive force to the Capture Wire.
11. Gently apply pressure to the Primary Wire Exit Port. Flush until all air is removed and fluid passes from the Capture Wire Exit Port (40 cm proximal to Catheter distal tip).

WARNING: Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.

Delivery and Deployment

12. Access the vessel being treated using standard technique, and advance the primary guidewire at least 5 cm beyond the distal edge of the lesion being treated.
13. Observe the Primary Wire Exit Port indicated by a white stripe on the Catheter, to ensure the Port hole is visible.

NOTE: *When loading the primary guidewire, gently bend the Catheter at the Primary Wire Exit Port to create a 2.5 cm radius.*

CAUTION: *Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.*

14. Load the distal tip of the SpiderFX Device Delivery End (green) onto the proximal end of the primary guidewire and advance, so the primary wire exits at the Primary Wire Exit Port.

CAUTION: *DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.*

15. Gently advance the SpiderFX Delivery End carrying the Capture Wire over the primary wire and into the guide catheter/sheath. Continue advancing until the radiopaque marker at the distal tip of the Delivery End is at least 4-5 cm beyond the distal edge of the lesion.

CAUTION: *Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the Catheter.*

WARNING: Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.

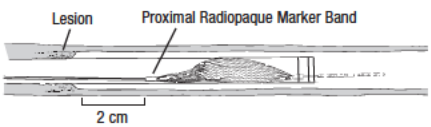
WARNING: Do not apply excessive force to Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

16. Hold the Catheter stationary, and withdraw the primary guidewire, leaving the Delivery Catheter and Capture Wire in place.
17. Hold the Catheter stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow wire movement. This may lead to embolization of debris, and vessel and/or device damage.

18. Observe the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the lesion being treated. Gently advance the entire Delivery End assembly if necessary so the Proximal Radiopaque Marker Band is at least 2 cm beyond the lesion distal edge.



Position of SpiderFX Catheter

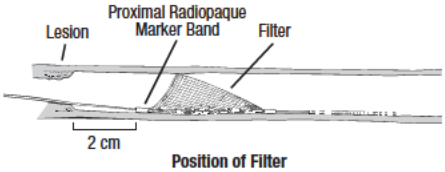
CAUTION: *Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting*

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the Filter proximal end.

19. Hold the Capture Wire stationary, and gently pull back on the Catheter to expose and deploy the Filter in the vessel. To reposition the Filter (if required),advance the Catheter back over the Filter, adjust the position of the Catheter and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter.



Position of Filter

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.

20. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Delivery Catheter together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
21. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
22. Once the Filter is deployed in the desired location, carefully remove the SpiderFX Catheter from the patient. Keep the Catheter in the sterile field. **DO NOT DISCARD THE CATHETER.** The Recovery End (blue) is required for Capture Wire recovery.
23. Place the SpiderFX Catheter in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter.
24. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow.

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use thrombectomy, atherectomy or laser devices with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).

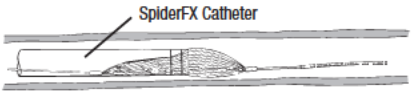
Recovery and Removal

25. After completion of the interventional procedure, wet the distal 20 cm of the Recovery End (blue) of the Catheter with heparinized saline. Flush the distal tip of the Recovery End to remove all air, until fluid passes from the Capture Wire Exit Port (25 cm from the tip).

WARNING: Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

26. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.
27. Advance the Catheter under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
28. There are two methods for Filter Recovery:

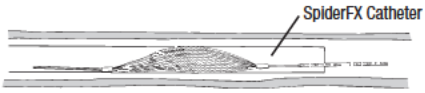
A – Partial Enclosure Recovery: Gently advance the Recovery End over the Filter, until the proximal portion of the Filter is inside the Catheter, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the radiopaque marker of the Recovery Catheter.



A. Partial Enclosure Recovery

WARNING: Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

B – Full Enclosure Recovery: Gently advance the Recovery End over the Filter until all radiopaque markers on the Filter are within the Catheter, proximal to the Catheter distal marker. The Distal Floppy Tip may remain outside the Catheter.



B. Full Enclosure Recovery

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

29. Carefully remove the Catheter and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the SpiderFX Catheter to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

STORAGE

- Do not store in direct sunlight
- Keep dry

WARRANTY DISCLAIMER

Although the product has been manufactured under carefully controlled conditions, ev3 Inc. has no control over the conditions under which this product is used. ev3 Inc., therefore disclaims all warranties, both express and implied, with respect to the product including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ev3 Inc. shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind ev3 Inc. to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

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SpiderFX is a trademark of ev3 and may be registered in the U.S. and other countries.

Protected under one or more of the following: US Patent 7,717,934; 7,637,920; 7,556,636; 7,556,635; 7,410,492; 7,404,820; 7,371,250; 7,367,986; 7,166,080; 6,979,343; 6,843,798; 6,712,835; 6,325,815. Non-US patents issued & pending.

500737-001 (F) AUG/10 - US

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STERILE EO

SpideRX™

Embolic Protection Device

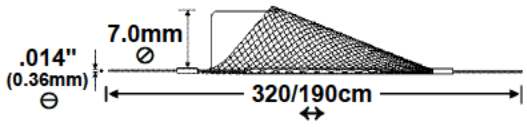
Embolic Protection Device, Dispositif de protection embolique, Embolieschutzvorrichtung, Dispositivo de protección embólica, Dispositivo di protezione embolica, Embolisch beschermingsinstrument, Anordning til beskyttelse mod emboli, Emboliskyddsanordning, Dispositivo de Protecção Embólica, Συσκευή εμβολικής προστασίας, 塞栓症予防デバイス

7.0 mm	320/190 cm	.014" 0.36mm
REF Model モデル	SPDRX-US-070	
LOT Lot. No. ロット番号	1234567	
Use By 使用期限	2012-05-10	
(1) Capture Wire, (1) SpideRX Catheter, Product Literature		
Recommended Carotid Vessel Size	5.5 - 7.0mm	
Recommended SVG Vessel Size	5.5 - 6.0mm	
Guide Compatibility	6F (min ID .066")	
Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.		
Manufactured in the U.S.A.		

ev3™ SpideRX™ 7.0mm LOT 1234567
REF: SPDRX-US-070 2012-05-10
(01) 0 0821684 03549 8 (17) 120510 (10) 1234567

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(01) 0 0821684 03549 8
(17) 120510 (10) 1234567

℞ only

500449-300 Rev. N

SpideRX™
(01) 0 0821684 03549 8 (17) 120510 (10) 1234567

ev3™

7.0 mm	320/190 cm	.014" 0.36mm	REF SPDRX-US-070
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			2012-05-10

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STERILE EO

SpideRX™

Embolic Protection Device

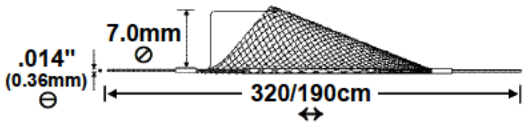
Embolic Protection Device, Dispositif de protection embolique, Embolieschutzvorrichtung, Dispositivo de protección embólica, Dispositivo di protezione embolica, Embolisch beschermingsinstrument, Anordning til beskyttelse mod emboli, Emboliskyddsanordning, Dispositivo de Protecção Embólica, Συσκευή εμβολικής προστασίας, 塞栓症予防デバイス

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Guide Compatibility	6F (min ID .066")	
Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.		
Manufactured in the U.S.A.		

ev3™ SpideRX™ 7.0mm
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(17) 120510 (10) 1234567

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500450-200 Rev. N

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SPIDERX™
EMBOLIC PROTECTION DEVICE

INSTRUCTIONS FOR USE
CAROTID INTERVENTIONS

CAUTION:
Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

ev3®
THE ENDOVASCULAR COMPANY

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PRODUCT DESCRIPTION

The SpideRX™ Embolic Protection Device is a percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The SpideRX Device Capture Wire is used as the 0.014 in. wire for interventional device delivery. The SpideRX Device can be delivered over any 0.014 in. or 0.018 in. primary wire used to gain access to the lesion site.

The SpideRX Embolic Protection Device package contains the following components:

- One **Capture Wire** composed of a nitinol mesh Filter with a Distal Floppy Tip, mounted on a convertible 190/320 cm PTFE-coated 0.014 in. stainless steel wire. The Filter features a heparin-coating designed to maintain patency during Filter deployment[1]. This Capture Wire acts as the primary guidewire for other interventional devices compatible with a 0.014 in. wire. This Capture Wire is scored, allowing the wire to be snapped to a 190 cm usable length for use with rapid exchange systems, if desired. The distal portion of the Capture Wire for rapid exchange use is gold. The proximal portion for standard over-the-wire use is black.

  [1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.

- One dual-ended **SpideRX Catheter** used to exchange the primary access guidewire with the Capture Wire, deploy the Capture Wire at the desired location, and recover the Capture Wire at the end of the procedure. A Primary Wire Exit Collar is attached to the Delivery End of the Catheter to assist in proper primary guidewire loading.

WARNING: The Primary Wire Exit Collar must be removed prior to insertion of the SpideRX Catheter into the patient. Failure to remove the Collar could cause embolization of the Collar, device damage and/or patient injury.

Components are delivered sterile, for use within a single vessel only. Do not re-sterilize or reuse.

INDICATIONS FOR USE

The SpideRX Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.

CONTRAINDICATIONS

Use of the SpideRX Embolic Protection Device is contraindicated under these circumstances:

- Do not use with patients in whom anti-coagulant and anti-platelet therapy is contraindicated
- Do not use in vessels with excessive tortuosity
- Do not use in patients with uncorrected bleeding disorders

WARNINGS

Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.

- Refer to the instructions supplied with all interventional devices to be used in conjunction with the SpideRX Embolic Protection Device for their intended uses, contraindications and potential complications.
- The safety and effectiveness of this device as an embolic protection system have not been established in vasculatures outside the carotid arteries (coronary, cerebral or peripheral).
- The safety and efficacy of the SpideRX Embolic Protection Device have not been demonstrated with carotid stent systems other than the over-the-wire or RX ACCULINK™ Carotid Stent System.
- The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure as suggested in these instructions.
- The Primary Wire Exit Collar must be removed prior to insertion of the SpideRX Catheter into the patient. Failure to remove the Collar could cause embolization of the Collar, device damage and/or patient injury.
- Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.
- Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpideRX Catheter may result in air embolism.
- Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris.
- Do not apply excessive force to the Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.
- Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.
- Do not place the SpideRX Capture Wire tip in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.
- Do not deploy the Filter within a previously implanted stent.
- Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.
- Do not use thrombectomy, atherectomy or laser devices with the Capture Wire.
- Do not attempt to reposition or remove the Capture Wire without the use of the SpideRX Catheter. This may lead to embolization of debris, and vessel and/or device damage.
- Frequently observe the SpideRX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow flow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See Recovery and Removal).
- Dwell time for the SpideRX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow.
- Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

PRECAUTIONS

- Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.
- Do not use the product if the packaging sterile barriers have been damaged or compromised.
- The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.
- Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.
- DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.
- Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpideRX Catheter, which can cause the wires to wrap around the catheter.
- Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.
- Do not re-sterilize or reuse this device.

OBSERVED ADVERSE EVENTS

The SpideRX Embolic Protection Device was evaluated for the treatment of internal and/or common carotid artery stenoses in high-risk patients via the Carotid Revascularization with **ev3** Arterial Technology Evolution (CREATE) Trial Clinical Trials series. A total of 609 patients were enrolled in the trial as follows:

- CREATE Feasibility evaluated the **ev3** over-the-wire (OTW) SPIDER™ Embolic Protection Device and Protégé® Self-expanding Nitinol Stent and included 30 patients. The primary objective of the study was to evaluate the safety of the Protégé Stent and SPIDER Embolic Protection Device in the treatment of common and/or internal carotid artery stenoses for subjects that are at high-risk for carotid endarterectomy.
- CREATE Pivotal also evaluated the **ev3** over-the-wire (OTW) SPIDER Embolic Protection Device and Protégé Self-expanding Nitinol Stent and included 419 patients. The primary objective of the study was to evaluate the safety and efficacy of the Protégé Stent and SPIDER Embolic Protection Device in the treatment of common and/or internal carotid artery stenoses for subjects that are at high-risk for carotid endarterectomy.
- The SpideRX Arm of the CREATE Trial evaluated the **ev3** rapid exchange SpideRX™ Embolic Protection Device and the commercially available ACCULINK™ Carotid Stent and included 160 patients. The primary objective of the study was to evaluate the safety and performance of the SpideRX Device in the treatment of common and/or internal carotid artery stenoses for patients at high-risk for carotid endarterectomy.

The SpideRX Embolic Protection Device is used in an acute manner and, therefore, peri-procedural adverse events are the most relevant evaluation of device safety. Table 1, below, presents the serious adverse events (defined as any event that may be either life-threatening or involve permanent long term injuries) that were reported through the 30-day follow-up visit in the SpideRX Arm and the CREATE Pivotal (SPIDER) Trial.

TABLE 1 – Serious Adverse Events Summary, 30 Days

Description of Event[1]	SpideRX (N=160)	SPIDER (N=419)	Difference (95% C.I.)	p-value
All Death, Stroke and MI	9/160 (5.6%)	26/419 (6.2%)	-0.6% (-4.8%, 3.7%)	1.000
Death	4/160 (2.5%)	8/419 (1.9%)	0.6% (-2.2%, 3.3%)	0.745
Ipsilateral Stroke				
Major	1/160 (0.6%)	11/419 (2.6%)	-2.0% (-4.0%, 0.0%)	0.1943
Minor	2/160 (1.3%)	2/419 (0.5%)	0.8% (-1.1%, 2.6%)	0.3066
Non-Ipsilateral	0/160 (0.0%)	2/419 (0.5%)	-0.50%	1.0000
Total patients with complications	37/160 (23.1%)	127/419 (30.3%)	- 7.2% (-15.1%, 0.7%)	0.0989
Access site complications:				
Hemorrhage	0/160 (0.0%)	4/419 (1.0%)	-1.00%	0.5798
Pseudoaneurysm	2/160 (1.3%)	6/419 (1.4%)	-0.2% (-2.2%, 1.9%)	1.0000
Puncture site infection	0/160 (0.0%)	1/419 (0.2%)	-0.20%	1.0000
Amaurosis Fugax	1/160 (0.6%)	0/419 (0.0%)	0.60%	0.2763
Angina	2/160 (1.3%)	0/419 (0.0%)	1.30%	0.0760
Arrhythmia	5/160 (3.1%)	11/419 (2.6%)	0.5% (-2.6%, 3.6%)	0.7784
Artery perforation contained	0/160 (0.0%)	1/419 (0.2%)	-0.20%	1.0000
Artery perforation - non-contained	0/160 (0.0%)	1/419 (0.2%)	-0.20%	1.0000
Congestive Heart Failure	3/160 (1.9%)	0/419 (0.0%)	1.90%	0.0208
Death	4/160 (2.5%)	8/419 (1.9%)	0.6% (-2.2%, 3.3%)	0.7449
Dissection	1/160 (0.6%)	5/419 (1.2%)	-0.6% (- 2.2%, 1.0%)	1.0000
Emergent surgery	0/160 (0.0%)	2/419 (0.5%)	-0.50%	1.0000
GI bleeding	1/160 (0.6%)	7/419 (1.7%)	-1.0% (- 2.8%, 0.7%)	0.4551
Hypotension	21/160 (13.1%)	71/419 (16.9%)	-3.8% (-10.2%, 2.5%)	0.3094
Intracerebral bleed	1/160 (0.6%)	0/419 (0.0%)	0.60%	0.2763
MI	1/160 (0.6%)	4/419 (1.0%)	- 0.3% (-1.9%, 1.2%)	1.0000
Renal failure requiring dialysis	0/160 (0.0%)	1/419 (0.2%)	-0.20%	1.0000
Renal insufficiency	2/160 (1.3%)	5/419 (1.2%)	0.1% (- 2.0%, 2.1%)	1.0000
Seizure	0/160 (0.0%)	2/419 (0.5%)	-0.50%	1.0000
Stent / Vessel thrombosis	1/160 (0.6%)	0/419 (0.0%)	0.60%	0.2763
Stent misplacement	0/160 (0.0%)	1/419 (0.2%)	-0.20%	1.0000
Stent or filter failure or deploy	0/160 (0.0%)	1/419 (0.2%)	-0.20%	1.0000
TIA	0/160 (0.0%)	4/419 (1.0%)	-1.00%	0.5798
Other	8/160 (5.0%)	35/419 (8.4%)	- 3.4% (-7.6%, 0.9%)	0.2148

[1] Patients may have had multiple events. Counts represent the number of events reported.

Table 2 indicates the number of deaths that were considered to be related to a stroke or myocardial infarction.

TABLE 2 – Cause of Death, 30 Days

Events	SpideRX (N=160)	SPIDER (N=419)
Stroke	2	6
Cardiac	2	0

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TABLE 3 – Adverse Events Summary, 30 Days

Description of Event[1]	SpideRX (N=160)	SPIDER (N=419)	Difference (95% C.I.)	p-value
Total patients with complications	12/160 (7.5%)	27/419 (6.4%)	1.1% (- 3.7%, 5.8%)	0.7110
Access site complication - hematoma	5/160 (3.1%)	2/419 (0.5%)	2.6% (- 0.1%, 5.4%)	0.0195
Access site complication - puncture site infection	0/160 (0.0%)	1/419 (0.2%)	-0.20%	1.0000
Allergic reaction to contrast dye	0/160 (0.0%)	1/419 (0.2%)	-0.20%	1.0000
Allergic reaction to procedure meds	0/160 (0.0%)	1/419 (0.2%)	-0.20%	1.0000
Arrhythmia	0/160 (0.0%)	2/419 (0.5%)	-0.50%	1.0000
Hypotension	0/160 (0.0%)	2/419 (0.5%)	-0.50%	1.0000
Renal insufficiency	2/160 (1.3%)	3/419 (0.7%)	0.5% (- 1.4%, 2.4%)	0.6200
Stroke - Minor	2/160 (1.3%)	0/419 (0.0%)	1.30%	0.0760
Ipsilateral stroke - Minor	2/160 (1.3%)	0/419 (0.0%)	1.30%	0.0760
TIA	1/160 (0.6%)	5/419 (1.2%)	- 0.6% (- 2.2%, 1.0%)	1.0000
Vasospasm	1/160 (0.6%)	0/419 (0.0%)	0.60%	0.2763
Other	1/160 (0.6%)	10/419 (2.4%)	- 1.8% (- 3.7%, 0.1%)	0.3049

[1] Patients may have had multiple events. Counts represent the number of events reported.

POTENTIAL COMPLICATIONS

- Access site adverse event (e.g., av fistula, hematoma, hemorrhage, pseudoaneurysm, puncture site infection)
- Adverse reaction to antiplatelet/anticoagulation agents or contrast media
- Allergic reaction to device materials
- Amaurosis Fugax
- Angina (unstable)
- Arterial dissection
- Cerebral hemorrhage
- Congestive heart failure
- Death
- Device(s) deformation, collapse, fracture, or rupture
- Device(s) thrombosis (acute and subacute)
- Dissection
- Embolization of air, debris, plaque or thrombus (evidenced by slow or no-flow) from mechanical disruption by the intervention, resulting in TIA or stroke
- Embolization or migration of the interventional device(s)
- Emergency surgery
- GI bleeding due to anticoagulation
- Hemodynamic compromise (e.g., prolonged hypotension requiring treatment with intravenous medications)
- Hyperperfusion syndrome
- Hypotension or hypertension
- Infection
- Intracerebral bleed
- Myocardial infarction
- Renal insufficiency
- Renal failure requiring dialysis
- Seizure
- Sepsis
- Significant cardiac arrhythmia requiring treatment with medications and/or transvenous pacing
- Stent entanglement
- Stroke
- Thrombosis (acute and subacute)
- Transient Ischemia Attach (TIA)
- Vasospasm
- Vessel dissection, perforation, rupture or intimal flap
- Vessel/filter occlusion

CLINICAL STUDIES

The Carotid Revascularization with **ev3** Arterial Technology Evolution (CREATE) Clinical Trials were a series of prospective, non-randomized, multi-center, single-arm clinical trials. A total of 609 patients were enrolled at 35 clinical sites in the United States in three trials designed to demonstrate the safety and efficacy of the **ev3** SPIDER over-the-wire and SpideRX Embolic Protection Devices as well as the Protégé Self-Expanding Nitinol Stent when used to treat high-risk symptomatic and asymptomatic patients with internal and/or common carotid artery stenoses.

ELIGIBILITY CRITERIA

Male and female patients who presented for percutaneous treatment of an internal and/or common carotid artery intervention were considered for enrollment. To be included, the patients were required to be at least 18 years old and considered to be at high risk for carotid endarterectomy. The general and angiographic inclusion and exclusion criteria for the three trials were identical with the exception of vessel size in the SpideRX Arm of the CREATE Trial. Vessel size was changed in this trial to accommodate the limitations of the commercially available carotid stent.

Patients were considered symptomatic if their target stenosis was associated with ipsilateral transient or visual TIA evidenced by amaurosis fugax, ipsilateral hemispheric TIAs or ipsilateral ischemic stroke within 6 months prior to enrollment. Patients who were characterized as symptomatic were also required to have a target lesion stenosis (as defined in the NASCET trial)≥50%. Asymptomatic patients were required to have a target lesion stenosis ≥70%.

High risk criteria are included in Table 4.

TABLE 4 – High Surgical Risk Criteria

Clinical Criteria[1]	Anatomical Criteria[1]
1. Age >75	1. Contralateral occlusion
2. CCS angina class 3-4 or unstable angina	2. High cervical lesion (above the angle of the jaw)
3. CHF class III-IV	3. Infraclavicular lesion
4. LVEF <35%	4. Tandem lesions >70%
5. MI <6 weeks	5. Hostile neck (cervical radiation treatment, tracheostomy/stoma, or radical neck dissection)
6. Coronary artery disease with >2 vessel disease in major vessel & history of angina	6. CEA restenosis
7. Severe pulmonary disease – home oxygen, resting pO2 <60 or FEV1 <50%	7. Cervical immobility due to fusion or arthritis
8. Permanent contralateral cranial nerve injury	8. Bilateral carotid stenoses, both requiring treatment*

[1] The subjects were required to meet at least ONE or more high-risk criterion in EITHER the clinical or anatomical section.

* Only the most severe lesion meeting the angiographic inclusion criteria could be treated in the SpideRX Arm of the CREATE Trial.

Baseline demographic characteristics are included in Table 5, below. They were evaluated to determine if subjects enrolled in the SpideRX Arm of the CREATE Trial and the CREATE Pivotal Trial are homogeneous. The differences reported, along with the associated p-values, correspond to the differences between the populations in the SpideRX Arm of the CREATE Trial and those enrolled in the CREATE Pivotal Trial. The only characteristics indicated to be significantly different were history of other treatment to the target artery (3.8% for RX, 0.7% for Pivotal), history of TIA (15.0% for SpideRX 23.2% for Pivotal), and lesion location in both the common and internal carotid artery (11.3% for SpideRX, 19.1% for Pivotal).

CLINICAL RESULTS SUMMARY

The primary endpoint of the SpideRX Arm of the CREATE Trial is a composite endpoint of MI, ipsilateral CVA, procedure-related contralateral CVA or death within 30 days of implantation (MACCE Table 5, below). There are no significant differences between the SpideRX Arm and the CREATE Pivotal Trial with respect to the primary endpoint.

The relationship of patient or baseline lesion characteristics to outcomes through 30-days was considered in a multivariate analysis. This analysis did not result in any statistically significant predictor of outcomes (all $p < 0.05$).

TABLE 5 – Primary and Secondary Endpoints

Efficacy Measures	SpideRX (N=160)	SPIDER (N=419)	Difference (95% C.I.)	p-value
Primary Endpoint				
30-Day MACCE	9 (5.6%)	26 (6.2%)	-0.6% (-4.8%, 3.7%)	1.000
Myocardial Infarction	1 (0.6%)	4 (1.0%)	-0.4% (-1.9%, 1.2%)	1.000
Ipsilateral CVA	7 (4.4%)	16 (3.8%)	0.6% (-3.1%, 4.2%)	0.813
- Major	2 (1.3%)	14 (3.3%)	-2.1% (-4.5%, 0.3%)	
- Minor	4 (2.5%)	2 (0.5%)	2.0% (0.5%, 4.5%)	
- Intracerebral Bleed	1 (0.6%)	0	0.6%	
Procedure-related Contralateral CVA	0 (0.0%)	3 (0.7%)	-0.7% (-3.1%, 4.2%)	0.565
Death	4 (2.5%)	8 (1.9%)	0.6% (-2.2%, 3.3%)	0.745
Secondary Endpoint				
Technical Success	156 (97.5%)	408 (97.4%)	0.1% (-2.7%, 3.0%)	1.000
Acute Procedure Success (QCA)	147 /148 (99.3%)	398 / 398 (100%)	-0.7% (-2.0%, 0.6%)	0.271
Acute Procedure Success (Site)	158 (98.8%)	437 / 441 (99.1%)	-0.3% (-2.3%, 1.6%)	0.659

CLINICAL USE INFORMATION

Pre-procedure anticoagulant and antiplatelet requirements were specified in the clinical trial. A baseline dose of acetylsalicylic acid (ASA) of 325 mg was required the day prior and the day of the procedure. For patients on regular Coumadin® therapy, the dose could be reduced to 81 mg.

Several options were given with respect to the loading dose of antiplatelet medication:

- Clopidogrel 75 mg for three days prior to the procedure and the day of the procedure **or**
- Clopidogrel 450 mg the day before the procedure and 75 mg the day of the procedure **or**
- Ticlopidine 1000 mg the day before the procedure and two 250 mg doses the day of the procedure.

Patients were required to take 325 mg ASA **and** either 75 mg of clopidogrel each day or 250 mg of ticlopidine twice a day for three months following the procedure. For patients on regular Coumadin® therapy, the post-procedure ASA dose could be reduced to 81 mg.

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DEVICE COMPONENTS

The SpideRX Embolic Protection Device package contains one each of the following components:

NOTE: *See **Table 6** for Device product specifications.*

Capture Wire– The Capture Wire has a Nitinol mesh Filter with a Distal Floppy Tip, mounted on a convertible 190/320 cm PTFE-coated 0.014 in. stainless steel wire. The Filter has a heparin coating designed to maintain patency[1]. The Capture Wire is pre-loaded through the Delivery End of the SpideRX Catheter with the Filter extending from the Catheter distal tip. The SpideRX Capture Wire and Catheter are provided in a single hoop.

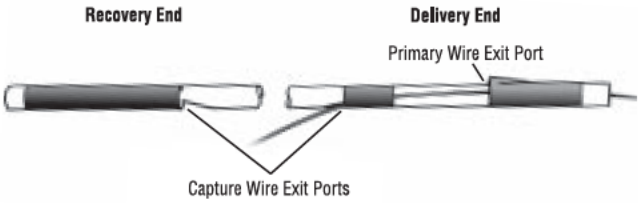
[1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.



Capture Wire

CAUTION: *Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.*

SpideRX Catheter – The SpideRX Catheter is dual-ended, with a Delivery End (green), and a Recovery End (blue) at the opposite end of the catheter.



SpideRX Catheter

- The **Delivery End** (green) of the SpideRX Catheter has an embedded radiopaque marker at the distal tip, a Clear Segment, and a Capture Wire Exit Port. The Capture Wire is pre-loaded into the Delivery End of the Catheter, with the Filter portion extending from the distal tip. A Primary Wire Exit Collar with Tab (black) is attached to the Delivery End of the Catheter to assist in proper primary guidewire loading, if needed.

  WARNING: The Primary Wire Exit Collar must be removed prior to insertion of the SpideRX Catheter into the patient. Failure to remove the Collar could cause embolization of the Collar, device damage and/or patient injury.

- The center **White Shaft** is used to manipulate the SpideRX Catheter during delivery and recovery of the SpideRX Capture Wire.
- The **Recovery End** (blue) of the SpideRX Catheter has an embedded radiopaque marker at its distal tip, and a Capture Wire Exit Port.

Latex is not a component of the SpideRX Embolic Protection Device.

TABLE 6 – SpideRX Embolic Protection Device Specifications*

SpideRX Capture Wire					
Filter Diameter (mm)	3.0	4.0	5.0	6.0	7.0
Capture Wire Length RX/OTW (cm)	190/320	190/320	190/320	190/320	190/320
Wire Diameter (in./mm)	**0.014/0.36**	**0.014/0.36**	**0.014/0.36**	**0.014/0.36**	**0.014/0.36**
Distal Floppy Tip coil Length (cm)	1.2	1.2	1.2	1.2	1.2
SpideRX Catheter - Delivery End (green)					
Nominal Diameter (in./mm)	0.040/1.02	0.040/1.02	0.040/1.02	0.040/1.02	0.040/1.02
Functional Length (cm)	140	140	140	140	140
SpideRX Catheter - Recovery End (blue)					
Diameter (Fr)	4.2	4.2	4.2	4.2	4.2
Functional Length (cm)	140	140	140	140	140
Total Catheter Length (cm)	180	180	180	180	180

*Nominal

INSTRUCTIONS FOR USE

Preparing the SpideRX Embolic Protection Device for Use

1. Administer anti-coagulation medications and monitor activated clotting time per standard institutional guidelines. Use of anti-platelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpideRX Device will be deployed, approximately 3 cm distal to the lesion site being treated. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the lesion, to allow for adequate Filter deployment.

   WARNING: Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris.

4. Ensure the guide catheter/sheath size will accommodate the SpideRX Catheter. **(Table 7).**

TABLE 7 – Sizing Guide[1]

Target Vessel Size (mm)	Filter Size (mm)	Primary Guidewire Size (inches)	Guide Catheter/ Sheath Min I.D.[2] (inches)
3.0	3.0	0.014-0.018	0.066"
3.1-4.0	4.0	0.014-0.018	0.066"
4.1-5.0	5.0	0.014-0.018	0.066"
4.5-6.0	6.0	0.014-0.018	0.066"
5.5-7.0	7.0	0.014-0.018	0.066"

[1] Nominal

[2] Select a guide catheter that provides coaxial alignment and stable backup support.

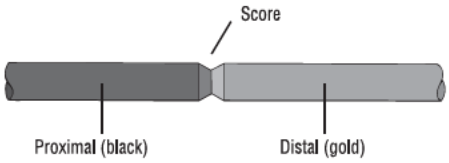
5. Using sterile technique, remove the SpideRX Device components with the hoop from the packaging, and place in a sterile work area.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Capture Wire Filter and the Delivery End (green) of the SpideRX Catheter.
7. Grasp the Catheter near the Primary Wire Exit Port and gently pull to expose the Catheter. The remaining Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the Catheter.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

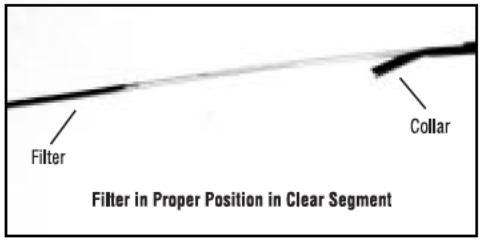
NOTE: *If using the SpideRX Device as a rapid exchange wire, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*



Capture Wire

8. Hold the Catheter at the distal tip and submerge the Filter in heparinized saline to wet and remove air.
9. Continue holding the Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter portion stops in the Clear Segment of the Catheter.

CAUTION: *The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.*



Filter in Proper Position in Clear Segment

10. Flush through the distal tip with heparinized saline until all air is removed and fluid passes from the Primary Wire Exit Port within the Primary Wire Exit Collar (22.5 cm proximal to the distal tip of the Catheter). A 23 gauge blunt needle may be used, if desired.
11. Gently apply pressure to the Primary Wire Exit Port within the Primary Wire Exit Collar. Flush until all air is removed and fluid passes from the Capture Wire Exit Port (40 cm proximal to Catheter distal tip).

    WARNING: Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpideRX Catheter may result in air embolism.

Delivery and Deployment

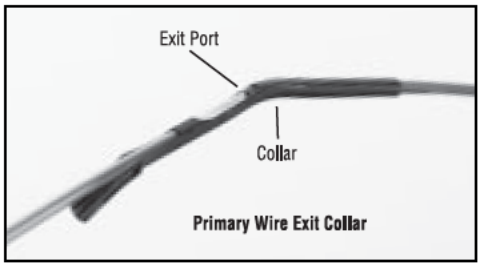
12. Access the vessel being treated using standard technique, and advance the primary guidewire at least 5 cm beyond the distal edge of the lesion being treated.
13. Observe the Primary Wire Exit Port to ensure the Port hole is visible within the opening of the black Primary wire Exit Collar. Adjust position of the Catheter within the Collar if necessary. The Primary Wire Exit Collar may also be removed and the primary guidewire may be loaded without this accessory. Alternative Option to Use without Primary Wire Exit Collar: After removing the Delivery End of the Catheter from the hoop (step #7), carefully remove the Exit Collar prior to wetting the filter and retracting it into the Delivery Catheter (step #8).

NOTE: *When loading the primary guidewire, gently bend the Catheter at the Primary Wire Exit Port to create a 2.5 cm radius.*

CAUTION: *Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.*

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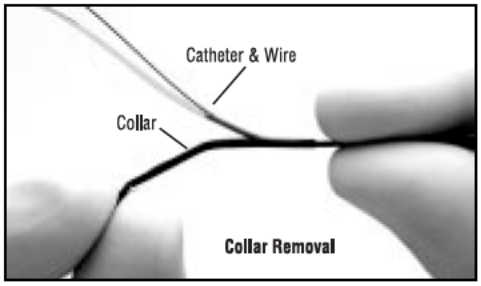


Primary Wire Exit Collar

14. Load the distal tip of the SpideRX Device Delivery End (green) onto the proximal end of the primary guidewire and advance, so the primary wire exits at the Primary Wire Exit Port.

CAUTION: *DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.*

15. After the primary wire exits the Primary Wire Exit Port, remove the Exit Collar, if still attached, by grasping the tab at the proximal end of the Collar, and pulling it off of the Catheter through the slot in the Collar. Discard the Primary Wire Exit Collar.



Collar Removal

WARNING: The Primary Wire Exit Collar must be removed prior to insertion of the SpideRX Catheter into the patient. Failure to remove the Collar could cause embolization of the Collar, device damage and/or patient injury.

16. Gently advance the SpideRX Delivery End carrying the Capture Wire over the primary wire and into the guide catheter/sheath. Continue advancing until the radiopaque marker at the distal tip of the Delivery End is at least 4-5 cm beyond the distal edge of the lesion.

CAUTION: *Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpideRX Catheter, which can cause the wires to wrap around the catheter.*

WARNING: Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.

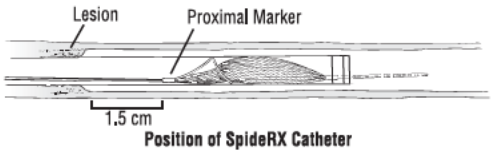
WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

17. Hold the Catheter stationary, and withdraw the primary guidewire, leaving the Delivery Catheter and Capture Wire in place.

18. Hold the Catheter stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter distal tip.

WARNING: Do not place the SpideRX Capture Wire in a vessel that does not allow wire movement. This may lead to embolization of debris, and vessel and/or device damage.

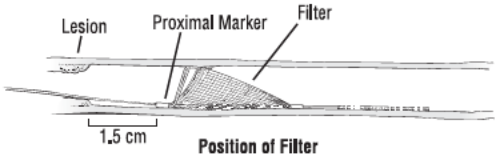
19. Observe the position of the Filter under fluoroscopy to ensure the proximal radiopaque marker is at least 1.5 cm distal to the lesion being treated. Gently advance the entire Delivery End assembly if necessary so the proximal Filter marker is at least 1.5 cm beyond the lesion distal edge.



Position of SpideRX Catheter

CAUTION: *Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.*

20. Hold the Capture Wire stationary, and gently pull back on the Catheter to expose and deploy the Filter in the vessel. To reposition the Filter (if required), advance the Catheter back over the Filter, adjust the position of the Catheter and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter.



Position of Filter

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the SpideRX Catheter. This may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not deploy the Filter within a previously implanted stent.

21. A radiopaque proximal loop seen as a rounded shape indicates the Filter is properly opened. If not, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Delivery Catheter together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.

22. Obtain two orthogonal views to verify filter apposition to the vessel wall.

23. Once the Filter is deployed in the desired location, carefully remove the SpideRX Catheter from the patient. Keep the Catheter in the sterile field. **DO NOT DISCARD THE CATHETER.** The Recovery End (blue) is required for Capture Wire recovery.

24. Place the SpideRX Catheter in sterile heparinized saline or sterile field, and save for recovery of the SpideRX Capture Wire. Do not bend or kink the Catheter.

25. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use thrombectomy, atherectomy or laser devices with the Capture Wire

WARNING: Frequently observe the SpideRX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).

Recovery and Removal

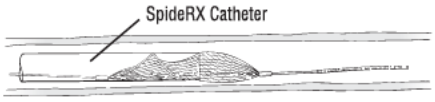
26. After completion of the interventional procedure, wet the distal 20 cm of the Catheter with heparinized saline. Flush the distal tip of the Recovery End (blue) to remove all air, until fluid passes from the Capture Wire Exit Port (25 cm from the tip).

27. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.

28. Advance the Catheter under fluoroscopy until the distal tip radiopaque marker aligns with the radiopaque marker at the proximal end of the Filter.

29. There are two methods for Filter Recovery:

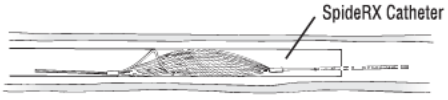
A – Partial Enclosure Recovery: Gently advance the Recovery End over the Filter, until the proximal portion of the Filter is inside the Catheter, and the radiopaque proximal loop of the Filter is fully compressed against the Capture Wire within the catheter.



A. Partial Enclosure Recovery

WARNING: Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

B – Full Enclosure Recovery: Gently advance the Recovery End over the Filter until both radiopaque markers on the Filter are within the Catheter, proximal to the Catheter distal marker. The Distal Floppy Tip may remain outside the Catheter.



B. Full Enclosure Recovery

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

30. Carefully remove the Catheter and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the SpideRX Catheter to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

CAUTION: *Do not re-sterilize or reuse this device.*

STORAGE

- Do not store in direct sunlight
- Keep dry

WARRANTY DISCLAIMER

Although the product has been manufactured under carefully controlled conditions, **ev3** Inc. has no control over the conditions under which this product is used. **ev3** Inc., therefore disclaims all warranties, both express and implied, with respect to the product including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. **ev3** Inc. shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind **ev3** Inc. to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

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Protected under one or more of the following: U.S. Patent 6,843,798; 6,740,061; 6,712,835; 6,325,815. Non-US patents issued & pending.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Attachment D: Acute Animal Study

(b)(4) Acute Animal Study

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ev3®

THE ENDOVASCULAR COMPANY

SpiderFX™

Embolic Protection Device

INSTRUCTIONS FOR USE
CAROTID INTERVENTIONS

103 of 215 R-3377

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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PRODUCT DESCRIPTION

The SpiderFX™ Embolic Protection Device is a percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The SpiderFX Device Capture Wire is used as the 0.014 in. wire for interventional device delivery. The SpiderFX Device can be delivered over any 0.014 in. or 0.018 in. primary wire used to gain access to the lesion site.

The SpiderFX Embolic Protection Device package contains the following components:

- One **Capture Wire** composed of a nitinol mesh Filter with a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter features a heparin-coating designed to maintain patency during Filter deployment[1]. This Capture Wire acts as the primary guidewire for other interventional devices compatible with a 0.014 in. wire. The convertible 320/190 cm Capture Wire is scored, allowing the wire to be snapped to a 190 cm usable length for use with rapid exchange systems, if desired. The distal portion of the Capture Wire for rapid exchange use is gold. The proximal portion for standard over-the-wire use is black.

  [1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.
- One dual-ended **SpiderFX Catheter** used to exchange the primary access guidewire with the Capture Wire, deploy the Capture Wire at the desired location, and recover the Capture Wire at the end of the procedure.
- One 23 gauge Blunt Needle for attachment to a syringe with Luer connector for priming and flushing the Catheter.

Components are delivered sterile, for use within a single vessel only. Do not re-sterilize or reuse.

INDICATIONS FOR USE

The SpiderFX Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.

CONTRAINDICATIONS

Use of the SpiderFX Embolic Protection Device is contraindicated under these circumstances:

- Do not use with patients in whom anticoagulant and antiplatelet therapy is contraindicated
- Do not use in vessels with excessive tortuosity
- Do not use in patients with uncorrected bleeding disorders

WARNINGS

Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.

- Refer to the instructions supplied with all interventional devices to be used in conjunction with the SpiderFX Embolic Protection Device for their intended uses, contraindications and potential complications.
- The safety and effectiveness of this device as an embolic protection system have not been established in vasculatures outside the carotid arteries (coronary, cerebral or peripheral).
- The safety and efficacy of the SpideRX Embolic Protection Device have not been demonstrated with carotid stent systems other than the over-the-wire or RX ACCULINK™ Carotid Stent System.
- The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure in accordance with standard medical practice.
- Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.
- Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.
- Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.
- Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 7 Sizing Guide).
- Do not apply excessive force to the Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.
- Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.
- Do not place the SpiderFX Capture Wire tip in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.
- Do not deploy the Filter within a previously implanted stent.
- Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.
- Do not use thrombectomy, atherectomy, or laser devices with the Capture Wire.
- Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.
- Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow flow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See Recovery and Removal).
- Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow.
- Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

PRECAUTIONS

- Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.
- Do not use the product if the packaging sterile barriers have been damaged or compromised.
- The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.
- Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.
- DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.
- Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the catheter.
- Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.
- Do not re-sterilize or reuse this device.

OBSERVED ADVERSE EVENTS - CLINICAL STUDY

The SpideRX® Embolic Protection Device was evaluated for the treatment of internal and/or common carotid artery stenoses in high-risk patients via the Carotid Revascularization with ev3 Arterial Technology Evolution (CREATE) Trial Clinical series. A total of 609 patients were enrolled in the trial as follows:

- CREATE Feasibility evaluated the ev3 over-the-wire (OTW) SPIDER™ Embolic Protection Device and PROTÉGÉ® Self-expanding Nitinol Stent and included 30 patients. The primary objective of the study was to evaluate the safety of the PROTÉGÉ Stent and SPIDER Embolic Protection Device in the treatment of common and/or internal carotid artery stenoses for subjects that are at high-risk for carotid endarterectomy.
- CREATE Pivotal also evaluated the ev3 over-the-wire (OTW) SPIDER Embolic Protection Device and PROTÉGÉ Self-expanding Nitinol Stent and included 419 patients. The primary objective of the study was to evaluate the safety and efficacy of the PROTÉGÉ Stent and SPIDER Embolic Protection Device in the treatment of common and/or internal carotid artery stenoses for subjects that are at high-risk for carotid endarterectomy.
- The SpideRX Arm of the CREATE Trial evaluated the ev3 rapid exchange SpideRX Embolic Protection Device and the commercially available ACCULINK™ Carotid Stent and included 160 patients. The primary objective of the study was to evaluate the safety and performance of the SpideRX Device in the treatment of common and/or internal carotid artery stenoses for patients at high-risk for carotid endarterectomy.

  The SpideRX Embolic Protection Device is used in an acute manner and, therefore, peri-procedural adverse events are the most relevant evaluation of device safety. Table 1, below, presents the serious adverse events (defined as any event that may be either life-threatening or involve permanent long term injuries) that were reported through the 30-day follow-up visit in the SpideRX Arm and the CREATE Pivotal (SPIDER) Trial.

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TABLE 1 – Serious Adverse Events Summary ≤ 30 Days

Description of Event[1]	SpideRX (N=160)	SPIDER (N=417)	Difference (95% C.I.)	p-value
Death	4/160 (2.5%)	8/417 (1.9%)	-0.6% (-3.3%, 2.2%)	0.7453
Ipsilateral Stroke				
Major	2/160 (1.3%)	14/417 (3.4%)	2.1% (-0.3%, 4.5%)	0.2569
Minor	2/160 (1.3%)	3/417 (0.7%)	-0.5% (-2.4%, 1.4%)	0.6207
Non-Ipsilateral Stroke	0/160 (0.0%)	3/417 (0.7%)	0.70%	0.5643
Total patients with complications	37/160 (23.1%)	130/417 (31.2%)	8.1% (0.2%, 16.0%)	0.0648
Access site complications:				
Hemorrhage	0/160 (0.0%)	4/417 (1.0%)	1.00%	0.0058
Pseudoaneurysm	2/160 (1.3%)	6/417 (1.4%)	0.2% (-1.9%, 2.3%)	1.0000
Puncture site infection	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Amaurosis Fugax	1/160 (0.6%)	1/417 (0.2%)	-0.4% (-3.1%, 0.5%)	0.0478
Angina	2/160 (1.3%)	0/417 (0.0%)	-1.30%	0.0765
Arrhythmia	5/160 (3.1%)	12/417 (2.9%)	-0.3% (-3.4%, 2.9%)	1.0000
Artery perforation:				
Contained	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Non-contained	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Congestive Heart Failure	3/160 (1.9%)	0/417 (0.0%)	-1.90%	0.0021
Dissection	1/160 (0.6%)	5/417 (1.2%)	0.6% (-1.0%, 2.2%)	1.0000
Emergent surgery	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
GI bleeding	1/160 (0.6%)	7/417 (1.7%)	0.8% (-0.9%, 2.5%)	0.6797
Hypotension	21/160 (13.1%)	73/417 (17.5%)	4.4% (-2.0%, 10.8%)	0.2568
Intracerebral bleed	1/160 (0.6%)	0/417 (0.0%)	-0.60%	0.2773
MI	1/160 (0.6%)	4/417 (1.0%)	0.3% (-1.2%, 1.9%)	1.0000
Renal failure requiring dialysis	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Renal insufficiency	2/160 (1.3%)	5/417 (1.2%)	-0.1% (-2.1%, 2.0%)	1.0000
Seizure	0/160 (0.0%)	3/417 (0.7%)	0.70%	0.5643
Stent / Vessel thrombosis	1/160 (0.6%)	0/417 (0.0%)	-0.60%	0.2773
Stent misplacement	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Stent or filter failure to deploy	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
TIA	0/160 (0.0%)	4/417 (1.0%)	1.00%	0.0058
Other	9/160 (5.6%)	40/417 (9.6%)	4.0% (-0.6%, 8.5%)	0.1365

[1] Patients may have had multiple events. Counts represent the number of events reported.

Table 2 indicates the number of deaths that were considered to be related to a stroke or myocardial infarction.

TABLE 2 – Cause of Death, 30 Days

Events	SpideRX (N=160)	SPIDER (N=417)
Stroke	2	5
Cardiac	2	3

TABLE 3 – Adverse Events Summary ≤ 30 Days

Description of Event[1]	SpideRX (N=160)	SPIDER (N=417)	Difference (95% C.I.)	p-value
Total patients with complications	12/160 (7.5%)	30/417 (7.2%)	- 0.3% (-5.1%, 4.5%)	0.8598
Access site complication:				
Hematoma	5/160 (3.1%)	2/417 (0.5%)	-2.6% (-5.4%, 0.1%)	0.0198
Puncture site infection	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
Allergic reaction to contrast dye	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Allergic reaction to procedure meds	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Arrhythmia	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
GI bleeding	0/160 (0.0%)	0/417 (0.0%)	NA	NA
Hypotension	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
Renal insufficiency	2/160 (1.3%)	3/417 (0.7%)	-0.5% (-2.4%, 1.4%)	0.6207
Restenosis	0/160 (0.0%)	0/417 (0.0%)	NA	NA
Stent or filter collapse or fracture	0/160 (0.0%)	0/417 (0.0%)	NA	NA
Stroke - Minor	2/160 (1.3%)	0/417 (0.0%)	-1.30%	0.0765
Ipsilateral stroke - Minor	2/160 (1.3%)	0/417 (0.0%)	-1.30%	0.0765
TIA	1/160 (0.6%)	6/417 (1.4%)	0.8% (-0.9%, 2.5%)	0.6797
Vasospasm	1/160 (0.6%)	0/417 (0.0%)	-0.60%	0.2773
Other	1/160 (0.6%)	11/417 (2.6%)	2.0% (0.0%, 4.0%)	0.1942

[1] Patients may have had multiple events. Counts represent the number of events reported.

POTENTIAL COMPLICATIONS

Complications associated with the use of the SpiderFX Embolic Protection Device may include, but are not limited to:

- Access site adverse event (e.g., av fistula, hematoma, hemorrhage, pseudoaneurysm, puncture site infection)
- Adverse reaction to antiplatelet/anticoagulation agents or contrast media
- Allergic reaction to device materials
- Amaurosis Fugax
- Angina (unstable)
- Arterial dissection
- Cerebral hemorrhage
- Congestive heart failure
- Death
- Device(s) deformation, collapse, fracture, or rupture
- Device(s) thrombosis (acute and subacute)
- Dissection
- Embolization of air, debris, plaque or thrombus (evidenced by slow or no-flow) from mechanical disruption by the intervention, resulting in TIA or stroke
- Embolization or migration of the interventional device(s)

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- Emergency surgery
- GI bleeding due to anticoagulation
- Hemodynamic compromise (e.g., prolonged hypotension requiring treatment with intravenous medications)
- Hyperperfusion syndrome
- Hypotension or hypertension
- Infection
- Intracerebral bleed
- Myocardial infarction
- Renal insufficiency
- Renal failure requiring dialysis
- Seizure
- Sepsis
- Significant cardiac arrhythmia requiring treatment with medications and/or transvenous pacing
- Stent entanglement
- Stroke
- Thrombosis (acute and subacute)
- Transient Ischemia Attack (TIA)
- Vasospasm
- Vessel dissection, perforation, rupture or intimal flap
- Vessel/filter occlusion

CLINICAL STUDIES

The Carotid Revascularization with ev3 Arterial Technology Evolution (CREATE) Clinical Trials were a series of prospective, non-randomized, multi-center, single-arm clinical trials. A total of 609 patients were enrolled at 35 clinical sites in the United States in three trials designed to demonstrate the safety and efficacy of the ev3 SPIDER over-the-wire and SpideRX Embolic Protection Devices as well as the PROTÉGÉ Self-Expanding Nitinol Stent when used to treat high-risk symptomatic and asymptomatic patients with internal and/or common carotid artery stenoses.

ELIGIBILITY CRITERIA

Male and female patients who presented for percutaneous treatment of an internal and/or common carotid artery intervention were considered for enrollment. To be included, the patients were required to be at least 18 years old and considered to be at high risk for carotid endarterectomy. The general and angiographic inclusion and exclusion criteria for the three trials were identical with the exception of vessel size in the SpideRX Arm of the CREATE Trial. Vessel size was changed in this trial to accommodate the limitations of the commercially available carotid stent.

Patients were considered symptomatic if their target stenosis was associated with ipsilateral transient or visual TIA evidenced by amaurosis fugax, ipsilateral hemispheric TIAs or ipsilateral ischemic stroke within 6 months prior to enrollment. Patients who were characterized as symptomatic were also required to have a target lesion stenosis (as defined in the NASCET trial) ≥ 50%. Asymptomatic patients were required to have a target lesion stenosis ≥ 70%.

High risk criteria are included in Table 4.

TABLE 4 – High Surgical Risk Criteria

Clinical Criteria[1]	Anatomical Criteria[1]
1. Age >75	1. Contralateral occlusion
2. CCS angina class 3-4 or unstable angina	2. High cervical lesion (above the angle of the jaw)
3. CHF class III-IV	3. Infraclavicular lesion
4. LVEF <35%	4. Tandem lesions >70%
5. MI <6 weeks	5. Hostile neck (cervical radiation treatment, tracheostomy/stoma, or radical neck dissection)
6. Coronary artery disease with >2 vessel disease in major vessel & history of angina	6. CEA restenosis
7. Severe pulmonary disease – home oxygen, resting pO2 <60 or FEV1 <50%	7. Cervical immobility due to fusion or arthritis
8. Permanent contralateral cranial nerve injury	8. Bilateral carotid stenoses, both requiring treatment*

[1] The subjects were required to meet at least ONE or more high-risk criterion in EITHER the clinical or anatomical section.
* Only the most severe lesion meeting the angiographic inclusion criteria could be treated in the SpideRX Arm of the CREATE Trial.

Baseline demographic characteristics are included in Table 5, below. They were evaluated to determine if subjects enrolled in the SpideRX Arm of the CREATE Trial and the CREATE Pivotal Trial are homogeneous. The differences reported, along with the associated p-values, correspond to the differences between the populations in the SpideRX Arm of the CREATE Trial and those enrolled in the CREATE Pivotal Trial. The only characteristics indicated to be significantly different were history of other treatment to the target artery (3.8% for RX, 0.7% for Pivotal), history of TIA (15.0% for SpideRX 23.2% for Pivotal), and lesion location in both the common and internal carotid artery (11.3% for SpideRX, 19.1% for Pivotal).

CLINICAL RESULTS SUMMARY

The primary endpoint of the SpideRX Arm of the CREATE Trial is a composite endpoint of MI, ipsilateral CVA, procedure-related contralateral CVA or death within 30 days of implantation (MACCE Table 5, below). There are no significant differences between the SpideRX Arm and the CREATE Pivotal Trial with respect to the primary endpoint.

The relationship of patient or baseline lesion characteristics to outcomes through 30-days was considered in a multivariate analysis. This analysis did not result in any statistically significant predictor of outcomes (all p <0.05).

TABLE 5 – Primary and Secondary Endpoints

Efficacy Measures	SpideRX (N=160)	SPIDER (N=417)	Difference (95% C.I.)	p-value
Primary Endpoint	9/160 (5.6%)	29/370 (7.8%)	N/A	N/A
30-Day MACCE	9/160 (5.6%)	26/414 (6.3%)	0.7% (-3.6%, 4.9%)	0.8480
Myocardial Infarction	1/160 (0.6%)	4/414 (1.0%)	0.3% (-1.2%, 1.9%)	0.6933
Ipsilateral CVA	7/160 (4.4%)	16/414 (3.9%)	-0.5% (-4.1%, 3.1%)	0.8133
Major	2/160 (1.3%)	14/414 (3.4%)	2.1% (-0.3%, 4.6%)	0.2570
Minor	4/160 (2.5%)	3/414 (0.7%)	-1.8% (-4.3%, 0.8%)	0.0988
Intracerebral Bleed	1/160 (0.6%)	0/414 (0.0%)	-0.60%	0.2800
Procedure-Related Contralateral CVA	0/160 (0.0%)	3/414 (0.7%)	0.70%	0.5638
Death	4/160 (2.6%)	8/414 (1.9%)	-0.6% (-3.4% , 2.2%)	0.7460
1 year Ipsilateral CVA	N/A	3/370 (0.8%)	N/A	N/A
Secondary Endpoints				
MANE	N/A	26/370 (7.0%)	N/A	N/A
TLR at 1 year	N/A	1/370 (0.2%)	N/A	N/A
TVR at 1 year	N/A	1/370 (0.2%)	N/A	N/A
Primary Patency at 1 year	N/A	286/304 (94.1%)	N/A	N/A
Technical Success	156/160 (97.5%)	408/419 (97.4%)	-0.13% (-3.01%, 2.76%)	0.9317
Acute Procedure Success (QCA)	147/148 (99.3%)	397/397 (100.0%)	0.68% (-0.65%, 2.01%)	0.1072
Acute Procedure Success (Site)	158/160 (98.8%)	437/444 (98.4%)	-0.3% (-2.4%, 1.8%)	1.0000

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CLINICAL USE INFORMATION

Pre-procedure anticoagulant and antiplatelet requirements were specified in the clinical trial. A baseline dose of acetylsalicylic acid (ASA) of 325 mg was required the day prior and the day of the procedure. For patients on regular Coumadin® therapy, the dose could be reduced to 81 mg.

Several options were given with respect to the loading dose of antiplatelet medication:

- Clopidogrel 75 mg for three days prior to the procedure and the day of the procedure **or**
- Clopidogrel 450 mg the day before the procedure and 75 mg the day of the procedure **or**
- Ticlopidine 1000 mg the day before the procedure and two 250 mg doses the day of the procedure.

Patients were required to take 325 mg ASA **and** either 75 mg of clopidogrel each day or 250 mg of ticlopidine twice a day for three months following the procedure. For patients on regular Coumadin® therapy, the post-procedure ASA dose could be reduced to 81 mg.

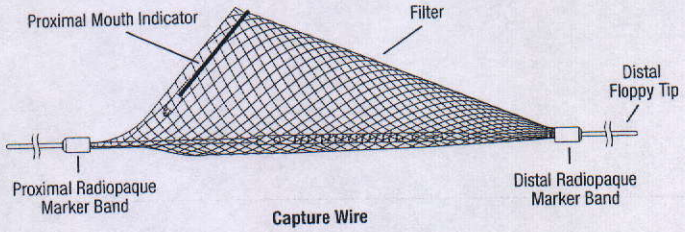
DEVICE COMPONENTS

The SpiderFX Embolic Protection Device package contains one each of the following components:

NOTE: *See **Table 6** for Device product specifications.*

Capture Wire– The Capture Wire has a Nitinol mesh Filter with a Proximal Mouth Indicator and a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter has a heparin coating designed to maintain patency[1]. The Capture Wire is pre-loaded through the Delivery End of the SpiderFX Catheter with the Filter extending from the Catheter distal tip. The SpiderFX Capture Wire and Catheter are provided in a single hoop.

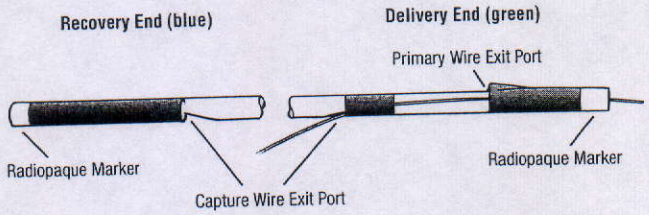
[1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.



Capture Wire

CAUTION: *Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.*

SpiderFX Catheter – The SpiderFX Catheter is dual-ended, with a Delivery End (green), and a Recovery End (blue) at the opposite end of the catheter



SpiderFX Catheter

- The **Delivery End** (green) of the SpiderFX Catheter has an embedded radiopaque marker at the distal tip, a primary wire exit port (indicated by a white stripe), a Clear Segment, and a Capture Wire Exit Port. The Capture Wire is pre-loaded into the Delivery End of the Catheter, with the Filter portion extending from the distal tip.
- The center **White Shaft** is used to manipulate the SpiderFX Catheter during delivery and recovery of the SpiderFX Capture Wire.
- The **Recovery End** (blue) of the SpiderFX Catheter has an embedded radiopaque marker at its distal tip, and a Capture Wire Exit Port.

Latex is not a component of the SpiderFX Embolic Protection Device.

TABLE 6 – SpiderFX Embolic Protection Device Specifications*

SpiderFX Capture Wire					
Filter Diameter (mm)	3.0	4.0	5.0	6.0	7.0
Capture Wire Length RX (cm)	190	190	190	190	190
Capture Wire Length OTW/RX (cm)	320/190	320/190	320/190	320/190	320/190
Wire Diameter (in./mm)	0.014/0.36	0.014/0.36	0.014/0.36	0.014/0.36	0.014/0.36
Distal Wire Tip Coil Length (mm)	1.2	1.2	1.2	1.2	1.2
SpiderFX Catheter - Delivery End (green)					
Nominal Diameter (in./mm)	0.040/1.02	0.040/1.02	0.040/1.02	0.040/1.02	0.040/1.02
Functional Length (cm)	140	140	140	140	140
SpiderFX Catheter - Recovery End (blue)					
Diameter (Fr)	4.2	4.2	4.2	4.2	4.2
Functional Length (cm)	140	140	140	140	140
Total Catheter Length (cm)	180	180	180	180	180

*Nominal

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INSTRUCTIONS FOR USE

Preparing the SpiderFX Embolic Protection Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the lesion site being treated. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the lesion, to allow for adequate Filter deployment.

WARNING: Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 7 Sizing Guide).

4. Ensure the guide catheter/sheath size will accommodate the SpiderFX Catheter. **(Table 7).**

TABLE 7 – Sizing Guide[1]

Target Vessel Size (mm)	Filter Size (mm)	Primary Guidewire Size (inches)	Guide Catheter/Sheath Min I.D.[2] (inches)
3.0	3.0	0.014-0.018	0.066
3.1-4.0	4.0	0.014-0.018	0.066
4.1-5.0	5.0	0.014-0.018	0.066
4.5-6.0	6.0	0.014-0.018	0.066
5.5-7.0	7.0	0.014-0.018	0.066

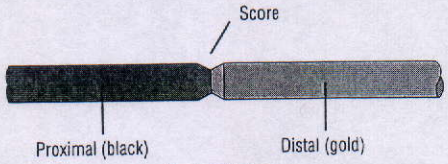
[1] Nominal
[2] Select a guide catheter that provides coaxial alignment and stable backup support.

5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the Catheter near the Primary Wire Exit Port and gently pull to expose the Catheter. The remaining Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the Catheter.

NOTE: *If using the 320/190 cm convertible version of the SpiderFX Device, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*



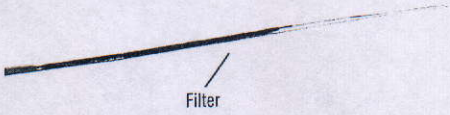
Capture Wire

8. Hold the Catheter at the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

9. Continue holding the Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter portion stops in the Clear Segment of the Catheter.

CAUTION: *The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.*



Filter in Proper Position in Clear Segment

10. Flush through the distal tip with heparinized saline until all air is removed and fluid passes from the Primary Wire Exit Port (22.5 cm proximal to the distal tip of the Catheter). A 23 gauge blunt needle included in the packaging may be used, if desired. Do not apply excessive force to the Capture Wire.
11. Gently apply pressure to the Primary Wire Exit Port. Flush until all air is removed and fluid passes from the Capture Wire Exit Port (40 cm proximal to Catheter distal tip).

WARNING: Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.

Delivery and Deployment

12. Access the vessel being treated using standard technique, and advance the primary guidewire at least 5 cm beyond the distal edge of the lesion being treated.
13. Observe the Primary Wire Exit Port indicated by a white stripe on the Catheter, to ensure the Port hole is visible.

NOTE: *When loading the primary guidewire, gently bend the Catheter at the Primary Wire Exit Port to create a 2.5 cm radius.*

CAUTION: *Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.*

14. Load the distal tip of the SpiderFX Device Delivery End (green) onto the proximal end of the primary guidewire and advance, so the primary wire exits at the Primary Wire Exit Port.

CAUTION: *DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.*

15. Gently advance the SpiderFX Delivery End carrying the Capture Wire over the primary wire and into the guide catheter/sheath. Continue advancing until the radiopaque marker at the distal tip of the Delivery End is at least 4-5 cm beyond the distal edge of the lesion.

CAUTION: *Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the Catheter.*

WARNING: Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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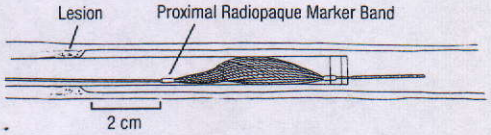
WARNING: Do not apply excessive force to Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

16. Hold the Catheter stationary, and withdraw the primary guidewire, leaving the Delivery Catheter and Capture Wire in place.
17. Hold the Catheter stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow wire movement. This may lead to embolization of debris, and vessel and/or device damage.

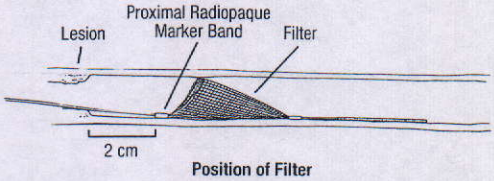
18. Observe the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the lesion being treated. Gently advance the entire Delivery End assembly if necessary so the Proximal Radiopaque Marker Band is at least 2 cm beyond the lesion distal edge.



Position of SpiderFX Catheter

CAUTION: *Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.*

19. Hold the Capture Wire stationary, and gently pull back on the Catheter to expose and deploy the Filter in the vessel. To reposition the Filter (if required), advance the Catheter back over the Filter, adjust the position of the Catheter and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter.



Position of Filter

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.

20. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Delivery Catheter together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
21. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
22. Once the Filter is deployed in the desired location, carefully remove the SpiderFX Catheter from the patient. Keep the Catheter in the sterile field. **DO NOT DISCARD THE CATHETER.** The Recovery End (blue) is required for Capture Wire recovery.
23. Place the SpiderFX Catheter in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter.
24. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow.

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use thrombectomy, atherectomy or laser devices with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).

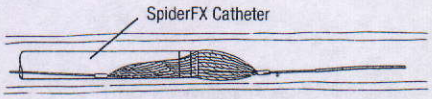
Recovery and Removal

25. After completion of the interventional procedure, wet the distal 20 cm of the Recovery End (blue) of the Catheter with heparinized saline. Flush the distal tip of the Recovery End to remove all air, until fluid passes from the Capture Wire Exit Port (25 cm from the tip).

WARNING: Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

26. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.
27. Advance the Catheter under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
28. There are two methods for Filter Recovery:

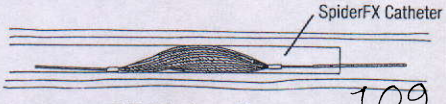
A – Partial Enclosure Recovery: Gently advance the Recovery End over the Filter, until the proximal portion of the Filter is inside the Catheter, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the radiopaque marker of the Recovery Catheter.



A. Partial Enclosure Recovery

WARNING: Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

B – Full Enclosure Recovery: Gently advance the Recovery End over the Filter until all radiopaque markers on the Filter are within the Catheter, proximal to the Catheter distal marker. The Distal Floppy Tip may remain outside the Catheter.



B. Full Enclosure Recovery

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WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

29. Carefully remove the Catheter and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the SpiderFX Catheter to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

CAUTION: *Do not re-sterilize or reuse this device.*

STORAGE

- Do not store in direct sunlight
- Keep dry

WARRANTY DISCLAIMER

Although the product has been manufactured under carefully controlled conditions, ev3 Inc. has no control over the conditions under which this product is used. ev3 Inc., therefore disclaims all warranties, both express and implied, with respect to the product including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ev3 Inc. shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind ev3 Inc. to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SILVERHAWK™

Plaque Excision System
INSTRUCTIONS FOR USE

CAUTION
Federal (US) Law restricts this device to sale by or on the order of a physician.

CE 0050

Device Description

The SilverHawk™ Peripheral Plaque Excision System and SilverHawk™ Cutter Driver are designed for the treatment of *de novo* and restenotic atherosclerotic lesions located in native peripheral arteries. The catheter consists of a flexible shaft designed to track over a 0.014" guidewire. At the distal end of the catheter is a small cutting assembly comprised of a rotating inner blade contained within a tubular housing. The proximal end of the catheter contains a connector and positioning lever designed to fit into a small, disposable, battery-driven Cutter Driver (provided separately), which powers the device.

When the catheter is connected to the Cutter Driver, retracting the positioning lever simultaneously turns on the motor and causes the distal portion of the cutter housing to deflect, forcing the device against the target lesion. At the same time, this motion exposes the inner rotating blade, preparing the device for lesion treatment. With the blade spinning, the catheter is slowly advanced across the lesion, "shaving" occlusive material from the artery. The excised tissue is captured and stored in the tip of the device. The cutting process is completed by advancing the positioning lever which brings the inner blade back into the housing, restoring the cutter to its "non-deflected" configuration, and automatically turns off the motor. This cutting sequence can be repeated as many times as necessary to achieve the desired degree of plaque excision.

Illustration and Nomenclature

Key Catheter Specifications

Catalog Number	P4023	P4016	P4012	P4015
Model	SX (Yellow)	MS (Violet)	LS (Gray)	LX (Gray)
Usable Length	136cm	110 cm	110 cm	113 cm
Tip Length	4.3cm	6.0 cm	6.0 cm	9.0 cm
Maximum Catheter Profile	0.095"	0.105"	0.105"	0.105"
Minimum Sheath Size	7F	8F	8F	8F
Shape Set	None	Mechanical	Mechanical	Mechanical
Maximum Guidewire Diameter	0.014"	0.014"	0.014"	0.014"
Minimum Vessel Diameter	3.0 mm	3.5 mm	4.5 mm	4.5 mm

- Hypotension
- Infection
- Ischemia
- Restenosis of the treated segment
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair

Iliac/Renal Vasculature Adverse Events

Field experience associated with use of this device in the iliac and/or renal vasculature are identified below:

- Arterial perforation
- Death
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair

How Supplied

The SilverHawk™ Peripheral Catheter and Cutter Driver are packaged and sterilized individually, but shipped in a single shelf carton. Both are intended for single patient use only.

Sterilization and Expiration Dating

The SilverHawk™ Peripheral Catheter is sterilized using ethylene oxide gas. The SilverHawk™ Cutter Driver is sterilized using gamma radiation. Both devices are STERILE if unit package is unopened and undamaged.

Both the Catheter and Cutter Driver are intended for single use only and should not be reused or resterilized. Use prior to the "Use by" date printed on the package labels.

Storage and Use Conditions

Store sterile packaged Catheters and Cutter Drivers in a cool dry place until ready to use. Do not expose to organic solvents, ionizing radiation, ultraviolet light or alcohol-based fluids.

Directions for Use

Inspection

1. Prior to use, carefully inspect the Catheter and Cutter Driver to verify that neither the sterile packaging nor the devices themselves have been damaged.
2. Connect the Catheter to the Cutter Driver by inserting the proximal end of the catheter into the motor. Ensure the cutter positioning lever aligns with the slot in the Cutter Driver. When fully inserted, the catheter connector will lock into the Cutter Driver. To remove the catheter from the Cutter Driver, depress the catheter lock release button and pull the catheter from the motor.
   Note: To avoid accidental activation of the Cutter Driver, be sure the cutter positioning lever is in the fully forward position prior to insertion into the Cutter Driver.
3. To confirm functionality of the catheter, advance and retract the cutter positioning lever. Ensure that the motor turns on and off automatically and that the inner blade moves freely. The catheter tip should deflect and return to its original configuration as the cutter position is cycled. Advance the positioning lever to close the cutter and turn off the motor.

   Note: The automatic motor control feature of the Cutter Driver can be disabled by using the motor override

P/N: LS 03735, Rev. T

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- Prolonged cardiopulmonary resuscitation
- Endoscopic peptic ulcer disease in the past 3 years or gastrointestinal bleeding within the past 3 months
- Genitourinary bleeding within the past 3 months
- Severe persistent hypertension (systolic pressure >180 mm)
- Allergy or intolerance to aspirin

linical Contraindications

e SilverHawk™ Peripheral Catheter System is specifically ntraindicated:

- in the carotid artery; or
- in the iliac or renal vasculature; or
- for in-stent restenosis at the peripheral vascular site.

estrictions

- Federal (U.S.A) Law restricts this device to sale by or on the order of a physician.
- This device is intended for **single use** only. Do not resterilize and/or reuse this device.

arnings

ways use direct fluoroscopic observation when anipulating the SilverHawk™ Peripheral Catheter in the ripheral vessels. If resistance is met during manipulation, termine the cause of the resistance before proceeding.

ever advance the distal tip of the catheter near the floppy d of the guidewire. A catheter advanced to this position ay not follow the guidewire when it is retracted and cause e guidewire to buckle into a loop. If this occurs, catheter d guidewire should be removed together to prevent tential damage to vessel walls. If resistance is still felt, the eath should also be removed as part of the unit.

void excessive movement of the SilverHawk™ Peripheral atheter within the vessel at all times as doing so could sult in embolization or vessel damage. In addition, cessive catheter manipulation with the cutter window open uld result in embolization of previously excised tissue agments.

he SilverHawk™ Peripheral Plaque Excision may only be sed with the SilverHawk™ Cutter Driver.

his device is not to be used in the presence of combustible r flammable gases, anesthetics, or cleaners/disinfectants.

recautions

he SilverHawk™ Peripheral Plaque Excision System ould only be used by physicians trained in percutaneous eripheral interventional procedures.

se of this device should be limited to hospitals where rgical support is readily available in the event of a serious mplication.

dverse Events

otential adverse events associated with use of this device and ther interventional catheters include, but are not limited to the llowing:

Arterial perforation
Arterial rupture
Arteriovenous fistula
Bleeding complications
Arterial spasm
Embolism and/or arterial thrombosis
Death
Arterial dissection
Emergency or non-emergency surgical bypass surgery

- Entry site complications
- Hypotension
- Infection
- Ischemia
- Restenosis of the treated segment
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair

Iliac/Renal Vasculature Adverse Events

Field experience associated with use of this device in the iliac and/or renal vasculature are identified below:

- Arterial perforation
- Death
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair

How Supplied

The SilverHawk™ Peripheral Catheter and Cutter Driver are packaged and sterilized individually, but shipped in a single shelf carton. Both are intended for single patient use only.

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The SilverHawk™ Peripheral Catheter is sterilized using ethylene oxide gas. The SilverHawk™ Cutter Driver is sterilized using gamma radiation. Both devices are STERILE if unit package is unopened and undamaged.

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Storage and Use Conditions

Store sterile packaged Catheters and Cutter Drivers in a cool dry place until ready to use. Do not expose to organic solvents, ionizing radiation, ultraviolet light or alcohol-based fluids.

Directions for Use

Inspection

1. Prior to use, carefully inspect the Catheter and Cutter Driver to verify that neither the sterile packaging nor the devices themselves have been damaged.
2. Connect the Catheter to the Cutter Driver by inserting the proximal end of the catheter into the motor. Ensure the cutter positioning lever aligns with the slot in the Cutter Driver. When fully inserted, the catheter connector will lock into the Cutter Driver. To remove the catheter from the Cutter Driver, depress the catheter lock release button and pull the catheter from the motor.
   Note: To avoid accidental activation of the Cutter Driver, be sure the cutter positioning lever is in the fully forward position prior to insertion into the Cutter Driver.
3. To confirm functionality of the catheter, advance and retract the cutter positioning lever. Ensure that the motor turns on and off automatically and that the inner blade moves freely. The catheter tip should deflect and return to its original configuration as the cutter position is cycled. Advance the positioning lever to close the cutter and turn off the motor.

   Note: The automatic motor control feature of the Cutter Driver can be disabled by using the motor override

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switch. When the switch is up, the automatic motor control is enabled. When the switch is down, the cutter positioning lever can be advanced and retracted without activating the motor.

4. Inspect the shaft, cutter housing and distal tip for smooth transitions. Do not use the catheter if a sharp edge or protrusion is detected.

CAUTION: Do not sharply bend or kink the catheter shaft during handling as this could damage the device and impair its function.

5. Check the catheter shaft for functionality of the hydrophilic coating. When wetted with sterile saline, the catheter shaft should feel slippery.

Note: To facilitate catheter handling, the proximal most portion of shaft is not coated.

6. Should the catheter become kinked or damaged during use, replace the damaged catheter with a new catheter and return used device to FoxHollow Technologies for evaluation.

Preparation

1. Purge Air From the Catheter.
   a) Fill a syringe (3cc or larger) with heparinized saline.
   b) Attach the syringe to the distal end of the catheter tip and gently inject saline until all air is eliminated from the tip.
   c) Next, flush the catheter shaft by attaching the heparinized saline filled syringe to the catheter flush luer. With the cutter closed, gently apply pressure to the syringe until all air has been flushed from the catheter and saline is seen exiting the cutter.

Insertion and Use

Once prepared, the catheter is ready for insertion into the patient.

1. Insertion
   a) Prepare the patient and administer the appropriate anticoagulant and vasodilator therapy for standard percutaneous intervention.
   b) Insert the appropriate sized sheath and hemostasis valve using standard techniques.

CAUTION: Refer to the Key Catheter Specifications table for appropriate sheath size requirements. Use of sheaths smaller than those recommended may compromise device performance.

   c) Using standard technique, place a guidewire across the target lesion.
   d) Ensure that the cutter positioning lever is in its fully advanced, i.e. closed and off, position. Carefully backload the end of the guidewire through the tip of the SilverHawk™ Catheter.
   e) Loosen the hemostasis valve and carefully insert the SilverHawk™ Catheter into the sheath. Retighten the hemostasis valve to prevent blood loss.

CAUTION: Do not over tighten the hemostasis valve as this may inhibit smooth advancement and rotation of the catheter or possibly damage the shaft.

2. Lesion Treatment
   a) Using fluoroscopic guidance, carefully advance the SilverHawk™ Peripheral Catheter to the proximal edge of the target stenosis.

WARNING: The cutter section of the SilverHawk™ Peripheral Catheter is a rigid component. Do not use excessive force or torque to advance the SilverHawk™ Catheter as vessel trauma and/or device failure may result.

WARNING: Do not use the SilverHawk™ Peripheral Catheter in bends in excess of 90° or if excessive calcification is detected by IVUS or angiography.

Note: If the catheter cannot be advanced across the lesion, it may be necessary to carefully remove the catheter and pre-dilate the lesion with a small diameter balloon angioplasty catheter.

   b) Carefully rotate the SilverHawk™ Peripheral Catheter blade opening toward the treatment site. Additional angiographic assessment should be performed to confirm catheter position in relation to the lesion.

Note: The cutter housing is radiopaque to facilitate angiographic visualization of the device orientation.



Left



Anterior/Posterior



Right

In addition, a radiopaque ring is located just proximal to the distal most edge of the tip.

CAUTION: If device is not rotating easily, do not torque the catheter shaft more than 360° in one direction. Doing so could result in device failure such as shaft kinking or tip fracture. Device repositioning or lesion predilatation may be required.

   c) To begin plaque excision, retract the cutter positioning lever which will expose the rotating blade and deflect the catheter tip.

Note: When advancing or retracting the positioning lever, the lever must be moved until a "click" is felt at the end of the lever travel. This indicates that the catheter has achieved its FULLY retracted or FULLY advanced position.

WARNING: Operation of the device with the blade partially opened or closed could result in vessel trauma or possible embolization of previously excised tissue.

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d) With the motor running, slowly advance the SilverHawk™ Catheter through the target lesion under fluoroscopic guidance.

Reference the following matrix for the length of cut and number of cutting passes that may be completed for each Catalog Number before removing and emptying the device.

Catalog #	Length of Cut	# cuts per insertion
P4023	25 mm	2
P4016	50 mm	1
P4012	50 mm	1
P4015	75 mm	1

WARNING: The storage capacity of the catheter tip must not be exceeded or embolization of excised tissue fragment may result.

WARNING: If the catheter does not advance easily, close the cutter by advancing the positioning lever. Excessive force should not be used to advance the positioning lever. Device repositioning or predilation may be required.

e) Once the end of the target segment is reached, stop advancing the catheter. Carefully advance the cutter positioning lever to close the cutter and turn off the Cutter Driver, this will be indicated by a tactile "click".

f) At this point, a combination of angiographic and/or intravascular ultrasound imaging should be used to assess the extent of plaque excision.

g) For models that support multiple cuts per insertion, the catheter may be re-advanced and positioned for additional cuts by repeating steps a) through f). Otherwise, proceed to Catheter Removal and Tissue Removal sections, below.

3. Catheter Removal

a) The catheter should be carefully removed from the patient under fluoroscopic guidance.

b) Final angiographic and/or intravascular ultrasound evaluation should be performed post SilverHawk™ Catheter treatment.

4. Tissue Removal

a. Fill a syringe (3cc or larger) with saline.

b. Attach the syringe to proximal luer adaptor on the tissue pusher assembly.

c. Rotate the torque shaft to position the cutter window for optimal viewing.

d. Retract the cutter positioning lever to expose the cutter within the cutter window. Turn the main power switch on the Cutter Driver to OFF and detach the catheter from the Cutter Driver.

e. Insert nosecone into the tip clip.

f. Pinch the tip clip around the nosecone (it will not damage the nosecone).

g. Insert the tissue pusher tip into the catheter vent hole.

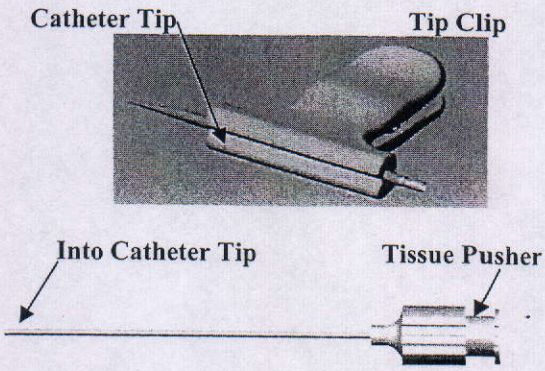
h. Apply pressure to the syringe and slowly advance the tissue pusher to flush tissue from the cutter window.

i. Use tweezers to retrieve exposed tissue from the cutter window if it does not fully exit the window during the flush.

j. Repeat above steps as needed to remove tissue.

k. Once all of the tissue has been removed from the tip, re-flush distal tip reservoir according to the Preparation for Use section, step 1.b.

l. Release the tip clip and slide it off the nosecone.



Please read this manual and follow its instructions carefully. The words WARNING, CAUTION and NOTE convey special meanings. When they are used throughout this manual, they should be carefully reviewed to ensure the safe and effective operation of this product.

⚠WARNING: A WARNING indicates that the personal safety of the patient or physician may be involved. Disregarding a WARNING could result in injury to the patient or physician.

CAUTION: A CAUTION indicates that particular service procedures or precautions must be followed to avoid possible damage to the product.

NOTE: A NOTE indicates special information to facilitate use of the product, or to clarify important information.

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components. Do not incinerate the Cutter Driver unit, as the enclosed batteries may explode at excessive temperatures.

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular setting. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving device
-Increase the separation between the equipment
-Consult the manufacturer or field service technician of the equipment experiencing interference for help.
-Warning: There are no user replaceable parts in the Cutter Driver

Contact Information

If you have any questions or comments regarding the use of this product contact:

FOXHOLLOW
740 Bay Road.
Redwood City, CA 94063 USA
Phone: 1-877-348-4295 Fax: 1-888-233-2849

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monorail™

MAVERICK2™

PTCA Dilatation Catheter

INSTRUCTIONS FOR USE

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Cathéter de dilatation pour ACTP
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取扱説明書

Boston Scientific

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English

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DEVICE NAME

Boston Scientific MAVERICK²™ Monorail™ PTCA Dilatation Catheter. The generic name of the device is rapid exchange Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter.

DESCRIPTION

The MAVERICK² Monorail Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter, from Boston Scientific, is a rapid exchange catheter with a balloon near the distal tip. The distal section of the catheter is dual lumen and coaxial. The outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guide wires (≤ 0.014 in. / 0,36 mm) to facilitate advancement of the catheter to and through the stenosis to be dilated. The proximal section of the catheter is a single-lumen, stainless steel hypotube with a single luer port for inflation/deflation of the balloon. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. A balloon protector is placed over the balloon to maintain a low profile and a mandrel is placed into the lumen to protect the patency. The catheter includes a tapered tip to facilitate advancement of the catheter to and through the stenosis. In addition, a hydrophilic coating is applied from the distal tip to the guide wire port for increased lubricity on the 15, 20, 25, and 30 mm length balloons. To prevent auto-adhesion of this hydrophilic coating on the balloon, a silicone coating is applied from the distal tip to just proximal of the balloon over the hydrophilic coating. The 9 and 12 mm balloon length models are only coated with the silicone coating from the distal tip to just proximal of the balloon to prevent the balloon from moving relative to the lesion during balloon inflation. The 1.5 mm MAVERICK² Monorail PTCA Dilatation Catheter models have one radiopaque marker band while all other MAVERICK² Monorail PTCA Dilatation Catheter models have two radiopaque markers that in conjunction with fluoroscopy, aid in the placement of the catheter's balloon segment. A needle with a luer port is included for flushing the distal inner lumen prior to the insertion of appropriate coronary guide wires. CLIPIT™ Clips are provided to aid in handling of the catheter.

INDICATIONS

- The MAVERICK² Monorail PTCA Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.
- The MAVERICK² Monorail PTCA Dilatation Catheter (balloon models 2.25 mm - 4.0 mm) is also indicated for the post-delivery expansion of balloon expandable stents.

NOTE: Bench testing was conducted with the MAVERICK² Monorail PTCA Dilatation Catheter and marketed balloon expandable stents. Consideration should be taken when this device is used with different manufacturers' stents due to differences in stent design.

CONTRAINDICATIONS

- Unprotected left main coronary artery
- Coronary artery spasm in the absence of a significant stenosis

WARNINGS

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration. This includes possible hemodynamic support during PTCA as treatment of this patient population carries special risk.

When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

Do not exceed the rated balloon burst pressure. The rated burst pressure is based on the results of *in vitro* testing. At least 99.9 percent of the balloons (with a 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.

PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Use the catheter prior to the "Use By" date specified on the package.

PRECAUTIONS

Prior to angioplasty, the catheter should be examined to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.

The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.

Before insertion of the dilatation catheter, administer appropriate anticoagulant and coronary vasodilator therapy.

Care should be taken to control the position of guide catheter tip during manipulation of the balloon catheter.

Caution should be taken not to over tighten a Touhy-Borst type hemostatic adapter around the dilatation catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

When loading or exchanging the balloon catheter, it is recommended to thoroughly wipe the guide wire clean for better balloon catheter movement on the wire.

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Nonpyrogenic.

Store in a dry, dark, cool place.

ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, the following:

- death
- acute myocardial infarction
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury
- restenosis of the dilated vessel
- hemorrhage or hematoma
- angina or unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypo/hypertension
- infection
- coronary artery spasm
- arteriovenous fistula
- embolism
- stroke
- cardiovascular accident
- transient ischemic attack
- myocardial ischemia
- pseudoanyreusm (at site of catheter insertion)
- cardiac tamponade / pericardial effusion
- renal failure
- coronary aneurysm
- vessel trauma requiring surgical repair or intervention
- cardiogenic shock
- coronary artery bypass graft surgery

INSTRUCTIONS FOR USE

Material Required for PTCA with the MAVERICK²™ Monorail™ PTCA Dilatation Catheter

Quantity	Description
1 or 2	Guide wire(s) of appropriate size for advancement of guide catheter
1	Arterial sheath and dilator set (for femoral approach only)
1 or more	Femoral or brachial guiding catheters in the appropriate size and configuration to select the coronary artery, minimum I.D. of guide catheter = 0.058 in. / 1,47 mm
1	Vial of contrast medium
1	Inflation device with manometer
1 or more	MAVERICK² Monorail PTCA Dilatation Catheter(s)
1 or more	≤ 0.014 in. / 0,36 mm x 175 cm guide wire(s)
1	10, 12, or 20 ml (cc) luer-lock syringe
1	Hemostatic adapter
2	CLIPIT™ Clips

Prior to angioplasty, carefully examine all equipment to be used during the procedure, including the dilatation catheter, to verify proper function. Verify that the catheter and sterile packaging have not been damaged in shipment and that the catheter size is suitable for the specific procedure for which it is intended.

NOTE: At any time during use of the MAVERICK² Monorail PTCA Dilatation Catheter, if the stainless steel proximal shaft has been bent or kinked, do not continue to use the catheter.

1. Inflation Device Preparation
   a. Prepare the inflation device according to the manufacturer's instructions.
   b. Purge the system of air.

2. Dilatation Catheter Selection
   The inflation diameter of the balloon must not exceed the diameter of the coronary artery proximal and distal to the stenosis. If the stenosis cannot be crossed with the desired dilatation catheter, use a smaller diameter catheter to predilate the lesion to facilitate passage of a more appropriate-sized dilatation catheter.

3. Dilatation Catheter Preparation
   a. Remove catheter from the protective hoop.
   b. Remove the balloon protector and mandrel by grasping the balloon catheter just proximal to the balloon, and with the other hand, gently grasp the proximal section of the balloon protector and slide distally. **If unusual resistance is felt during the product mandrel and/or balloon protector removal, do not use this product and replace with another. Follow product returns procedure for unused product.**
   c. Prepare the balloon dilatation catheter for purging. Fill a 10, 12, or 20 ml (cc) luer-lock syringe with 3 ml (cc) of contrast medium. Use only appropriate balloon inflation medium (e.g., the equivalent of a 50:50 mixture of contrast medium and sterile normal saline). **Do not use air or any gaseous medium to inflate the balloon.**
   d. Connect a three-way stopcock to the port fitting on the dilatation catheter. Flush through the stopcock.
   e. Connect the syringe to the stopcock.
   f. Hold the syringe with the nozzle pointing downward and aspirate for 5 seconds. Release the plunger.
   g. Remove the syringe and evacuate all air from the barrel.
   h. Reconnect the syringe and aspirate until bubbles no longer appear during aspiration. If air bubbles persist, remove catheter from hoop and inflate the balloon to verify that there are no leaks present prior to insertion.
   i. Release plunger and set aside until step **4b**.
   j. Carefully insert the luer-lock needle into the distal tip of the balloon catheter. Flush the wire lumen with sterile saline. Remove the needle from the distal tip. Do not discard the luer-lock needle until the end of the procedure, as additional flushing may be required.

4. Inflation Device Connection to Catheter
   a. To remove any air lodged in the distal luer fitting of the inflation device, purge approximately 1 ml (cc) of contrast medium.
   b. Applying positive pressure to the balloon, disconnect the syringe used in preparation. A meniscus will appear in the balloon port when the syringe is removed. Verify that a meniscus of contrast medium is evident in both the dilatation catheter balloon port and the inflation device connection. Securely couple the inflation device to the balloon port of the balloon dilatation catheter.

5. Use of the MAVERICK² Monorail PTCA Dilatation Catheter
   a. Insert a guide wire through the hemostatic valve following the manufacturer's instructions or standard practice. Advance the guide wire carefully into the guiding catheter. When complete, withdraw the guide wire introducer, if used.
   b. Attach a torque device to the wire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel, then across the stenosis.

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c. Backload the distal tip of the dilatation catheter onto the guide wire ensuring that the guide wire exits the midsection opening in the catheter.
NOTE: To avoid kinking, advance the dilatation catheter slowly, in small increments until the proximal end of the guide wire emerges from the catheter.

d. Advance the catheter through the hemostatic valve slowly, while the balloon is fully deflated. If resistance is encountered, do not advance the dilatation catheter through the adapter. Caution should be taken not to over tighten the hemostatic adapter around the dilatation catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

e. Thoroughly aspirate and flush the guiding catheter in preparation for introduction of the dilatation catheter.

f. Connect the side port of the guiding catheter hemostatic adapter to the proximal pressure recording/infusion line or manifold assembly, which permits proximal pressure recording or infusion through the guiding catheter.

g. Position the balloon relative to the lesion to be dilated and inflate the balloon to the appropriate pressure (reference balloon compliance table). Maintain negative pressure on the balloon between inflations.

h. Withdraw the deflated dilatation catheter and guide wire from the guiding catheter through the hemostatic valve. Tighten the knurled knob on the hemostatic valve.

i. The catheter may be coiled once and secured using the CLIPIT™ Clips provided in the catheter package. Only the hypotube should be inserted into the coil clip; the clip is not intended for the distal end of the catheter.
NOTE: Care should be taken not to kink or bend the shaft upon application or removal of the coil clip.

6. Dilatation Catheter Exchange Procedure
Boston Scientific brand of rapid exchange Monorail™ catheters have been specifically designed for rapid, single operator balloon exchanges. To perform a catheter exchange:
   a. Loosen the knurled knob on the hemostatic valve.
   b. Hold the wire and hemostatic valve in one hand, while grasping the balloon shaft in the other hand.
   c. Maintain the guide wire position in the coronary artery by holding the wire stationary, and begin pulling the dilatation catheter out of the guiding catheter while monitoring the wire position under fluoroscopy.
   d. Withdraw the deflated catheter until the opening in the guide wire lumen is reached. Carefully inch the flexible, distal portion of the balloon catheter off the guide wire while maintaining guide wire position across the lesion. Close the knurled knob on the hemostatic valve.
   e. Slide the distal tip of the catheter out of the hemostatic valve, and tighten the knurled knob onto the wire to hold it securely in place. Completely remove the balloon from the wire.
   f. Prepare the next balloon catheter to be used as previously described.
   g. Backload the new catheter onto the guide wire as previously described under the "Use of the MAVERICK²™ Monorail PTCA Dilatation Catheter", step 5, and continue the procedure accordingly.

Table 1
Typical MAVERICK² Monorail PTCA Dilatation Catheter Compliance

Pressure ATM (kPa)	Balloon Size 1.5 mm	2.0 mm	2.25 mm	2.5 mm	2.75 mm	3.0 mm	3.25 mm	3.5 mm	3.75 mm	4.0 mm
1.0 (101)	*1.39*	*1.85*	*2.09*	*2.29*	*2.55*	*2.77*	*3.02*	*3.24*	*3.50*	*3.75*
2.0 (203)	*1.41*	*1.88*	*2.12*	*2.34*	*2.59*	*2.82*	*3.07*	*3.29*	*3.55*	*3.80*
3.0 (304)	*1.43*	*1.91*	*2.15*	*2.38*	*2.63*	*2.86*	*3.11*	*3.35*	*3.60*	*3.85*
4.0 (405)	*1.46*	*1.94*	*2.19*	*2.42*	*2.67*	*2.91*	*3.16*	*3.40*	*3.65*	*3.90*
5.0 (507)	1.48	1.97	2.22	2.46	2.71	2.95	3.20	3.45	3.70	3.95
6.0 (608) **Nominal**	1.50	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
7.0 (709)	1.52	2.03	2.28	2.54	2.79	3.05	3.30	3.55	3.80	4.05
8.0 (811)	1.55	2.06	2.31	2.58	2.83	3.09	3.34	3.60	3.85	4.10
9.0 (912)	1.57	2.09	2.35	2.62	2.87	3.14	3.39	3.65	3.90	4.15
10.0 (1013)	1.59	2.12	2.38	2.67	2.91	3.18	3.43	3.71	3.95	4.20
11.0 (1115)	1.61	2.15	2.41	2.71	2.95	3.23	3.48	3.76	4.00	4.25
12.0 (1216)	1.63*	2.19*	2.44	2.75	2.99	3.28	3.52	3.81*	4.05*	4.31*
13.0 (1317)	1.66	2.22	2.47	2.79	3.03	3.32	3.57	3.86	4.10	4.36
14.0 (1419)	1.68	2.25	2.51*	2.83*	3.07*	3.37*	3.61*	3.91	4.15	4.41
15.0 (1520)	1.70	2.28	2.54	2.87	3.11	3.41	3.66	3.96	4.20	4.46
16.0 (1621)			2.57	2.91	3.15	3.46	3.70			
17.0 (1723)			2.60	2.95	3.19	3.50	3.75			
18.0 (1824)			2.63	2.99	3.23	3.55	3.79			

*Rated Burst Pressure. Do not exceed.
*Stent Rated Burst Pressure only applies to 2.25 - 4.0 sizes. Do not exceed.

NOTE: Numbers in italics reflect extrapolated data points.

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REFERENCES

The physician should consult current medical practice literature on balloon dilatation, such as that published by ACC/AHA.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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Attachment E: Chronic Animal Study

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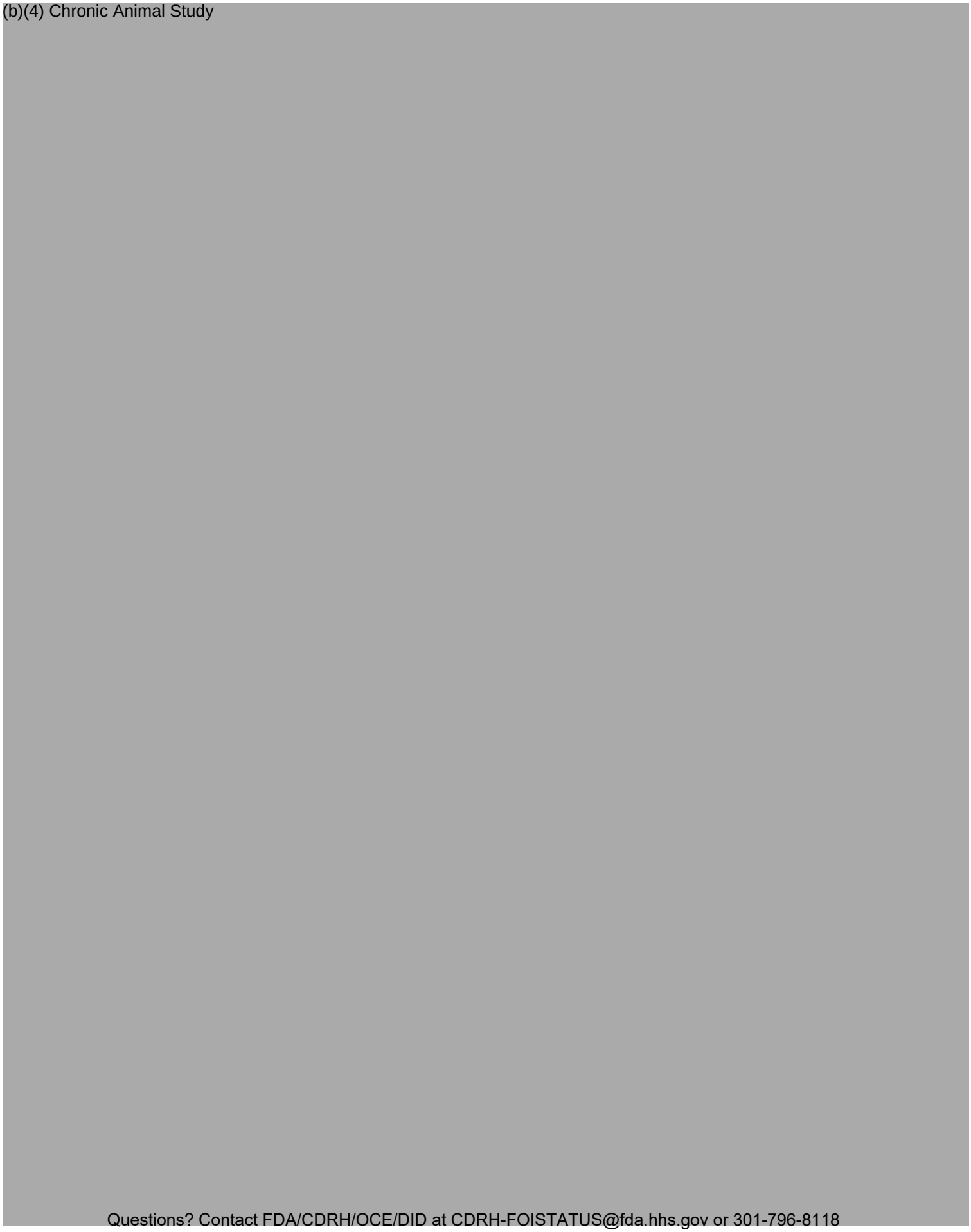
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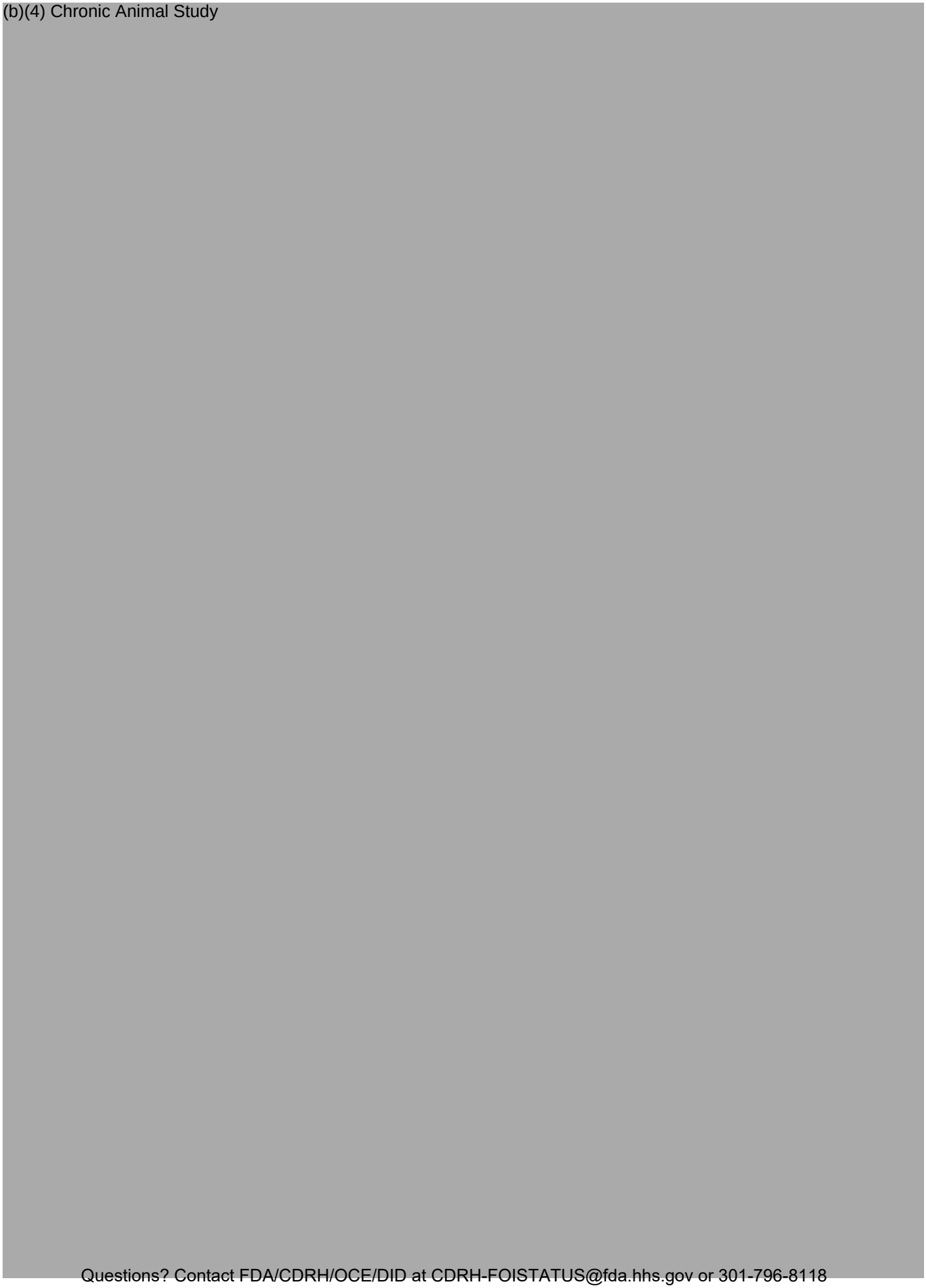
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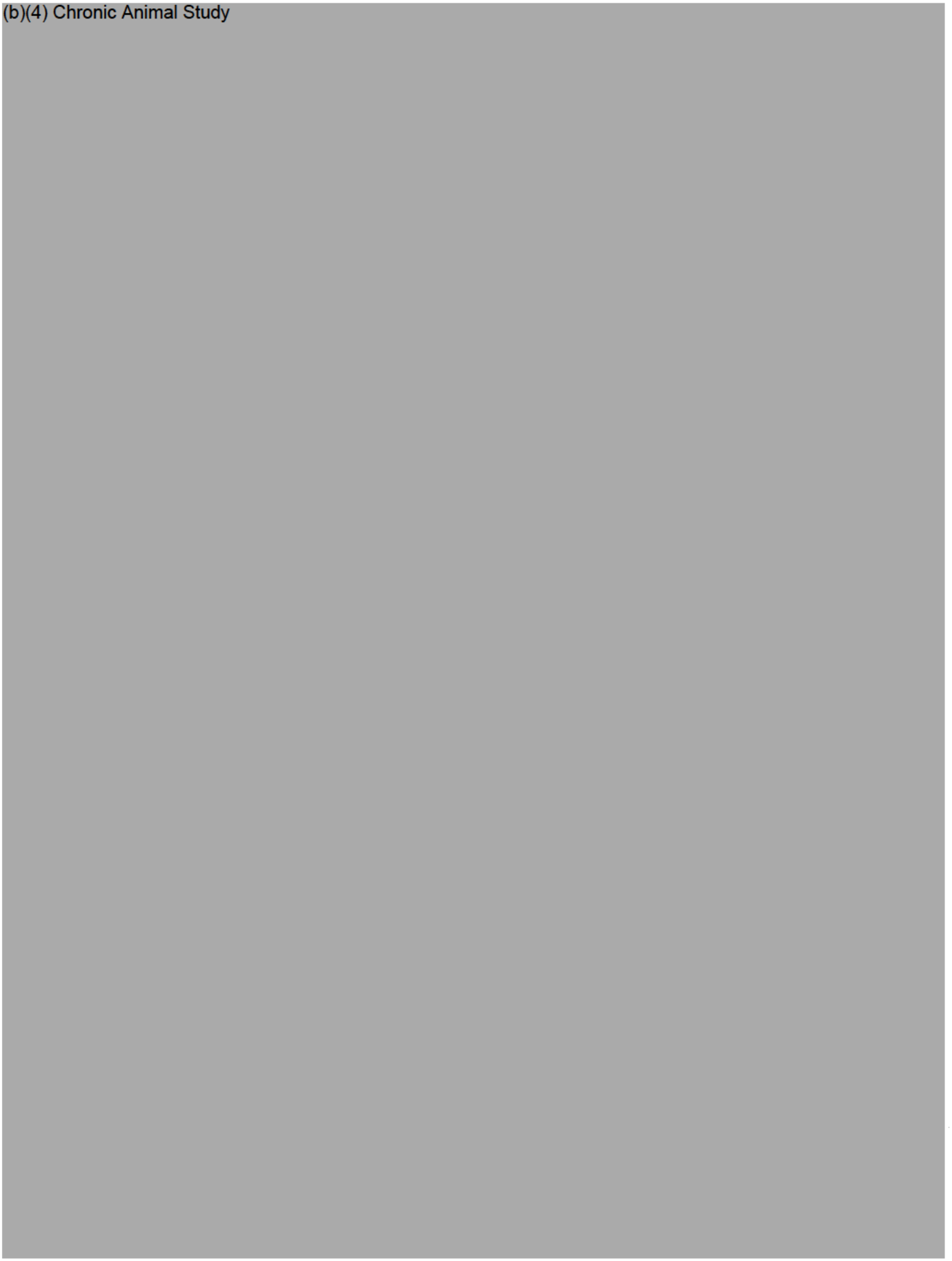
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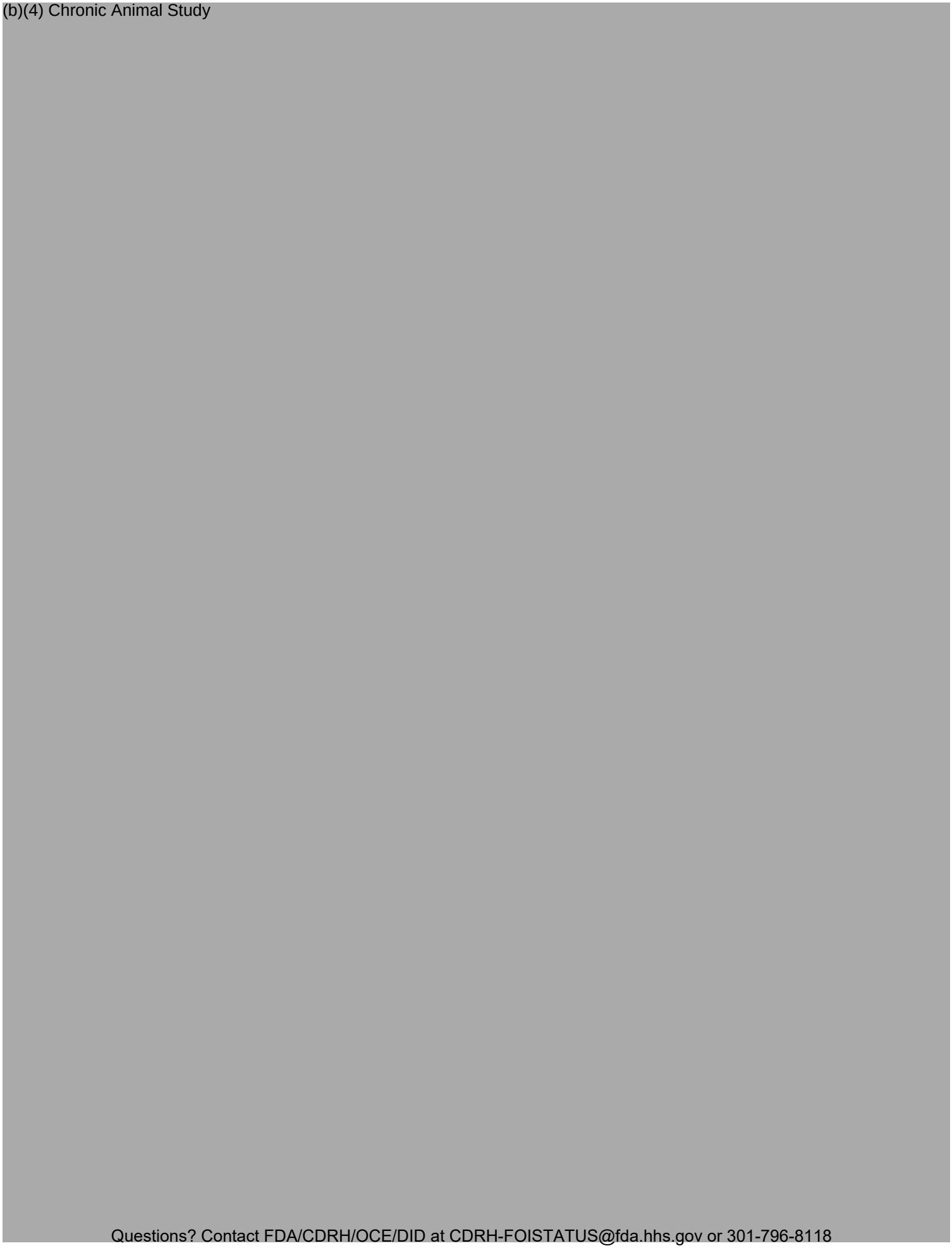
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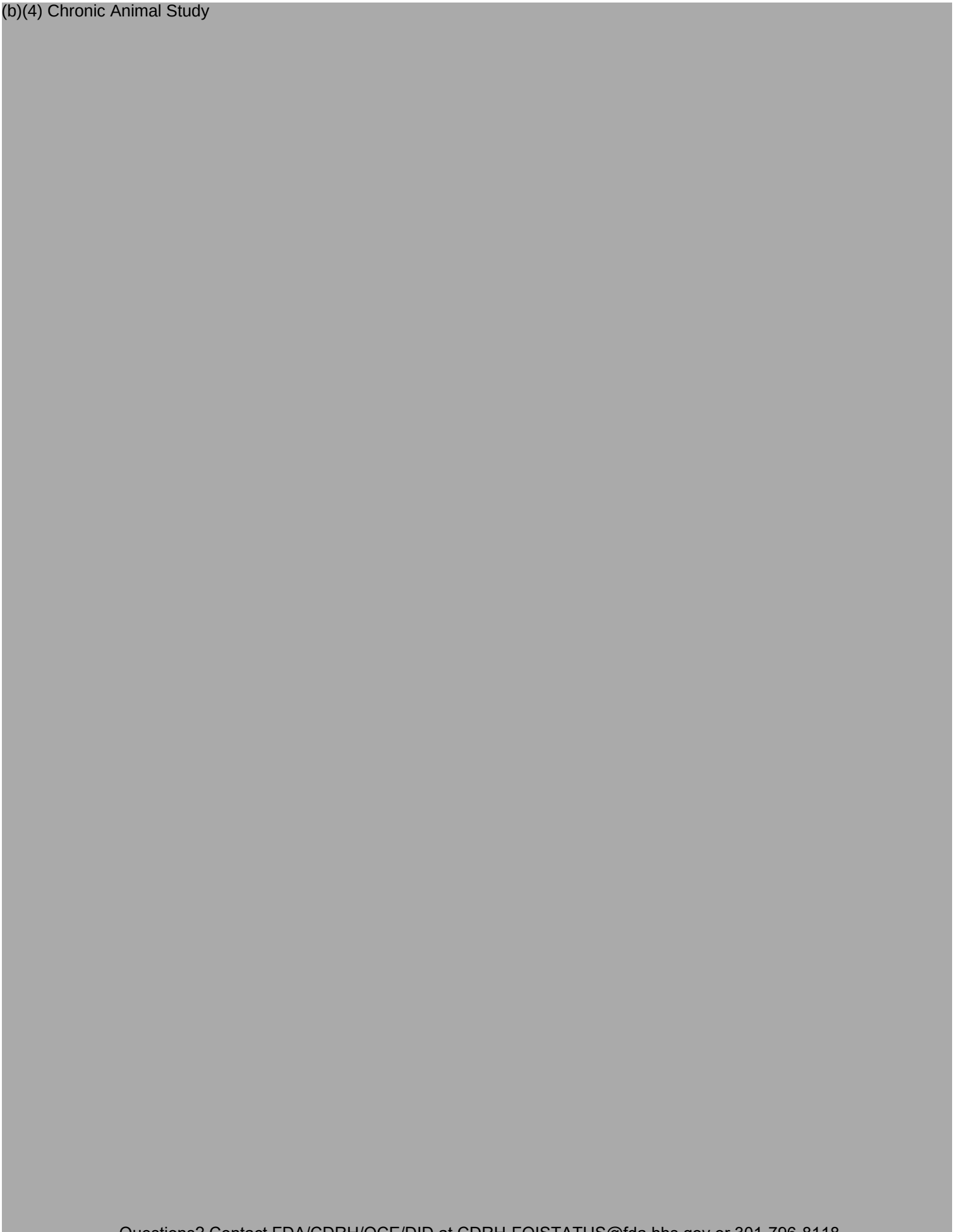
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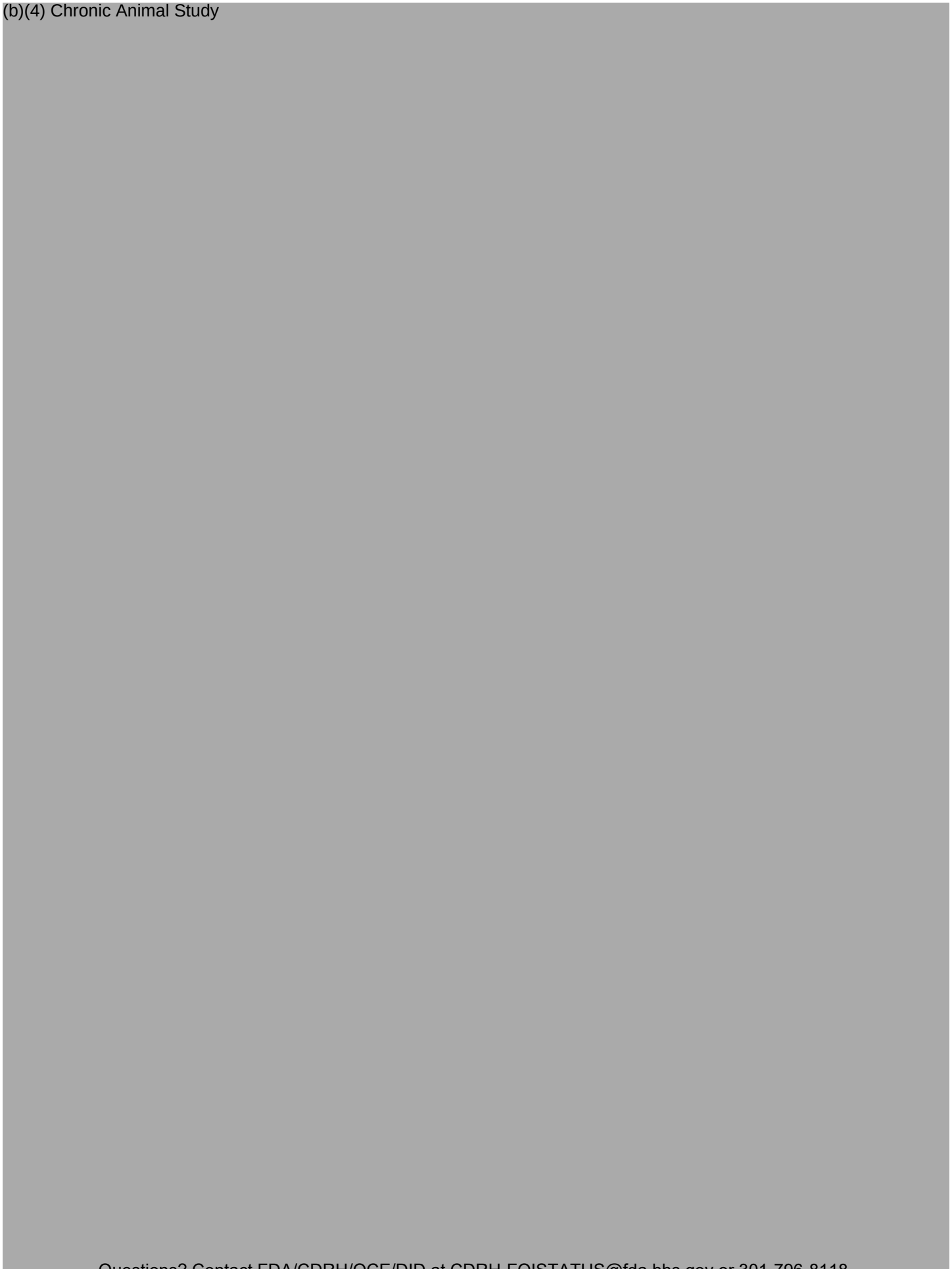
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(b)(4) Chronic Animal Study



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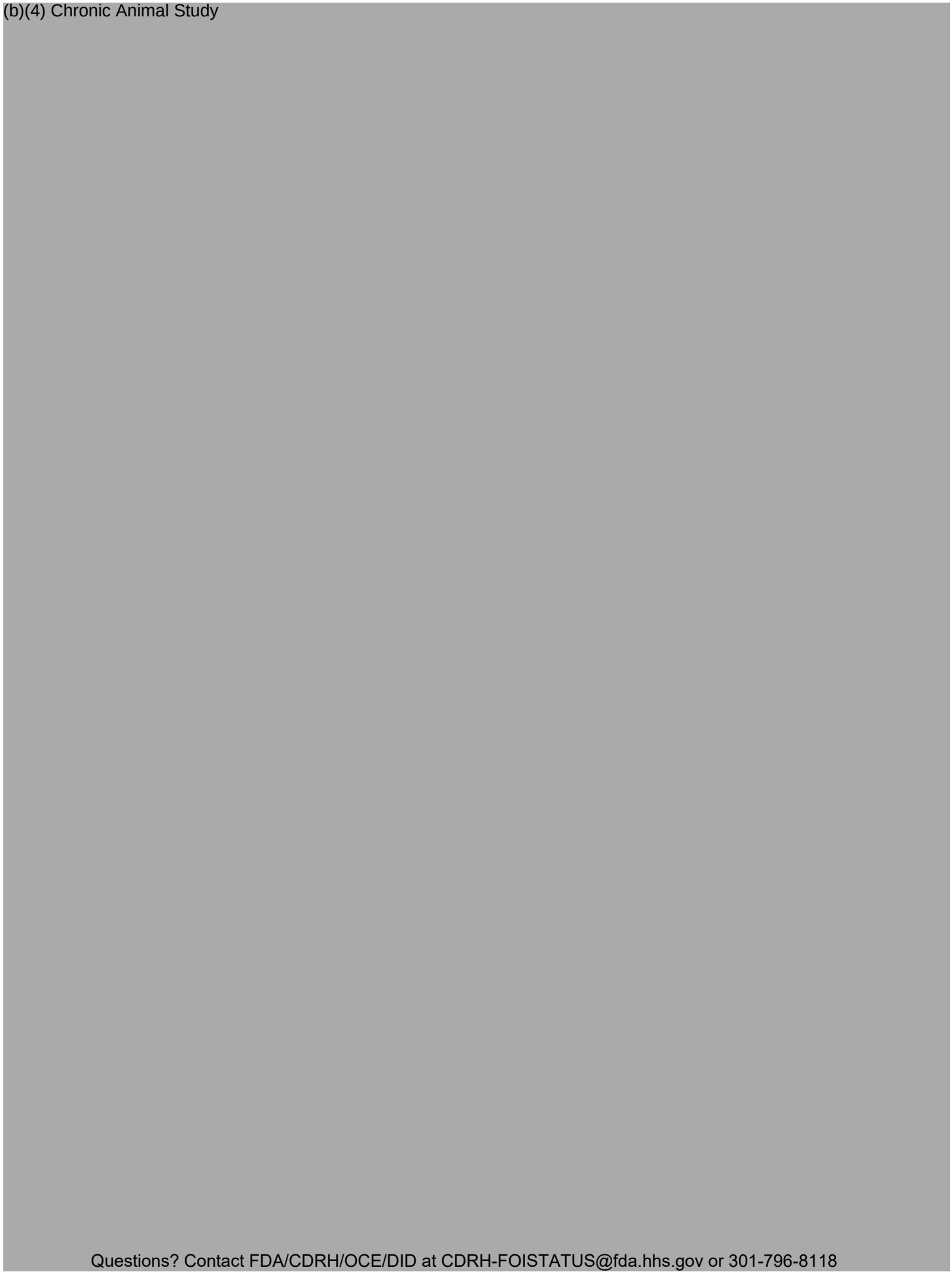
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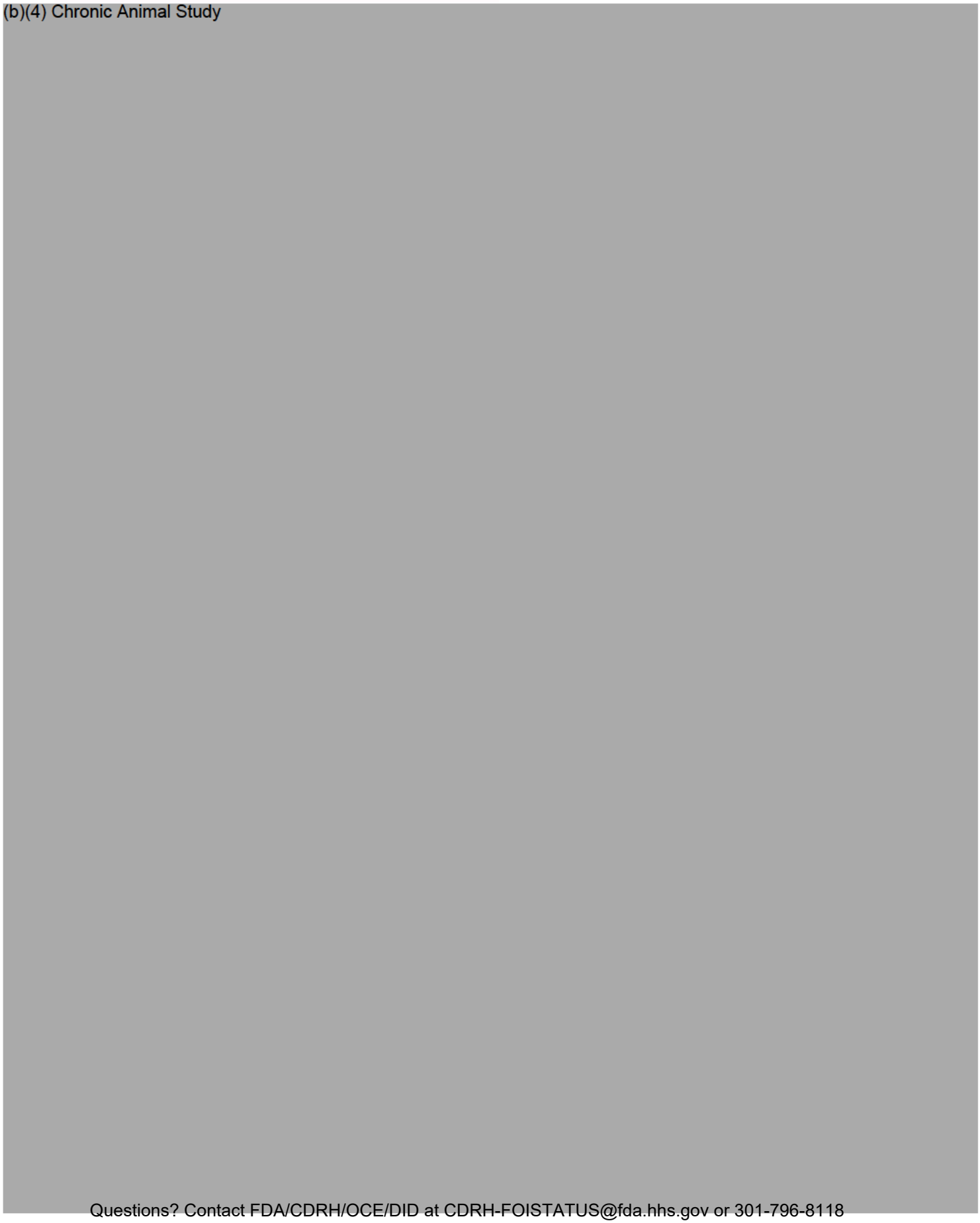
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ev3®
THE ENDOVASCULAR COMPANY

SpiderFX™

Embolic Protection Device

INSTRUCTIONS FOR USE
CAROTID INTERVENTIONS

(b) (4)

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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PRODUCT DESCRIPTION

The SpiderFX™ Embolic Protection Device is a percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The SpiderFX Device Capture Wire is used as the 0.014 in. wire for interventional device delivery. The SpiderFX Device can be delivered over any 0.014 in. or 0.018 in. primary wire used to gain access to the lesion site.

The SpiderFX Embolic Protection Device package contains the following components:

- One Capture Wire composed of a nitinol mesh Filter with a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter features a heparin-coating designed to maintain patency during Filter deployment[1]. This Capture Wire acts as the primary guidewire for other interventional devices compatible with a 0.014 in. wire. The convertible 320/190 cm Capture Wire is scored, allowing the wire to be snapped to a 190 cm usable length for use with rapid exchange systems, if desired. The distal portion of the Capture Wire for rapid exchange use is gold. The proximal portion for standard over-the-wire use is black.

  [1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.
- One dual-ended SpiderFX Catheter used to exchange the primary access guidewire with the Capture Wire, deploy the Capture Wire at the desired location, and recover the Capture Wire at the end of the procedure.
- One 23 gauge Blunt Needle for attachment to a syringe with Luer connector for priming and flushing the Catheter.

Components are delivered sterile, for use within a single vessel only. Do not re-sterilize or reuse.

INDICATIONS FOR USE

The SpiderFX Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.

CONTRAINDICATIONS

Use of the SpiderFX Embolic Protection Device is contraindicated under these circumstances:

- Do not use with patients in whom anticoagulant and antiplatelet therapy is contraindicated
- Do not use in vessels with excessive tortuosity
- Do not use in patients with uncorrected bleeding disorders

WARNINGS

Only physicians who have received appropriate training and are familiar with the principles, clinical applications, complications, side effects and hazards commonly associated with carotid interventional procedures should use this device.

- Refer to the instructions supplied with all interventional devices to be used in conjunction with the SpiderFX Embolic Protection Device for their intended uses, contraindications and potential complications.
- The safety and effectiveness of this device as an embolic protection system have not been established in vasculatures outside the carotid arteries (coronary, cerebral or peripheral).
- The safety and efficacy of the SpideRX Embolic Protection Device have not been demonstrated with carotid stent systems other than the over-the-wire or RX ACCULINK™ Carotid Stent System.
- The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure in accordance with standard medical practice.
- Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.
- Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.
- Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.
- Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 7 Sizing Guide).
- Do not apply excessive force to the Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.
- Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.
- Do not place the SpiderFX Capture Wire tip in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.
- Do not deploy the Filter within a previously implanted stent.
- Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.
- Do not use thrombectomy, atherectomy, or laser devices with the Capture Wire.
- Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.
- Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow flow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See Recovery and Removal).
- Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow.
- Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

PRECAUTIONS

- Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.
- Do not use the product if the packaging sterile barriers have been damaged or compromised.
- The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.
- Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.
- DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.
- Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the catheter.
- Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.
- Do not re-sterilize or reuse this device.

OBSERVED ADVERSE EVENTS - CLINICAL STUDY

The SpideRX® Embolic Protection Device was evaluated for the treatment of internal and/or common carotid artery stenoses in high-risk patients via the Carotid Revascularization with ev3 Arterial Technology Evolution (CREATE) Trial Clinical series. A total of 609 patients were enrolled in the trial as follows:

- CREATE Feasibility evaluated the ev3 over-the-wire (OTW) SPIDER™ Embolic Protection Device and PROTÉGÉ® Self-expanding Nitinol Stent and included 30 patients. The primary objective of the study was to evaluate the safety of the PROTÉGÉ Stent and SPIDER Embolic Protection Device in the treatment of common and/or internal carotid artery stenoses for subjects that are at high-risk for carotid endarterectomy.
- CREATE Pivotal also evaluated the ev3 over-the-wire (OTW) SPIDER Embolic Protection Device and PROTÉGÉ Self-expanding Nitinol Stent and included 419 patients. The primary objective of the study was to evaluate the safety and efficacy of the PROTÉGÉ Stent and SPIDER Embolic Protection Device in the treatment of common and/or internal carotid artery stenoses for subjects that are at high-risk for carotid endarterectomy.
- The SpideRX Arm of the CREATE Trial evaluated the ev3 rapid exchange SpideRX Embolic Protection Device and the commercially available ACCULINK™ Carotid Stent and included 160 patients. The primary objective of the study was to evaluate the safety and performance of the SpideRX Device in the treatment of common and/or internal carotid artery stenoses for patients at high-risk for carotid endarterectomy.

The SpideRX Embolic Protection Device is used in an acute manner and, therefore, peri-procedural adverse events are the most relevant evaluation of device safety. Table 1, below, presents the serious adverse events (defined as any event that may be eithe[illegible] (b) (4) term injuries) that were reported through the 30-day follow-up visit in the SpideRX Arm and the CREATE Pi[illegible]

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TABLE 1 – Serious Adverse Events Summary ≤ 30 Days

Description of Event[1]	SpideRX (N=160)	SPIDER (N=417)	Difference (95% C.I.)	p-value
Death	4/160 (2.5%)	8/417 (1.9%)	-0.6% (-3.3%, 2.2%)	0.7453
Ipsilateral Stroke				
Major	2/160 (1.3%)	14/417 (3.4%)	2.1% (-0.3%, 4.5%)	0.2569
Minor	2/160 (1.3%)	3/417 (0.7%)	-0.5% (-2.4%, 1.4%)	0.6207
Non-Ipsilateral Stroke	0/160 (0.0%)	3/417 (0.7%)	0.70%	0.5643
Total patients with complications	37/160 (23.1%)	130/417 (31.2%)	8.1% (0.2%, 16.0%)	0.0648
Access site complications:				
Hemorrhage	0/160 (0.0%)	4/417 (1.0%)	1.00%	0.0058
Pseudoaneurysm	2/160 (1.3%)	6/417 (1.4%)	0.2% (-1.9%, 2.3%)	1.0000
Puncture site infection	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Amaurosis Fugax	1/160 (0.6%)	1/417 (0.2%)	-0.4% (-3.1%, 0.5%)	0.0478
Angina	2/160 (1.3%)	0/417 (0.0%)	-1.30%	0.0765
Arrhythmia	5/160 (3.1%)	12/417 (2.9%)	-0.3% (-3.4%, 2.9%)	1.0000
Artery perforation:				
Contained	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Non-contained	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Congestive Heart Failure	3/160 (1.9%)	0/417 (0.0%)	-1.90%	0.0021
Dissection	1/160 (0.6%)	5/417 (1.2%)	0.6% (-1.0%, 2.2%)	1.0000
Emergent surgery	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
GI bleeding	1/160 (0.6%)	7/417 (1.7%)	0.8% (-0.9%, 2.5%)	0.6797
Hypotension	21/160 (13.1%)	73/417 (17.5%)	4.4% (-2.0%, 10.8%)	0.2568
Intracerebral bleed	1/160 (0.6%)	0/417 (0.0%)	-0.60%	0.2773
MI	1/160 (0.6%)	4/417 (1.0%)	0.3% (-1.2%, 1.9%)	1.0000
Renal failure requiring dialysis	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Renal insufficiency	2/160 (1.3%)	5/417 (1.2%)	-0.1% (-2.1%, 2.0%)	1.0000
Seizure	0/160 (0.0%)	3/417 (0.7%)	0.70%	0.5643
Stent / Vessel thrombosis	1/160 (0.6%)	0/417 (0.0%)	-0.60%	0.2773
Stent misplacement	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Stent or filter failure to deploy	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
TIA	0/160 (0.0%)	4/417 (1.0%)	1.00%	0.0058
Other	9/160 (5.6%)	40/417 (9.6%)	4.0% (-0.6%, 8.5%)	0.1365

[1]Patients may have had multiple events. Counts represent the number of events reported.

Table 2 indicates the number of deaths that were considered to be related to a stroke or myocardial infarction.

TABLE 2 – Cause of Death, 30 Days

Events	SpideRX (N=160)	SPIDER (N=417)
Stroke	2	5
Cardiac	2	3

TABLE 3 – Adverse Events Summary ≤ 30 Days

Description of Event[1]	SpideRX (N=160)	SPIDER (N=417)	Difference (95% C.I.)	p-value
Total patients with complications	12/160 (7.5%)	30/417 (7.2%)	- 0.3% (-5.1%, 4.5%)	0.8598
Access site complication:				
Hematoma	5/160 (3.1%)	2/417 (0.5%)	-2.6% (-5.4%, 0.1%)	0.0198
Puncture site infection	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
Allergic reaction to contrast dye	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Allergic reaction to procedure meds	0/160 (0.0%)	1/417 (0.2%)	0.20%	1.0000
Arrhythmia	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
GI bleeding	0/160 (0.0%)	0/417 (0.0%)	NA	NA
Hypotension	0/160 (0.0%)	2/417 (0.5%)	0.50%	1.0000
Renal insufficiency	2/160 (1.3%)	3/417 (0.7%)	-0.5% (-2.4%, 1.4%)	0.6207
Restenosis	0/160 (0.0%)	0/417 (0.0%)	NA	NA
Stent or filter collapse or fracture	0/160 (0.0%)	0/417 (0.0%)	NA	NA
Stroke - Minor	2/160 (1.3%)	0/417 (0.0%)	-1.30%	0.0765
Ipsilateral stroke - Minor	2/160 (1.3%)	0/417 (0.0%)	-1.30%	0.0765
TIA	1/160 (0.6%)	6/417 (1.4%)	0.8% (-0.9%, 2.5%)	0.6797
Vasospasm	1/160 (0.6%)	0/417 (0.0%)	-0.60%	0.2773
Other	1/160 (0.6%)	11/417 (2.6%)	2.0% (0.0%, 4.0%)	0.1942

[1]Patients may have had multiple events. Counts represent the number of events reported.

POTENTIAL COMPLICATIONS

Complications associated with the use of the SpiderFX Embolic Protection Device may include, but are not limited to:

- Access site adverse event (e.g., av fistula, hematoma, hemorrhage, pseudoaneurysm, puncture site infection)
- Adverse reaction to antiplatelet/anticoagulation agents or contrast media
- Allergic reaction to device materials
- Amaurosis Fugax
- Angina (unstable)
- Arterial dissection
- Cerebral hemorrhage
- Congestive heart failure
- Death
- Device(s) deformation, collapse, fracture, or rupture
- Device(s) thrombosis (acute and subacute)
- Dissection
- Embolization of air, debris, plaque or thrombus (evidenced by slow or no-flow) from mechanical disruption by the inte
- Embolization or migration of the interventional device(s)

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- Emergency surgery
- GI bleeding due to anticoagulation
- Hemodynamic compromise (e.g., prolonged hypotension requiring treatment with intravenous medications)
- Hyperperfusion syndrome
- Hypotension or hypertension
- Infection
- Intracerebral bleed
- Myocardial infarction
- Renal insufficiency
- Renal failure requiring dialysis
- Seizure
- Sepsis
- Significant cardiac arrhythmia requiring treatment with medications and/or transvenous pacing
- Stent entanglement
- Stroke
- Thrombosis (acute and subacute)
- Transient Ischemia Attack (TIA)
- Vasospasm
- Vessel dissection, perforation, rupture or intimal flap
- Vessel/filter occlusion

CLINICAL STUDIES

The Carotid Revascularization with ev3 Arterial Technology Evolution (CREATE) Clinical Trials were a series of prospective, non-randomized, multi-center, single-arm clinical trials. A total of 609 patients were enrolled at 35 clinical sites in the United States in three trials designed to demonstrate the safety and efficacy of the ev3 SPIDER over-the-wire and SpideRX Embolic Protection Devices as well as the PROTÉGÉ Self-Expanding Nitinol Stent when used to treat high-risk symptomatic and asymptomatic patients with internal and/or common carotid artery stenoses.

ELIGIBILITY CRITERIA

Male and female patients who presented for percutaneous treatment of an internal and/or common carotid artery intervention were considered for enrollment. To be included, the patients were required to be at least 18 years old and considered to be at high risk for carotid endarterectomy. The general and angiographic inclusion and exclusion criteria for the three trials were identical with the exception of vessel size in the SpideRX Arm of the CREATE Trial. Vessel size was changed in this trial to accommodate the limitations of the commercially available carotid stent.

Patients were considered symptomatic if their target stenosis was associated with ipsilateral transient or visual TIA evidenced by amaurosis fugax, ipsilateral hemispheric TIAs or ipsilateral ischemic stroke within 6 months prior to enrollment. Patients who were characterized as symptomatic were also required to have a target lesion stenosis (as defined in the NASCET trial) ≥ 50%. Asymptomatic patients were required to have a target lesion stenosis ≥ 70%.

High risk criteria are included in Table 4.

TABLE 4 – High Surgical Risk Criteria

Clinical Criteria[1]	Anatomical Criteria[1]
1. Age >75	1. Contralateral occlusion
2. CCS angina class 3-4 or unstable angina	2. High cervical lesion (above the angle of the jaw)
3. CHF class III-IV	3. Infraclavicular lesion
4. LVEF <35%	4. Tandem lesions >70%
5. MI <6 weeks	5. Hostile neck (cervical radiation treatment, tracheostomy/stoma, or radical neck dissection)
6. Coronary artery disease with >2 vessel disease in major vessel & history of angina	6. CEA restenosis
7. Severe pulmonary disease – home oxygen, resting pO2 <60 or FEV1 <50%	7. Cervical immobility due to fusion or arthritis
8. Permanent contralateral cranial nerve injury	8. Bilateral carotid stenoses, both requiring treatment*

[1] The subjects were required to meet at least ONE or more high-risk criterion in EITHER the clinical or anatomical section.
* Only the most severe lesion meeting the angiographic inclusion criteria could be treated in the SpideRX Arm of the CREATE Trial.

Baseline demographic characteristics are included in Table 5, below. They were evaluated to determine if subjects enrolled in the SpideRX Arm of the CREATE Trial and the CREATE Pivotal Trial are homogeneous. The differences reported, along with the associated p-values, correspond to the differences between the populations in the SpideRX Arm of the CREATE Trial and those enrolled in the CREATE Pivotal Trial. The only characteristics indicated to be significantly different were history of other treatment to the target artery (3.8% for RX, 0.7% for Pivotal), history of TIA (15.0% for SpideRX 23.2% for Pivotal), and lesion location in both the common and internal carotid artery (11.3% for SpideRX, 19.1% for Pivotal).

CLINICAL RESULTS SUMMARY

The primary endpoint of the SpideRX Arm of the CREATE Trial is a composite endpoint of MI, ipsilateral CVA, procedure-related contralateral CVA or death within 30 days of implantation (MACCE Table 5, below). There are no significant differences between the SpideRX Arm and the CREATE Pivotal Trial with respect to the primary endpoint.

The relationship of patient or baseline lesion characteristics to outcomes through 30-days was considered in a multivariate analysis. This analysis did not result in any statistically significant predictor of outcomes (all $p < 0.05$).

TABLE 5 – Primary and Secondary Endpoints

Efficacy Measures	SpideRX (N=160)	SPIDER (N=417)	Difference (95% C.I.)	p-value
Primary Endpoint	9/160 (5.6%)	29/370 (7.8%)	N/A	N/A
30-Day MACCE	9/160 (5.6%)	26/414 (6.3%)	0.7% (-3.6%, 4.9%)	0.8480
Myocardial Infarction	1/160 (0.6%)	4/414 (1.0%)	0.3% (-1.2%, 1.9%)	0.6933
Ipsilateral CVA	7/160 (4.4%)	16/414 (3.9%)	-0.5% (-4.1%, 3.1%)	0.8133
Major	2/160 (1.3%)	14/414 (3.4%)	2.1% (-0.3%, 4.6%)	0.2570
Minor	4/160 (2.5%)	3/414 (0.7%)	-1.8% (-4.3%, 0.8%)	0.0968
Intracerebral Bleed	1/160 (0.6%)	0/414 (0.0%)	-0.60%	0.2800
Procedure-Related Contralateral CVA	0/160 (0.0%)	3/414 (0.7%)	0.70%	0.5638
Death	4/160 (2.6%)	8/414 (1.9%)	-0.8% (-3.4% , 2.2%)	0.7460
1 year Ipsilateral CVA	N/A	3/370 (0.8%)	N/A	N/A
Secondary Endpoints				
MANE	N/A	26/370 (7.0%)	N/A	N/A
TLR at 1 year	N/A	1/370 (0.2%)	N/A	N/A
TVR at 1 year	N/A	1/370 (0.2%)	N/A	N/A
Primary Patency at 1 year	N/A	286/304 (94.1%)	N/A	N/A
Technical Success	155/160 (97.5%)	408/419 (97.4%)	-0.13% (-3.01%, 2.76%)	0.9317
Acute Procedure Success (QCA)	147/148 (99.3%)	397/397 (100.0%)	0.68% (-0.65%, 2.01%)	(b) (4)
Acute Procedure Success (Site)	158/160 (98.8%)	437/444 (98.4%)	-0.3% (-2.4%, 1.8%)	

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CLINICAL USE INFORMATION

Pre-procedure anticoagulant and antiplatelet requirements were specified in the clinical trial. A baseline dose of acetylsalicylic acid (ASA) of 325 mg was required the day prior and the day of the procedure. For patients on regular Coumadin® therapy, the dose could be reduced to 81 mg.

Several options were given with respect to the loading dose of antiplatelet medication:

- Clopidogrel 75 mg for three days prior to the procedure and the day of the procedure or
- Clopidogrel 450 mg the day before the procedure and 75 mg the day of the procedure or
- Ticlopidine 1000 mg the day before the procedure and two 250 mg doses the day of the procedure.

Patients were required to take 325 mg ASA and either 75 mg of clopidogrel each day or 250 mg of ticlopidine twice a day for three months following the procedure. For patients on regular Coumadin® therapy, the post-procedure ASA dose could be reduced to 81 mg.

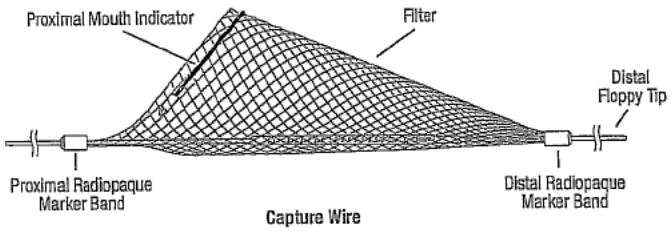
DEVICE COMPONENTS

The SpiderFX Embolic Protection Device package contains one each of the following components:

NOTE: See Table 6 for Device product specifications.

Capture Wire– The Capture Wire has a Nitinol mesh Filter with a Proximal Mouth Indicator and a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter has a heparin coating designed to maintain patency[1]. The Capture Wire is pre-loaded through the Delivery End of the SpiderFX Catheter with the Filter extending from the Catheter distal tip. The SpiderFX Capture Wire and Catheter are provided in a single hoop.

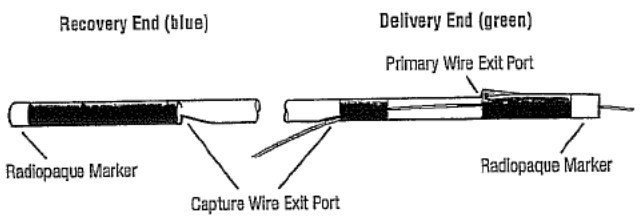
[1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.



Capture Wire

CAUTION: Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.

SpiderFX Catheter – The SpiderFX Catheter is dual-ended; with a Delivery End (green), and a Recovery End (blue) at the opposite end of the catheter



SpiderFX Catheter

- The Delivery End (green) of the SpiderFX Catheter has an embedded radiopaque marker at the distal tip, a primary wire exit port (indicated by a white stripe), a Clear Segment, and a Capture Wire Exit Port. The Capture Wire is pre-loaded into the Delivery End of the Catheter, with the Filter portion extending from the distal tip.
- The center **White Shaft** is used to manipulate the SpiderFX Catheter during delivery and recovery of the SpiderFX Capture Wire.
- The **Recovery End** (blue) of the SpiderFX Catheter has an embedded radiopaque marker at its distal tip, and a Capture Wire Exit Port.

Latex is not a component of the SpiderFX Embolic Protection Device.

TABLE 6 – SpiderFX Embolic Protection Device Specifications*

SpiderFX Capture Wire					
Filter Diameter (mm)	3.0	4.0	5.0	6.0	7.0
Capture Wire Length RX (cm)	190	190	190	190	190
Capture Wire Length OTW/RX (cm)	320/190	320/190	320/190	320/190	320/190
Wire Diameter (in./mm)	0.014/0.36	0.014/0.36	0.014/0.36	0.014/0.36	0.014/0.36
Distal Wire Tip Coil Length (mm)	1.2	1.2	1.2	1.2	1.2
SpiderFX Catheter - Delivery End (green)					
Nominal Diameter (in./mm)	0.040/1.02	0.040/1.02	0.040/1.02	0.040/1.02	0.040/1.02
Functional Length (cm)	140	140	140	140	140
SpiderFX Catheter - Recovery End (blue)					
Diameter (Fr)	4.2	4.2	4.2	4.2	4.2
Functional Length (cm)	140	140	140	140	140
Total Catheter Length (cm)	180	180	180	180	180

*Nominal

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INSTRUCTIONS FOR USE

Preparing the SpiderFX Embolic Protection Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the lesion site being treated. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the lesion, to allow for adequate Filter deployment.

WARNING: Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 7 Sizing Guide).

4. Ensure the guide catheter/sheath size will accommodate the SpiderFX Catheter. **(Table 7).**

TABLE 7 – Sizing Guide[1]

Target Vessel Size (mm)	Filter Size (mm)	Primary Guidewire Size (inches)	Guide Catheter/Sheath Min I.D.[2] (inches)
3.0	3.0	0.014-0.018	0.066
3.1-4.0	4.0	0.014-0.018	0.066
4.1-5.0	5.0	0.014-0.018	0.066
4.5-6.0	6.0	0.014-0.018	0.066
5.5-7.0	7.0	0.014-0.018	0.066

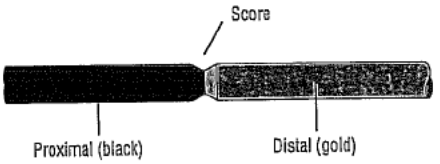
[1] Nominal
[2] Select a guide catheter that provides coaxial alignment and stable backup support.

5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the Catheter near the Primary Wire Exit Port and gently pull to expose the Catheter. The remaining Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the Catheter.

NOTE: *If using the 320/190 cm convertible version of the SpiderFX Device, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*



Capture Wire

8. Hold the Catheter at the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

9. Continue holding the Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter portion stops in the Clear Segment of the Catheter.

CAUTION: *The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.*



Filter in Proper Position in Clear Segment

10. Flush through the distal tip with heparinized saline until all air is removed and fluid passes from the Primary Wire Exit Port (22.5 cm proximal to the distal tip of the Catheter). A 23 gauge blunt needle included in the packaging may be used, if desired. Do not apply excessive force to the Capture Wire.
11. Gently apply pressure to the Primary Wire Exit Port. Flush until all air is removed and fluid passes from the Capture Wire Exit Port (40 cm proximal to Catheter distal tip).

WARNING: Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.

Delivery and Deployment

12. Access the vessel being treated using standard technique, and advance the primary guidewire at least 5 cm beyond the distal edge of the lesion being treated.
13. Observe the Primary Wire Exit Port indicated by a white stripe on the Catheter, to ensure the Port hole is visible.

NOTE: *When loading the primary guidewire, gently bend the Catheter at the Primary Wire Exit Port to create a 2.5 cm radius.*

CAUTION: *Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.*

14. Load the distal tip of the SpiderFX Device Delivery End (green) onto the proximal end of the primary guidewire and advance, so the primary wire exits at the Primary Wire Exit Port.

CAUTION: *DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.*

15. Gently advance the SpiderFX Delivery End carrying the Capture Wire over the primary wire and into the guide catheter/sheath. Continue advancing until the radiopaque marker at the distal tip of the Delivery End is at least 4-5 cm beyond the distal edge of the lesion.

CAUTION: *Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the Catheter.*

WARNING: Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.

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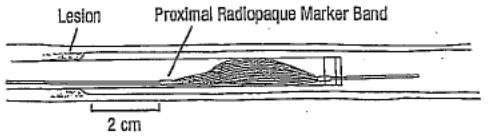
WARNING: Do not apply excessive force to Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

16. Hold the Catheter stationary, and withdraw the primary guidewire, leaving the Delivery Catheter and Capture Wire in place.
17. Hold the Catheter stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow wire movement. This may lead to embolization of debris, and vessel and/or device damage.

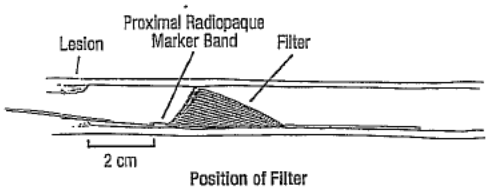
18. Observe the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the lesion being treated. Gently advance the entire Delivery End assembly if necessary so the Proximal Radiopaque Marker Band is at least 2 cm beyond the lesion distal edge.



Position of SpiderFX Catheter

CAUTION: *Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.*

19. Hold the Capture Wire stationary, and gently pull back on the Catheter to expose and deploy the Filter in the vessel. To reposition the Filter (if required),advance the Catheter back over the Filter, adjust the position of the Catheter and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter.



Position of Filter

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.

20. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Delivery Catheter together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
21. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
22. Once the Filter is deployed in the desired location, carefully remove the SpiderFX Catheter from the patient. Keep the Catheter in the sterile field. **DO NOT DISCARD THE CATHETER.** The Recovery End (blue) is required for Capture Wire recovery.
23. Place the SpiderFX Catheter in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter.
24. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow.

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use thrombectomy, atherectomy or laser devices with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).

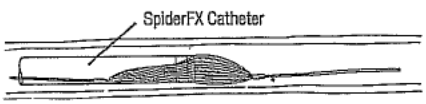
Recovery and Removal

25. After completion of the interventional procedure, wet the distal 20 cm of the Recovery End (blue) of the Catheter with heparinized saline. Flush the distal tip of the Recovery End to remove all air, until fluid passes from the Capture Wire Exit Port (25 cm from the tip).

WARNING: Do not grip the Catheter at the distal white tip. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

26. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.
27. Advance the Catheter under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
28. There are two methods for Filter Recovery:

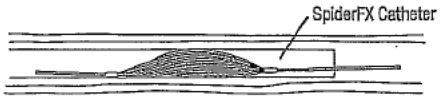
A – Partial Enclosure Recovery: Gently advance the Recovery End over the Filter, until the proximal portion of the Filter is inside the Catheter, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the radiopaque marker of the Recovery Catheter.



A. Partial Enclosure Recovery

WARNING: Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

B – Full Enclosure Recovery: Gently advance the Recovery End over the Filter until all radiopaque markers on the Filter are within the Catheter, proximal to the Catheter distal marker. The Distal Floppy Tip may remain outside the Catheter.



B. Full Enclosure Recovery

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WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

29. Carefully remove the Catheter and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the SpiderFX Catheter to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

CAUTION: *Do not re-sterilize or reuse this device.*

STORAGE

- Do not store in direct sunlight
- Keep dry

WARRANTY DISCLAIMER

Although the product has been manufactured under carefully controlled conditions, ev3 Inc. has no control over the conditions under which this product is used. ev3 Inc., therefore disclaims all warranties, both express and implied, with respect to the product including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ev3 Inc. shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind ev3 Inc. to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

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SILVERHAWK™

Plaque Excision System
INSTRUCTIONS FOR USE

CAUTION
Federal (US) Law restricts this device to sale by or on the order of a physician.

CE 0050

Device Description

The SilverHawk™ Peripheral Plaque Excision System and SilverHawk™ Cutter Driver are designed for the treatment of *de novo* and restenotic atherosclerotic lesions located in native peripheral arteries. The catheter consists of a flexible shaft designed to track over a 0.014" guidewire. At the distal end of the catheter is a small cutting assembly comprised of a rotating inner blade contained within a tubular housing. The proximal end of the catheter contains a connector and positioning lever designed to fit into a small, disposable, battery-driven Cutter Driver (provided separately), which powers the device.

When the catheter is connected to the Cutter Driver, retracting the positioning lever simultaneously turns on the motor and causes the distal portion of the cutter housing to deflect, forcing the device against the target lesion. At the same time, this motion exposes the inner rotating blade, preparing the device for lesion treatment. With the blade spinning, the catheter is slowly advanced across the lesion, "shaving" occlusive material from the artery. The excised tissue is captured and stored in the tip of the device. The cutting process is completed by advancing the positioning lever which brings the inner blade back into the housing, restoring the cutter to its "non-deflected" configuration, and automatically turns off the motor. This cutting sequence can be repeated as many times as necessary to achieve the desired degree of plaque excision.

Illustration and Nomenclature

Key Catheter Specifications

Catalog Number	P4023	P4016	P4012	P4015
Model	SX (Yellow)	MS (Violet)	LS (Gray)	LX (Gray)
Usable Length	136cm	110 cm	110 cm	113 cm
Tip Length	4.3cm	6.0 cm	6.0 cm	9.0 cm
Maximum Catheter Profile	0.095"	0.105"	0.105"	0.105"
Minimum Sheath Size	7F	8F	8F	8F
Shape Set	None	Mechanical	Mechanical	Mechanical
Maximum Guidewire Diameter	0.014"	0.014"	0.014"	0.014"
Minimum Vessel Diameter	3.0 mm	3.5 mm	4.5 mm	4.5 mm

- Dissection
- Hypotension
- Infection
- Ischemia
- Restenosis of the treated segment
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair

Iliac/Renal Vasculature Adverse Events

Field experience associated with use of this device in the iliac and/or renal vasculature are identified below:

- Arterial perforation
- Death
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair

How Supplied

The SilverHawk™ Peripheral Catheter and Cutter Driver are packaged and sterilized individually, but shipped in a single shelf carton. Both are intended for single patient use only.

Sterilization and Expiration Dating

The SilverHawk™ Peripheral Catheter is sterilized using ethylene oxide gas. The SilverHawk™ Cutter Driver is sterilized using gamma radiation. Both devices are STERILE if unit package is unopened and undamaged.

Both the Catheter and Cutter Driver are intended for single use only and should not be reused or resterilized. Use prior to the "Use by" date printed on the package labels.

Storage and Use Conditions

Store sterile packaged Catheters and Cutter Drivers in a cool dry place until ready to use. Do not expose to organic solvents, ionizing radiation, ultraviolet light or alcohol-based fluids.

Directions for Use

Inspection

1. Prior to use, carefully inspect the Catheter and Cutter Driver to verify that neither the sterile packaging nor the devices themselves have been damaged.
2. Connect the Catheter to the Cutter Driver by inserting the proximal end of the catheter into the motor. Ensure the cutter positioning lever aligns with the slot in the Cutter Driver. When fully inserted, the catheter connector will lock into the Cutter Driver. To remove the catheter from the Cutter Driver, depress the catheter lock release button and pull the catheter from the motor.
   Note: To avoid accidental activation of the Cutter Driver, be sure the cutter positioning lever is in the fully forward position prior to insertion into the Cutter Driver.
3. To confirm functionality of the catheter, advance and retract the cutter positioning lever. Ensure that the motor turns on and off automatically and that the inner blade moves freely. The catheter tip should deflect and return to its original configuration as the cutter position is cycled. Advance the positioning lever to close the cutter and turn off the motor.

   Note: The automatic motor control feature of the Cutter Driver can be disabled by using the motor override

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Prolonged cardiopulmonary resuscitation
Endoscopic peptic ulcer disease in the past 3 years or gastrointestinal bleeding within the past 3 months
Genitourinary bleeding within the past 3 months
Severe persistent hypertension (systolic pressure >180 mm)
Allergy or intolerance to aspirin

nical Contraindications

SilverHawk™ Peripheral Catheter System is specifically traindicated:
in the carotid artery; or
in the iliac or renal vasculature; or
for in-stent restenosis at the peripheral vascular site.

strictions

Federal (U.S.A) Law restricts this device to sale by or on the order of a physician.
This device is intended for **single use** only. Do not resterilize and/or reuse this device.

arnings

ways use direct fluoroscopic observation when nipulating the SilverHawk™ Peripheral Catheter in the ripheral vessels. If resistance is met during manipulation, termine the cause of the resistance before proceeding.

ver advance the distal tip of the catheter near the floppy d of the guidewire. A catheter advanced to this position y not follow the guidewire when it is retracted and cause e guidewire to buckle into a loop. If this occurs, catheter d guidewire should be removed together to prevent tential damage to vessel walls. If resistance is still felt, the eath should also be removed as part of the unit.

oid excessive movement of the SilverHawk™ Peripheral atheter within the vessel at all times as doing so could sult in embolization or vessel damage. In addition, cessive catheter manipulation with the cutter window open uld result in embolization of previously excised tissue agments.

e SilverHawk™ Peripheral Plaque Excision may only be ed with the SilverHawk™ Cutter Driver.

is device is not to be used in the presence of combustible flammable gases, anesthetics, or cleaners/disinfectants.

recautions

e SilverHawk™ Peripheral Plaque Excision System ould only be used by physicians trained in percutaneous ripheral interventional procedures.

se of this device should be limited to hospitals where rgical support is readily available in the event of a serious mplication.

dverse Events

otential adverse events associated with use of this device and her interventional catheters include, but are not limited to the llowing:
Arterial perforation
Arterial rupture
Arteriovenous fistula
Bleeding complications
Arterial spasm
Embolism and/or arterial thrombosis
Death
Arterial dissection
Entry site complications
Hypotension
Infection
Ischemia
Restenosis of the treated segment
Total occlusion of the peripheral artery
Vascular complications which may require surgical repair

(b) (4)

Iliac/Renal Vasculature Adverse Events

Field experience associated with use of this device in the iliac and/or renal vasculature are identified below:
- Arterial perforation
- Death
- Total occlusion of the peripheral artery
- Vascular complications which may require surgical repair

How Supplied

The SilverHawk™ Peripheral Catheter and Cutter Driver are packaged and sterilized individually, but shipped in a single shelf carton. Both are intended for single patient use only.

Sterilization and Expiration Dating

The SilverHawk™ Peripheral Catheter is sterilized using ethylene oxide gas. The SilverHawk™ Cutter Driver is sterilized using gamma radiation. Both devices are STERILE if unit package is unopened and undamaged.

Both the Catheter and Cutter Driver are intended for single use only and should not be reused or resterilized. Use prior to the "Use by" date printed on the package labels.

Storage and Use Conditions

Store sterile packaged Catheters and Cutter Drivers in a cool dry place until ready to use. Do not expose to organic solvents, ionizing radiation, ultraviolet light or alcohol-based fluids.

Directions for Use

Inspection

1. Prior to use, carefully inspect the Catheter and Cutter Driver to verify that neither the sterile packaging nor the devices themselves have been damaged.
2. Connect the Catheter to the Cutter Driver by inserting the proximal end of the catheter into the motor. Ensure the cutter positioning lever aligns with the slot in the Cutter Driver. When fully inserted, the catheter connector will lock into the Cutter Driver. To remove the catheter from the Cutter Driver, depress the catheter lock release button and pull the catheter from the motor.
   Note: To avoid accidental activation of the Cutter Driver, be sure the cutter positioning lever is in the fully forward position prior to insertion into the Cutter Driver.
3. To confirm functionality of the catheter, advance and retract the cutter positioning lever. Ensure that the motor turns on and off automatically and that the inner blade moves freely. The catheter tip should deflect and return to its original configuration as the cutter position is cycled. Advance the positioning lever to close the cutter and turn off the motor.

   Note: The automatic motor control feature of the Cutter Driver can be disabled by using the motor override

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switch. When the switch is up, the automatic motor control is enabled. When the switch is down, the cutter positioning lever can be advanced and retracted without activating the motor.

4. Inspect the shaft, cutter housing and distal tip for smooth transitions. Do not use the catheter if a sharp edge or protrusion is detected.

CAUTION: Do not sharply bend or kink the catheter shaft during handling as this could damage the device and impair its function.

5. Check the catheter shaft for functionality of the hydrophilic coating. When wetted with sterile saline, the catheter shaft should feel slippery.

Note: To facilitate catheter handling, the proximal most portion of shaft is not coated.

6. Should the catheter become kinked or damaged during use, replace the damaged catheter with a new catheter and return used device to FoxHollow Technologies for evaluation.

Preparation

1. Purge Air From the Catheter.
   a) Fill a syringe (3cc or larger) with heparinized saline.
   b) Attach the syringe to the distal end of the catheter tip and gently inject saline until all air is eliminated from the tip.
   c) Next, flush the catheter shaft by attaching the heparinized saline filled syringe to the catheter flush luer. With the cutter closed, gently apply pressure to the syringe until all air has been flushed from the catheter and saline is seen exiting the cutter.

Insertion and Use

Once prepared, the catheter is ready for insertion into the patient.

1. Insertion
   a) Prepare the patient and administer the appropriate anticoagulant and vasodilator therapy for standard percutaneous intervention.
   b) Insert the appropriate sized sheath and hemostasis valve using standard techniques.

CAUTION: Refer to the Key Catheter Specifications table for appropriate sheath size requirements. Use of sheaths smaller than those recommended may compromise device performance.

   c) Using standard technique, place a guidewire across the target lesion.
   d) Ensure that the cutter positioning lever is in its fully advanced, i.e. closed and off, position. Carefully backload the end of the guidewire through the tip of the SilverHawk™ Catheter.
   e) Loosen the hemostasis valve and carefully insert the SilverHawk™ Catheter into the sheath. Retighten the hemostasis valve to prevent blood loss.

CAUTION: Do not over tighten the hemostasis valve as this may inhibit smooth advancement and rotation of the catheter or possibly damage the shaft.

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2. Lesion Treatment
   a) Using fluoroscopic guidance, carefully advance the SilverHawk™ Peripheral Catheter to the proximal edge of the target stenosis.

WARNING: The cutter section of the SilverHawk™ Peripheral Catheter is a rigid component. Do not use excessive force or torque to advance the SilverHawk™ Catheter as vessel trauma and/or device failure may result.

WARNING: Do not use the SilverHawk™ Peripheral Catheter in bends in excess of 90° or if excessive calcification is detected by IVUS or angiography.

Note: If the catheter cannot be advanced across the lesion, it may be necessary to carefully remove the catheter and pre-dilate the lesion with a small diameter balloon angioplasty catheter.

   b) Carefully rotate the SilverHawk™ Peripheral Catheter blade opening toward the treatment site. Additional angiographic assessment should be performed to confirm catheter position in relation to the lesion.

Note: The cutter housing is radiopaque to facilitate angiographic visualization of the device orientation.



Left



Anterior/Posterior



Right

In addition, a radiopaque ring is located just proximal to the distal most edge of the tip.

CAUTION: If device is not rotating easily, do not torque the catheter shaft more than 360° in one direction. Doing so could result in device failure such as shaft kinking or tip fracture. Device repositioning or lesion predilatation may be required.

   c) To begin plaque excision, retract the cutter positioning lever which will expose the rotating blade and deflect the catheter tip.

Note: When advancing or retracting the positioning lever, the lever must be moved until a "click" is felt at the end of the lever travel. This indicates that the catheter has achieved its FULLY retracted or FULLY advanced position.

WARNING: Operation of the device with the blade partially opened or closed could result in [illegible] **of previously excised tissue.**

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d) With the motor running, slowly advance the SilverHawk™ Catheter through the target lesion under fluoroscopic guidance.

Reference the following matrix for the length of cut and number of cutting passes that may be completed for each Catalog Number before removing and emptying the device.

Catalog #	Length of Cut	# cuts per insertion
P4023	25 mm	2
P4016	50 mm	1
P4012	50 mm	1
P4015	75 mm	1

WARNING: The storage capacity of the catheter tip must not be exceeded or embolization of excised tissue fragment may result.

WARNING: If the catheter does not advance easily, close the cutter by advancing the positioning lever. Excessive force should not be used to advance the positioning lever. Device repositioning or predilation may be required.

e) Once the end of the target segment is reached, stop advancing the catheter. Carefully advance the cutter positioning lever to close the cutter and turn off the Cutter Driver, this will be indicated by a tactile "click".

f) At this point, a combination of angiographic and/or intravascular ultrasound imaging should be used to assess the extent of plaque excision.

g) For models that support multiple cuts per insertion, the catheter may be re-advanced and positioned for additional cuts by repeating steps a) through f). Otherwise, proceed to Catheter Removal and Tissue Removal sections, below.

3. Catheter Removal

a) The catheter should be carefully removed from the patient under fluoroscopic guidance.

b) Final angiographic and/or intravascular ultrasound evaluation should be performed post SilverHawk™ Catheter treatment.

4. Tissue Removal

a. Fill a syringe (3cc or larger) with saline.

b. Attach the syringe to proximal luer adaptor on the tissue pusher assembly.

c. Rotate the torque shaft to position the cutter window for optimal viewing.

d. Retract the cutter positioning lever to expose the cutter within the cutter window. Turn the main power switch on the Cutter Driver to OFF and detach the catheter from the Cutter Driver.

e. Insert nosecone into the tip clip.

f. Pinch the tip clip around the nosecone (it will not damage the nosecone).

g. Insert the tissue pusher tip into the catheter vent hole.

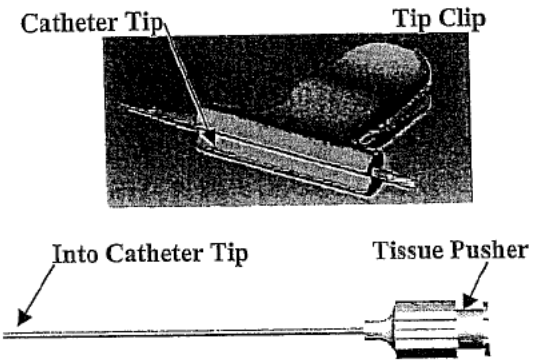
h. Apply pressure to the syringe and slowly advance the tissue pusher to flush tissue from the cutter window.

i. Use tweezers to retrieve exposed tissue from the cutter window if it does not fully exit the window during the flush.

j. Repeat above steps as needed to remove tissue.

k. Once all of the tissue has been removed from the tip, re-flush distal tip reservoir according to the Preparation for Use section, step 1.b.

l. Release the tip clip and slide it off the nosecone.



Please read this manual and follow its instructions carefully. The words WARNING, CAUTION and NOTE convey special meanings. When they are used throughout this manual, they should be carefully reviewed to ensure the safe and effective operation of this product.

⚠WARNING: A WARNING indicates that the personal safety of the patient or physician may be involved. Disregarding a WARNING could result in injury to the patient or physician.

CAUTION: A CAUTION indicates that particular service procedures or precautions must be followed to avoid possible damage to the product.

NOTE: A NOTE indicates special information to facilitate use of the product, or to clarify important information.

Follow local governing ordinances and recycling plans regarding disposal or recycling of device components. Do not incinerate the Cutter Driver unit, as the enclosed batteries may explode at excessive temperatures.

This equipment has been tested and found to comply with the EMC limits for the Medical Device Directive 93/42/EEC (EN 55011 Class B and EN 60601-1-2). These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. The equipment generates, uses and can radiate radio frequency energy and, if not used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular setting. If this equipment does cause harmful interference with other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

-Reorient or relocate the receiving device
-Increase the separation between the equipment
-Consult the manufacturer or field service technician of the equipment experiencing interference for help.
-Warning: There are no user replaceable parts in the Cutter Driver

Contact Information

If you have any questions or comments regarding the use of this product contact:

FOXHOLLOW
740 Bay Road.
Redwood City, CA 94063 USA
Phone: 1-877-348-4295 Fax: 1-888-233-2849

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monorail™ MAVERICK2™

PTCA Dilatation Catheter

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Boston Scientific

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English

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

DEVICE NAME
Boston Scientific MAVERICK²™ Monorail™ PTCA Dilatation Catheter. The generic name of the device is rapid exchange Percutaneous Transluminal Coronary Angioplasty Dilatation Catheter.

DESCRIPTION
The MAVERICK² Monorail Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter, from Boston Scientific, is a rapid exchange catheter with a balloon near the distal tip. The distal section of the catheter is dual lumen and coaxial. The outer lumen is used for inflation of the balloon, and the inner lumen permits the use of guide wires (≤ 0.014 in. / 0,36 mm) to facilitate advancement of the catheter to and through the stenosis to be dilated. The proximal section of the catheter is a single-lumen, stainless steel hypotube with a single luer port for inflation/deflation of the balloon. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. A balloon protector is placed over the balloon to maintain a low profile and a mandrel is placed into the lumen to protect the patency. The catheter includes a tapered tip to facilitate advancement of the catheter to and through the stenosis. In addition, a hydrophilic coating is applied from the distal tip to the guide wire port for increased lubricity on the 15, 20, 25, and 30 mm length balloons. To prevent auto-adhesion of this hydrophilic coating on the balloon, a silicone coating is applied from the distal tip to just proximal of the balloon over the hydrophilic coating. The 9 and 12 mm balloon length models are only coated with the silicone coating from the distal tip to just proximal of the balloon to prevent the balloon from moving relative to the lesion during balloon inflation. The 1.5 mm MAVERICK² Monorail PTCA Dilatation Catheter models have one radiopaque marker band while all other MAVERICK² Monorail PTCA Dilatation Catheter models have two radiopaque markers that in conjunction with fluoroscopy, aid in the placement of the catheter's balloon segment. A needle with a luer port is included for flushing the distal inner lumen prior to the insertion of appropriate coronary guide wires. CLIPIT™ Clips are provided to aid in handling of the catheter.

INDICATIONS
- The MAVERICK² Monorail PTCA Dilatation Catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion.
- The MAVERICK² Monorail PTCA Dilatation Catheter (balloon models 2.25 mm - 4.0 mm) is also indicated for the post-delivery expansion of balloon expandable stents.

NOTE: Bench testing was conducted with the MAVERICK² Monorail PTCA Dilatation Catheter and marketed balloon expandable stents. Consideration should be taken when this device is used with different manufacturers' stents due to differences in stent design.

CONTRAINDICATIONS
- Unprotected left main coronary artery
- Coronary artery spasm in the absence of a significant stenosis

WARNINGS
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

To reduce the potential for vessel damage, the inflated diameter of the balloon should approximate the diameter of the vessel just proximal and distal to the stenosis.

PTCA in patients who are not acceptable candidates for coronary artery bypass graft surgery requires careful consideration. This includes possible hemodynamic support during PTCA as treatment of this patient population carries special risk.

When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

Do not exceed the rated balloon burst pressure. The rated burst pressure is based on the results of *in vitro* testing. At least 99.9 percent of the balloons (with a 95 percent confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.

PTCA should only be performed at hospitals where emergency coronary artery bypass graft surgery can be quickly performed in the event of a potentially injurious or life-threatening complication.

Use only the recommended balloon inflation medium. Never use air or any gaseous medium to inflate the balloon.

Use the catheter prior to the "Use By" date specified on the package.

PRECAUTIONS
Prior to angioplasty, the catheter should be examined to verify functionality and to ensure that its size and shape are suitable for the specific procedure for which it is to be used.

The catheter system should be used only by physicians trained in the performance of percutaneous transluminal coronary angioplasty.

Before insertion of the dilatation catheter, administer appropriate anticoagulant and coronary vasodilator therapy.

Care should be taken to control the position of guide catheter tip during manipulation of the balloon catheter.

Caution should be taken not to over tighten a Touhy-Borst type hemostatic adapter around the dilatation catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

When loading or exchanging the balloon catheter, it is recommended to thoroughly wipe the guide wire clean for better balloon catheter movement on the wire.

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Nonpyrogenic.

Store in a dry, dark, cool place.

ADVERSE EFFECTS

Possible adverse effects include, but are not limited to, the following:

- death
- acute myocardial infarction
- total occlusion of the coronary artery or bypass graft
- coronary vessel dissection, perforation, rupture or injury
- restenosis of the dilated vessel
- hemorrhage or hematoma
- angina or unstable angina
- arrhythmias, including ventricular fibrillation
- drug reactions, allergic reaction to contrast medium
- hypo/hypertension
- infection
- coronary artery spasm
- arteriovenous fistula
- embolism
- stroke
- cardiovascular accident
- transient ischemic attack
- myocardial ischemia
- pseudoanyreusm (at site of catheter insertion)
- cardiac tamponade / pericardial effusion
- renal failure
- coronary aneurysm
- vessel trauma requiring surgical repair or intervention
- cardiogenic shock
- coronary artery bypass graft surgery

INSTRUCTIONS FOR USE

Material Required for PTCA with the MAVERICK²™ Monorail™ PTCA Dilatation Catheter

Quantity	Description
1 or 2	Guide wire(s) of appropriate size for advancement of guide catheter
1	Arterial sheath and dilator set (for femoral approach only)
1 or more	Femoral or brachial guiding catheters in the appropriate size and configuration to select the coronary artery, minimum I.D. of guide catheter = 0.058 in. / 1,47 mm
1	Vial of contrast medium
1	Inflation device with manometer
1 or more	MAVERICK² Monorail PTCA Dilatation Catheter(s)
1 or more	≤ 0.014 in. / 0,36 mm x 175 cm guide wire(s)
1	10, 12, or 20 ml (cc) luer-lock syringe
1	Hemostatic adapter
2	CLIPIT™ Clips

Prior to angioplasty, carefully examine all equipment to be used during the procedure, including the dilatation catheter, to verify proper function. Verify that the catheter and sterile packaging have not been damaged in shipment and that the catheter size is suitable for the specific procedure for which it is intended.

NOTE: At any time during use of the MAVERICK² Monorail PTCA Dilatation Catheter, if the stainless steel proximal shaft has been bent or kinked, do not continue to use the catheter.

1. Inflation Device Preparation
   a. Prepare the inflation device according to the manufacturer's instructions.
   b. Purge the system of air.

2. Dilatation Catheter Selection
   The inflation diameter of the balloon must not exceed the diameter of the coronary artery proximal and distal to the stenosis. If the stenosis cannot be crossed with the desired dilatation catheter, use a smaller diameter catheter to predilate the lesion to facilitate passage of a more appropriate-sized dilatation catheter.

3. Dilatation Catheter Preparation
   a. Remove catheter from the protective hoop.
   b. Remove the balloon protector and mandrel by grasping the balloon catheter just proximal to the balloon, and with the other hand, gently grasp the proximal section of the balloon protector and slide distally. **If unusual resistance is felt during the product mandrel and/or balloon protector removal, do not use this product and replace with another. Follow product returns procedure for unused product.**
   c. Prepare the balloon dilatation catheter for purging. Fill a 10, 12, or 20 ml (cc) luer-lock syringe with 3 ml (cc) of contrast medium. Use only appropriate balloon inflation medium (e.g., the equivalent of a 50:50 mixture of contrast medium and sterile normal saline). **Do not use air or any gaseous medium to inflate the balloon.**
   d. Connect a three-way stopcock to the port fitting on the dilatation catheter. Flush through the stopcock.
   e. Connect the syringe to the stopcock.
   f. Hold the syringe with the nozzle pointing downward and aspirate for 5 seconds. Release the plunger.
   g. Remove the syringe and evacuate all air from the barrel.
   h. Reconnect the syringe and aspirate until bubbles no longer appear during aspiration. If air bubbles persist, remove catheter from hoop and inflate the balloon to verify that there are no leaks present prior to insertion.
   i. Release plunger and set aside until step **4b.**
   j. Carefully insert the luer-lock needle into the distal tip of the balloon catheter. Flush the wire lumen with sterile saline. Remove the needle from the distal tip. Do not discard the luer-lock needle until the end of the procedure, as additional flushing may be required.

4. Inflation Device Connection to Catheter
   a. To remove any air lodged in the distal luer fitting of the inflation device, purge approximately 1 ml (cc) of contrast medium.
   b. Applying positive pressure to the balloon, disconnect the syringe used in preparation. A meniscus will appear in the balloon port when the syringe is removed. Verify that a meniscus of contrast medium is evident in both the dilatation catheter balloon port and the inflation device connection. Securely couple the inflation device to the balloon port of the balloon dilatation catheter.

5. Use of the MAVERICK² Monorail PTCA Dilatation Catheter
   a. Insert a guide wire through the hemostatic valve following the manufacturer's instructions or standard practice. Advance the guide wire carefully into the guiding catheter. When complete, withdraw the guide wire introducer, if used.
   b. Attach a torque device to the wire, if desired. Under fluoroscopy, advance the guide wire to the desired vessel, then across the stenosis.

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c. Backload the distal tip of the dilatation catheter onto the guide wire ensuring that the guide wire exits the midsection opening in the catheter.
NOTE: To avoid kinking, advance the dilatation catheter slowly, in small increments until the proximal end of the guide wire emerges from the catheter.

d. Advance the catheter through the hemostatic valve slowly, while the balloon is fully deflated. If resistance is encountered, do not advance the dilatation catheter through the adapter. Caution should be taken not to over tighten the hemostatic adapter around the dilatation catheter shaft as lumen constriction may occur, affecting inflation/deflation of the balloon.

e. Thoroughly aspirate and flush the guiding catheter in preparation for introduction of the dilatation catheter.

f. Connect the side port of the guiding catheter hemostatic adapter to the proximal pressure recording/infusion line or manifold assembly, which permits proximal pressure recording or infusion through the guiding catheter.

g. Position the balloon relative to the lesion to be dilated and inflate the balloon to the appropriate pressure (reference balloon compliance table). Maintain negative pressure on the balloon between inflations.

h. Withdraw the deflated dilatation catheter and guide wire from the guiding catheter through the hemostatic valve. Tighten the knurled knob on the hemostatic valve.

i. The catheter may be coiled once and secured using the CLIPIT™ Clips provided in the catheter package. Only the hypotube should be inserted into the coil clip; the clip is not intended for the distal end of the catheter.
NOTE: Care should be taken not to kink or bend the shaft upon application or removal of the coil clip.

6. Dilatation Catheter Exchange Procedure
Boston Scientific brand of rapid exchange Monorail™ catheters have been specifically designed for rapid, single operator balloon exchanges. To perform a catheter exchange:

a. Loosen the knurled knob on the hemostatic valve.

b. Hold the wire and hemostatic valve in one hand, while grasping the balloon shaft in the other hand.

c. Maintain the guide wire position in the coronary artery by holding the wire stationary, and begin pulling the dilatation catheter out of the guiding catheter while monitoring the wire position under fluoroscopy.

d. Withdraw the deflated catheter until the opening in the guide wire lumen is reached. Carefully inch the flexible, distal portion of the balloon catheter off the guide wire while maintaining guide wire position across the lesion. Close the knurled knob on the hemostatic valve.

e. Slide the distal tip of the catheter out of the hemostatic valve, and tighten the knurled knob onto the wire to hold it securely in place. Completely remove the balloon from the wire.

f. Prepare the next balloon catheter to be used as previously described.

g. Backload the new catheter onto the guide wire as previously described under the "Use of the MAVERICK²™ Monorail PTCA Dilatation Catheter", step 5, and continue the procedure accordingly.

Table 1
Typical MAVERICK² Monorail PTCA Dilatation Catheter Compliance

Pressure ATM (kPa)	Balloon Size 1.5 mm	2.0 mm	2.25 mm	2.5 mm	2.75 mm	3.0 mm	3.25 mm	3.5 mm	3.75 mm	4.0 mm
1.0 (101)	*1.39*	*1.85*	*2.09*	*2.29*	*2.55*	*2.77*	*3.02*	*3.24*	*3.50*	*3.75*
2.0 (203)	*1.41*	*1.88*	*2.12*	*2.34*	*2.59*	*2.82*	*3.07*	*3.29*	*3.55*	*3.80*
3.0 (304)	*1.43*	*1.91*	*2.15*	*2.38*	*2.63*	*2.86*	*3.11*	*3.35*	*3.60*	*3.85*
4.0 (405)	*1.46*	*1.94*	*2.19*	*2.42*	*2.67*	*2.91*	*3.16*	*3.40*	*3.65*	*3.90*
5.0 (507)	1.48	1.97	2.22	2.46	2.71	2.95	3.20	3.45	3.70	3.95
6.0 (608) Nominal	1.50	2.00	2.25	2.50	2.75	3.00	3.25	3.50	3.75	4.00
7.0 (709)	1.52	2.03	2.28	2.54	2.79	3.05	3.30	3.55	3.80	4.05
8.0 (811)	1.55	2.06	2.31	2.58	2.83	3.09	3.34	3.60	3.85	4.10
9.0 (912)	1.57	2.09	2.35	2.62	2.87	3.14	3.39	3.65	3.90	4.15
10.0 (1013)	1.59	2.12	2.38	2.67	2.91	3.18	3.43	3.71	3.95	4.20
11.0 (1115)	1.61	2.15	2.41	2.71	2.95	3.23	3.48	3.76	4.00	4.25
12.0 (1216)	1.63*	2.19*	2.44	2.75	2.99	3.28	3.52	3.81*	4.05*	4.31*
13.0 (1317)	1.66	2.22	2.47	2.79	3.03	3.32	3.57	3.86	4.10	4.36
14.0 (1419)	1.68	2.25	2.51*	2.83*	3.07*	3.37*	3.61*	3.91	4.15	4.41
15.0 (1520)	1.70	2.28	2.54	2.87	3.11	3.41	3.66	3.96	4.20	4.46
16.0 (1621)			2.57	2.91	3.15	3.46	3.70			
17.0 (1723)			2.60	2.95	3.19	3.50	3.75			
18.0 (1824)			2.63	2.99	3.23	3.55	3.79			

*Rated Burst Pressure. Do not exceed.
*Stent Rated Burst Pressure only applies to 2.25 - 4.0 sizes. Do not exceed.

NOTE: Numbers in italics reflect extrapolated data points.

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REFERENCES

The physician should consult current medical practice literature on balloon dilatation, such as that published by ACC/AHA.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss; damage, or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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Attachment F: Final Clinical Report

(b)(4) Third Party Clinical Report

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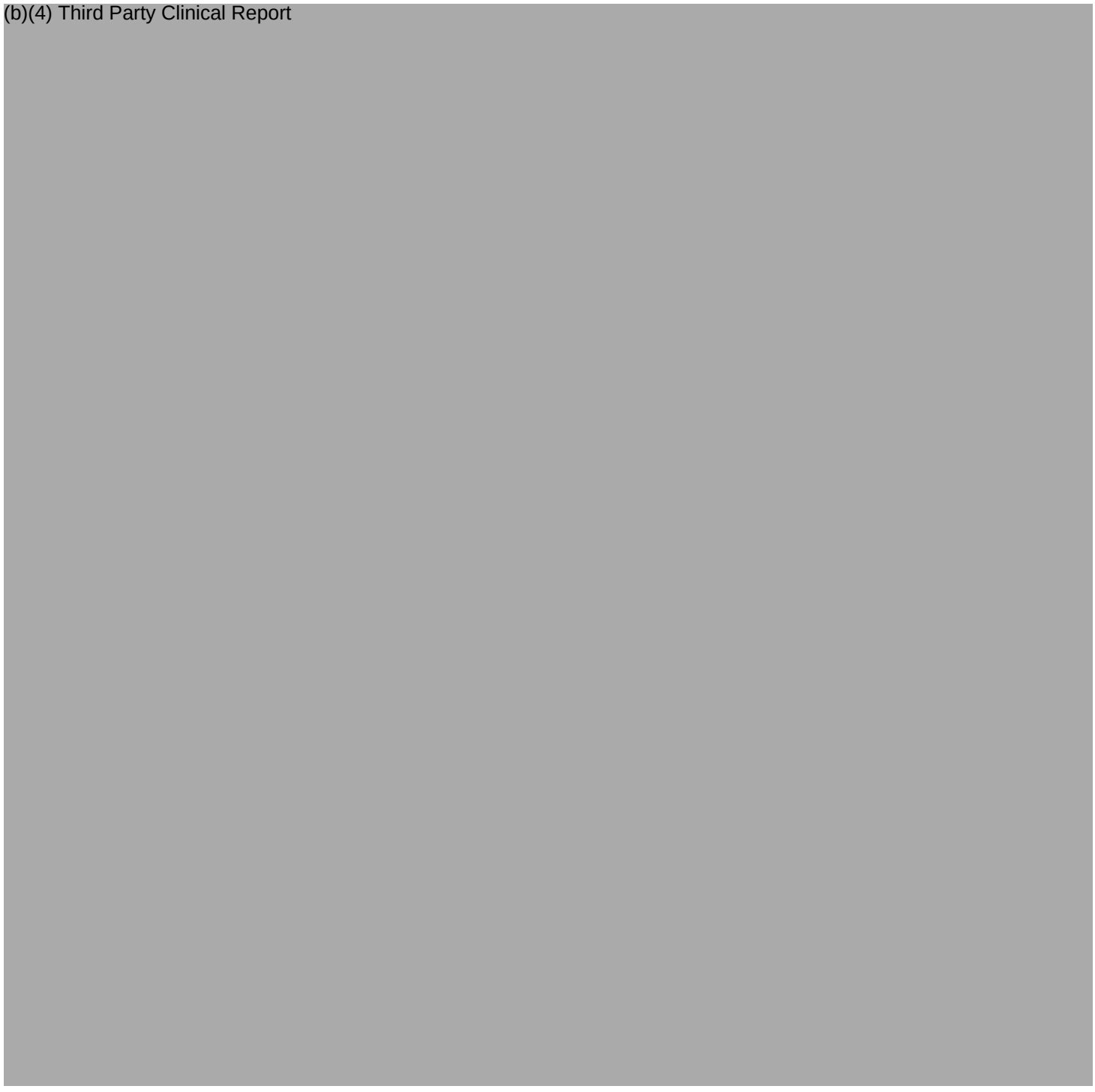
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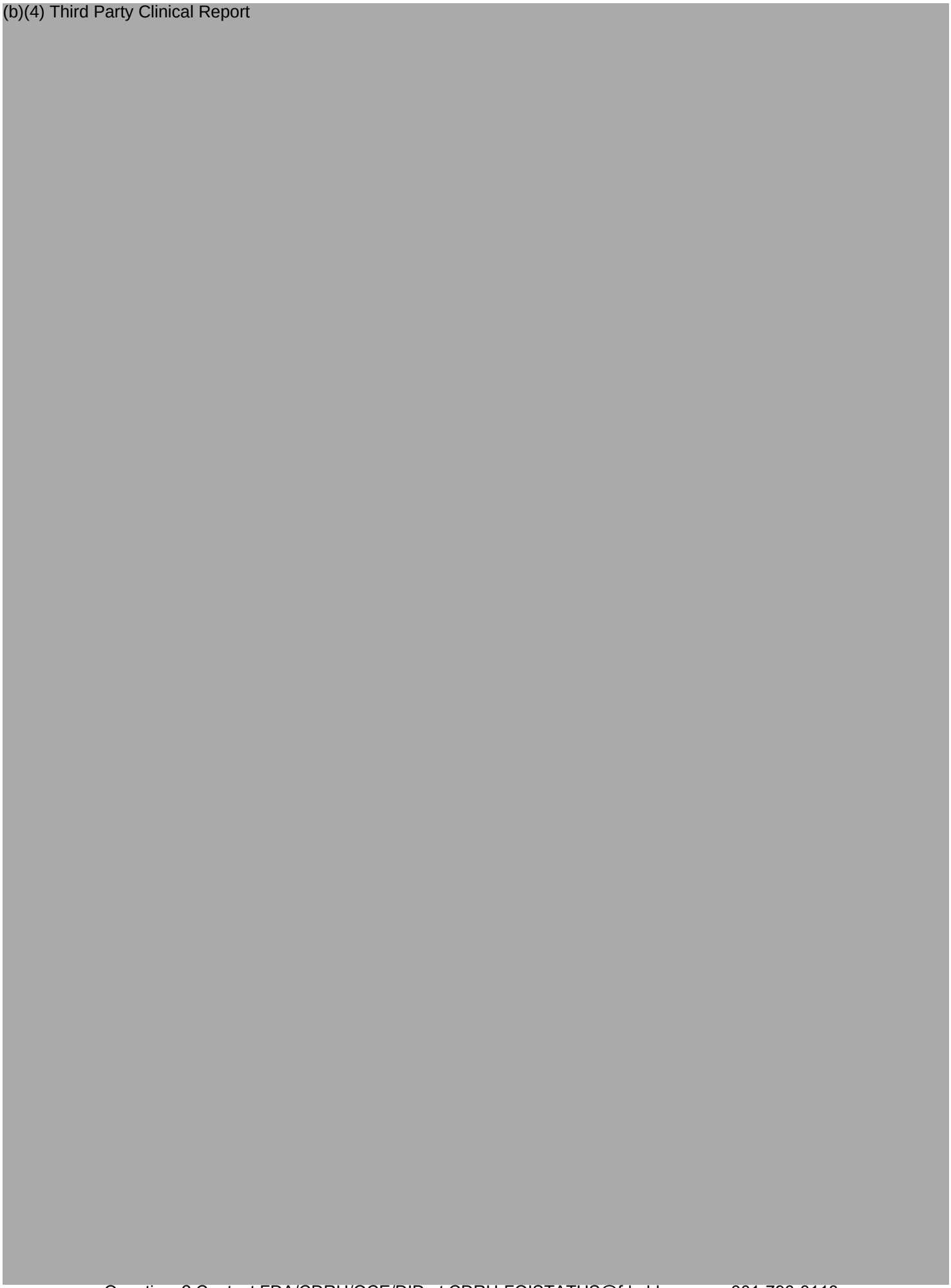
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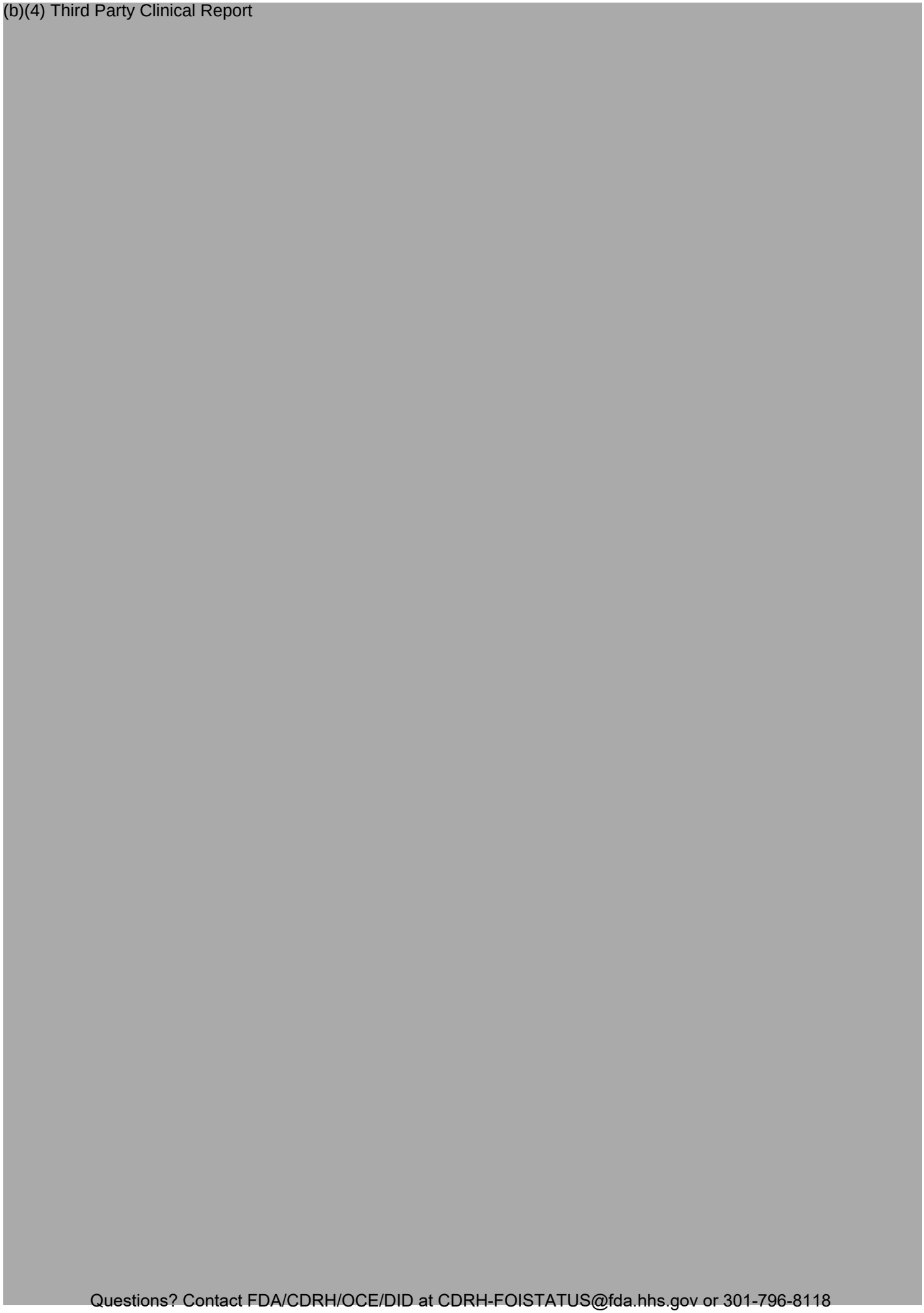
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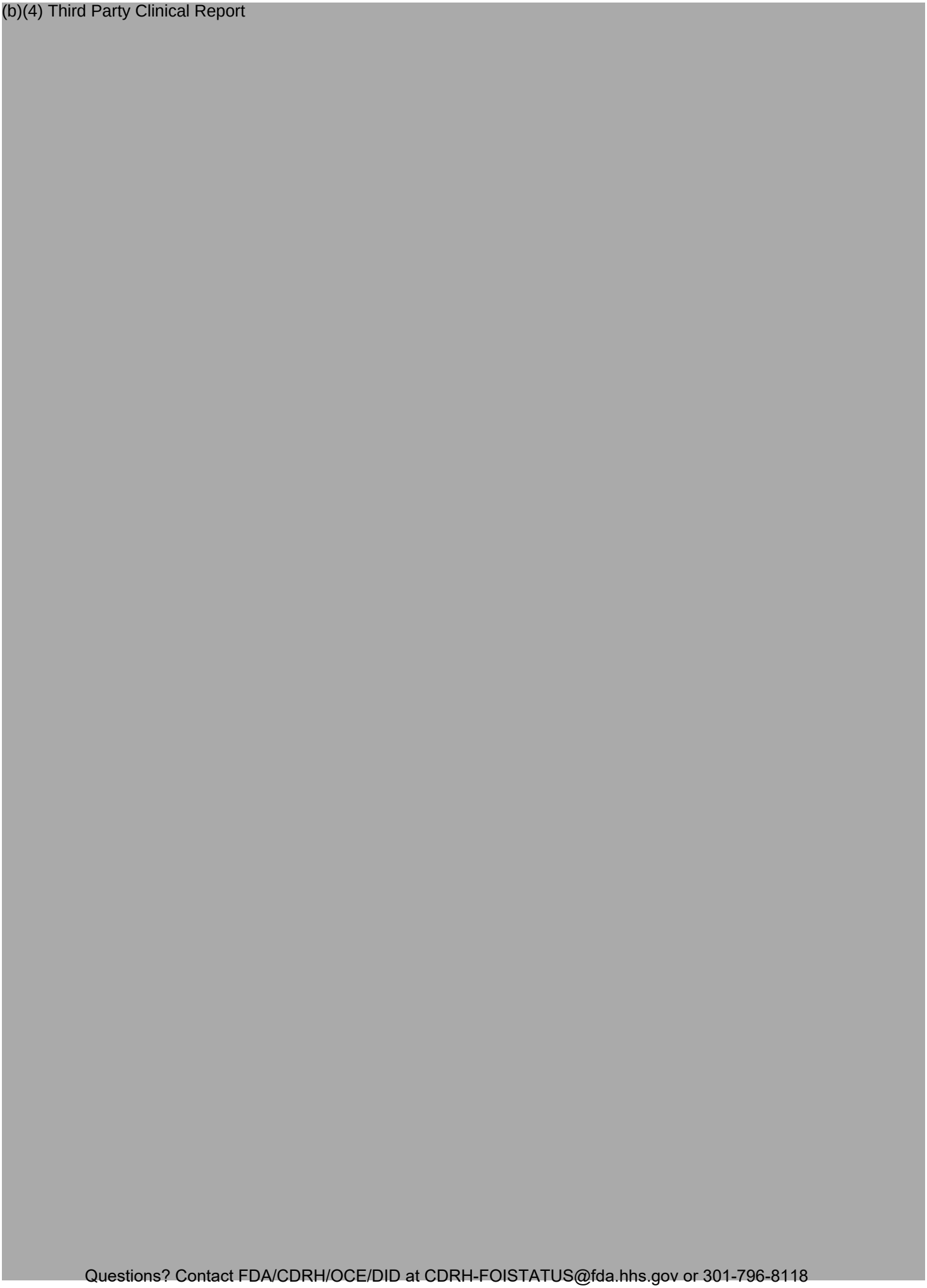
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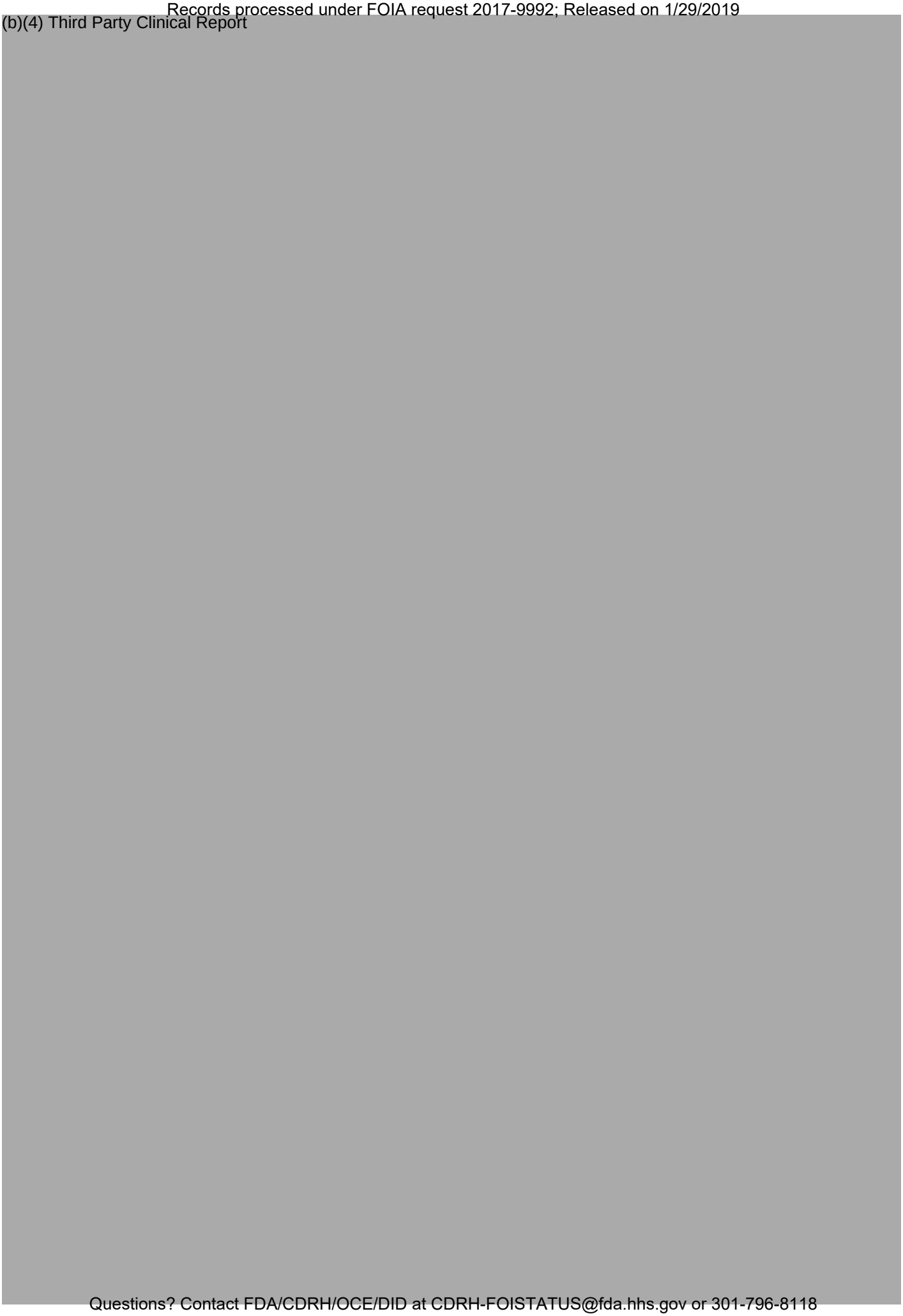
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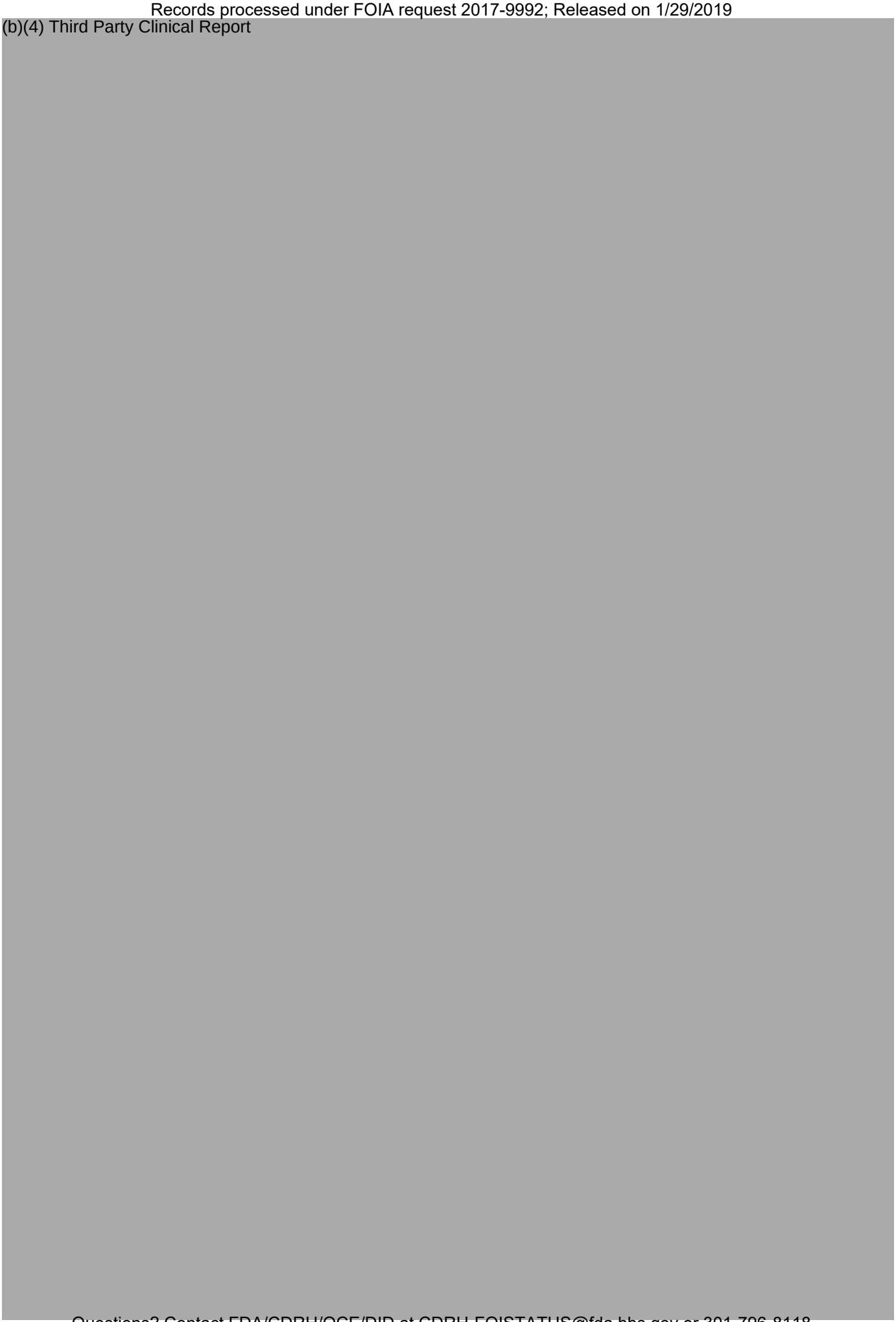
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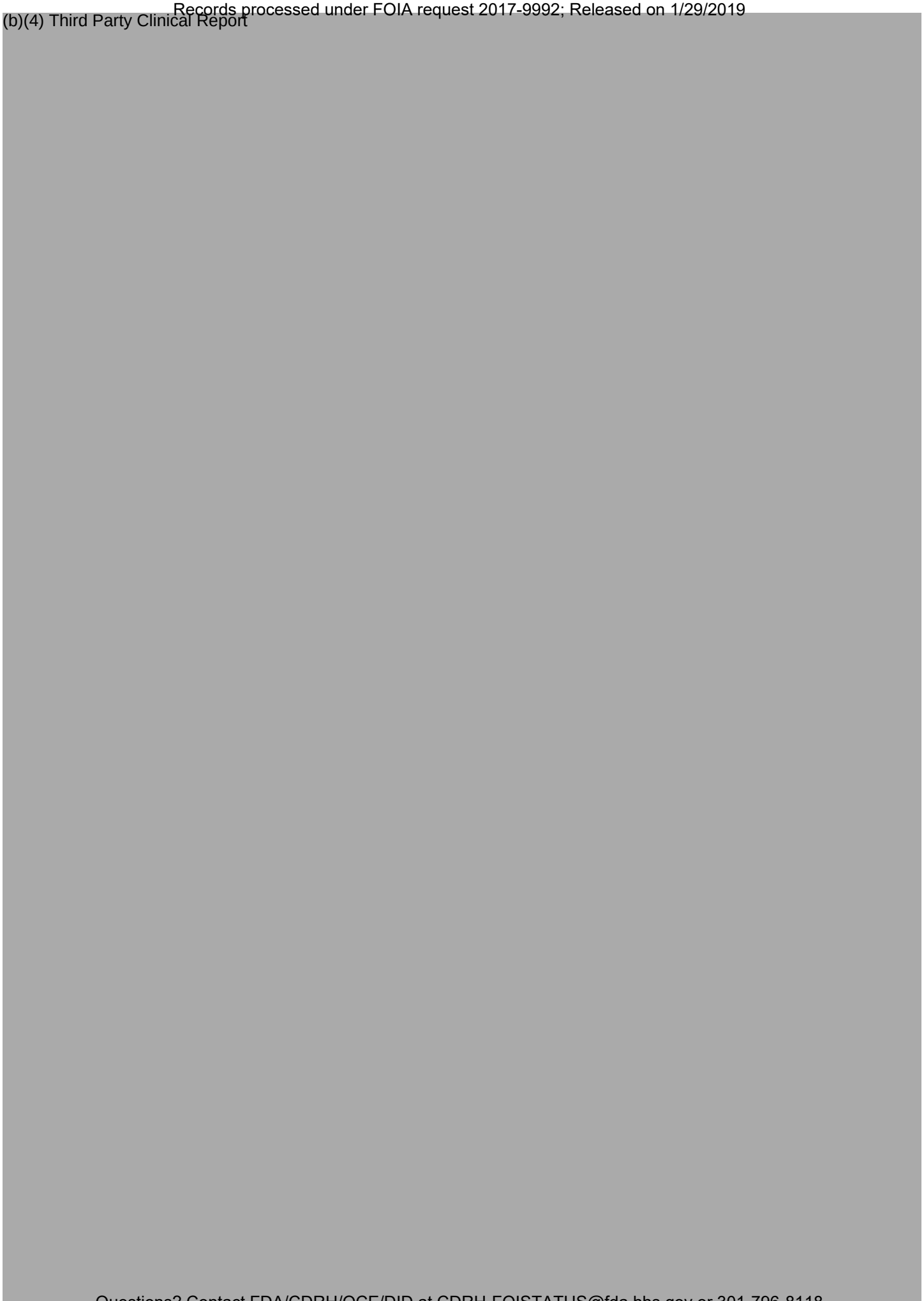
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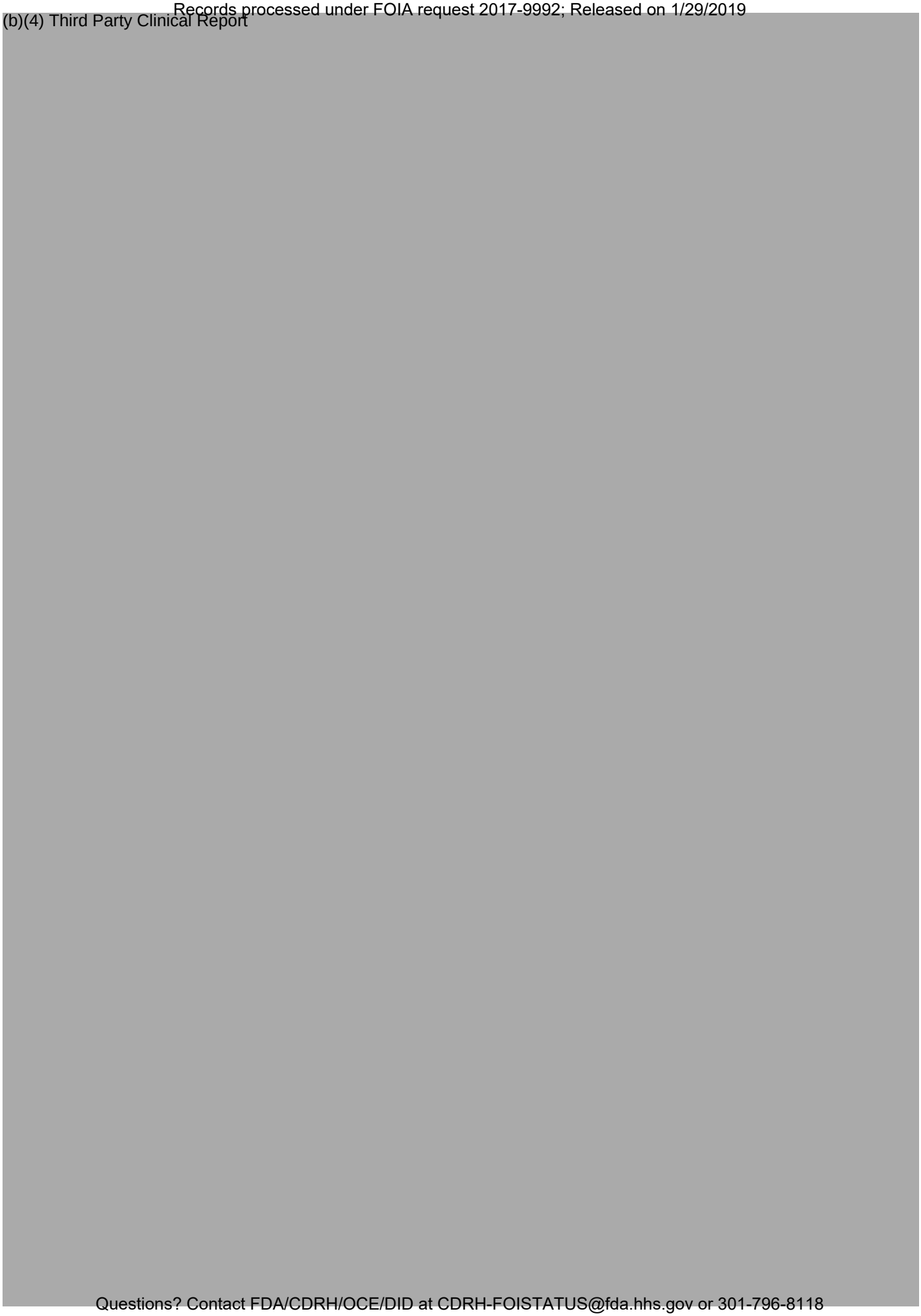
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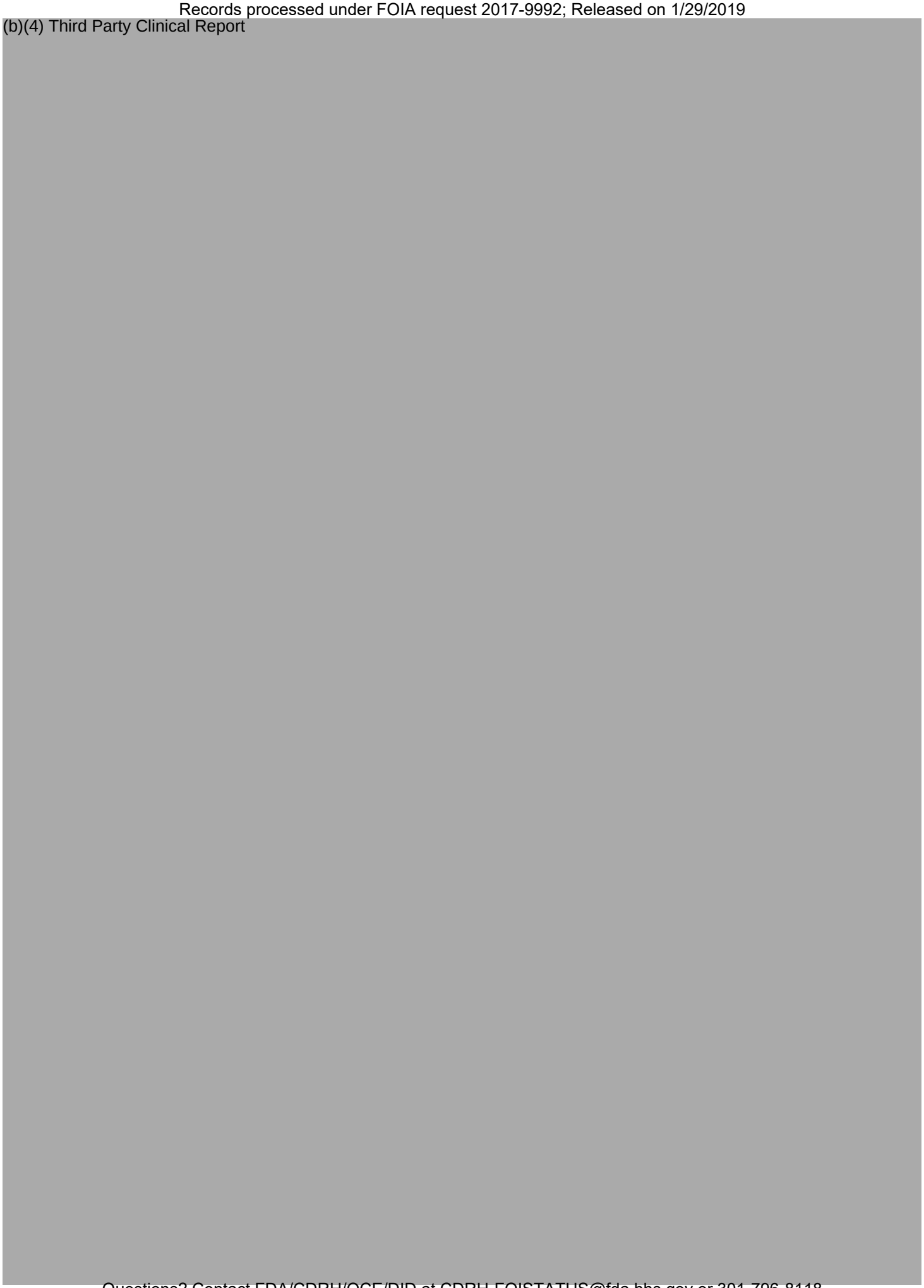
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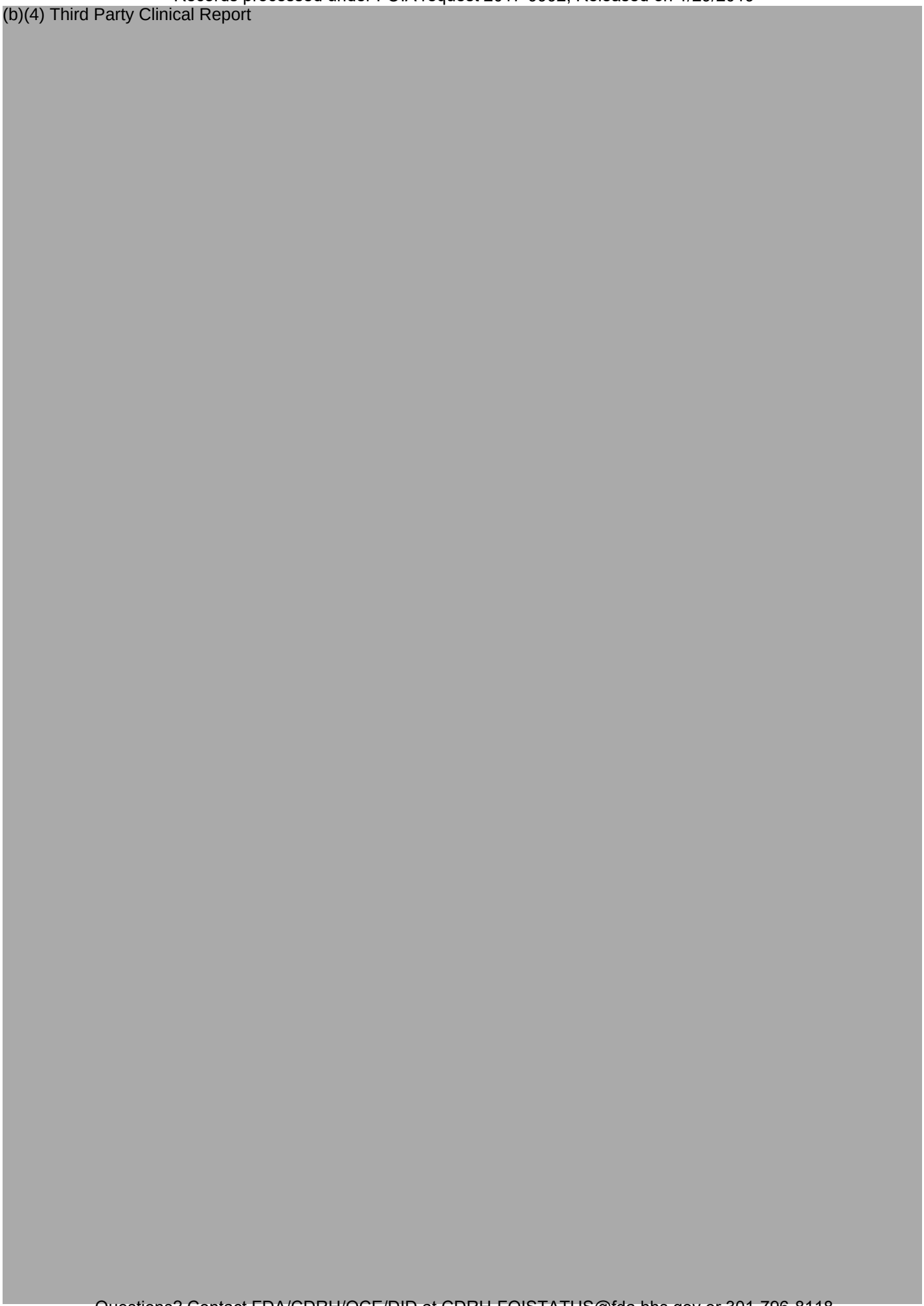


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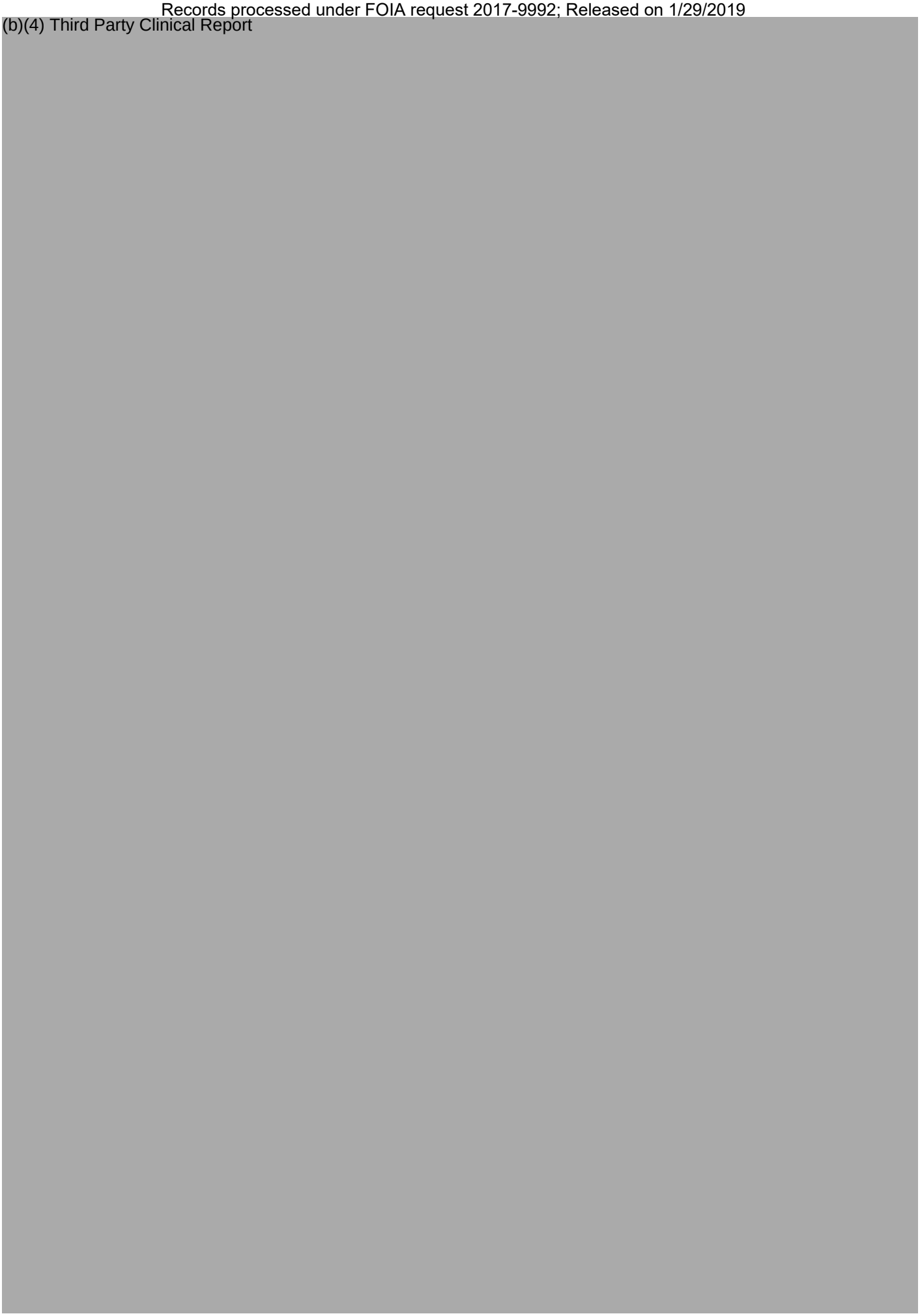
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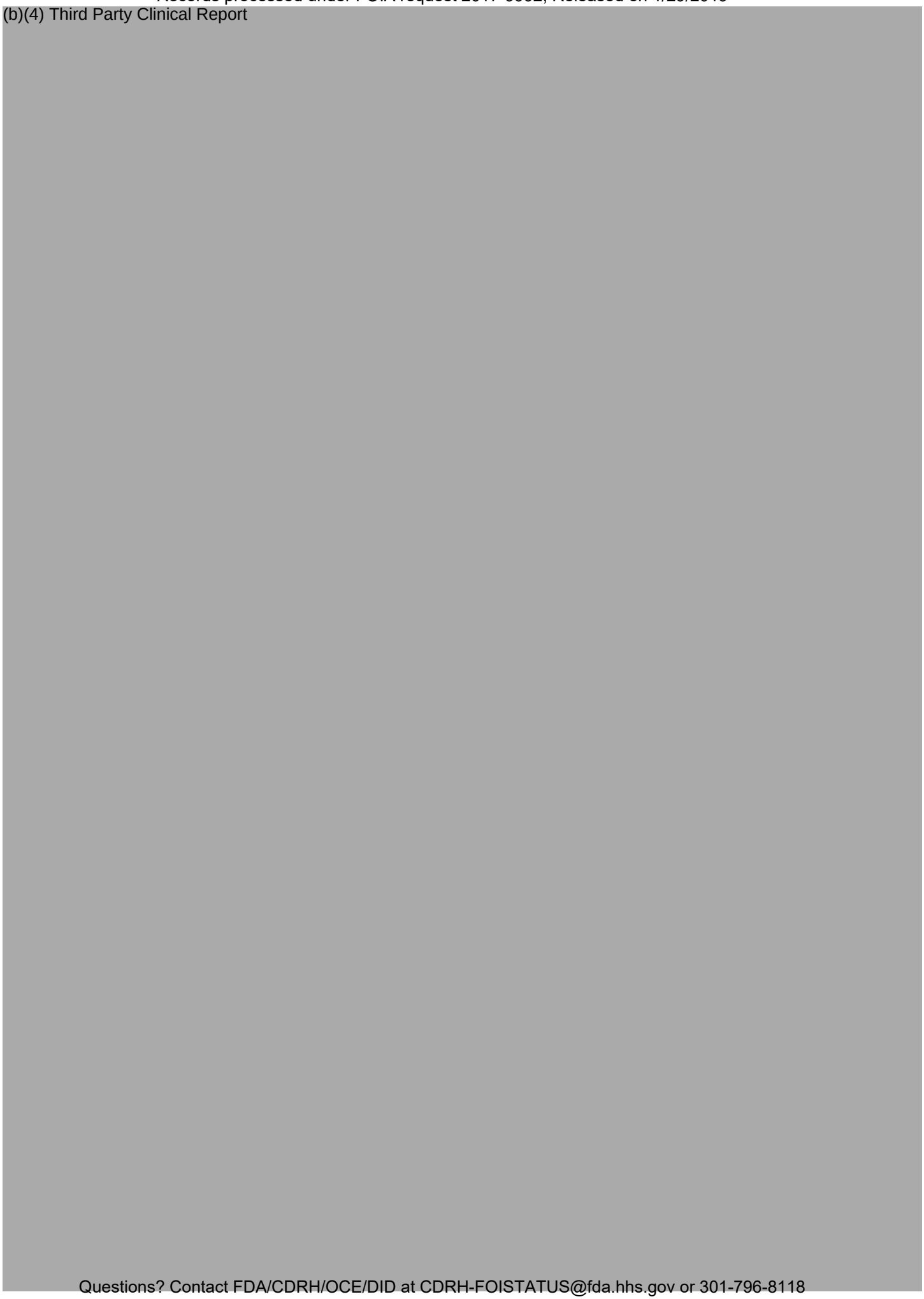
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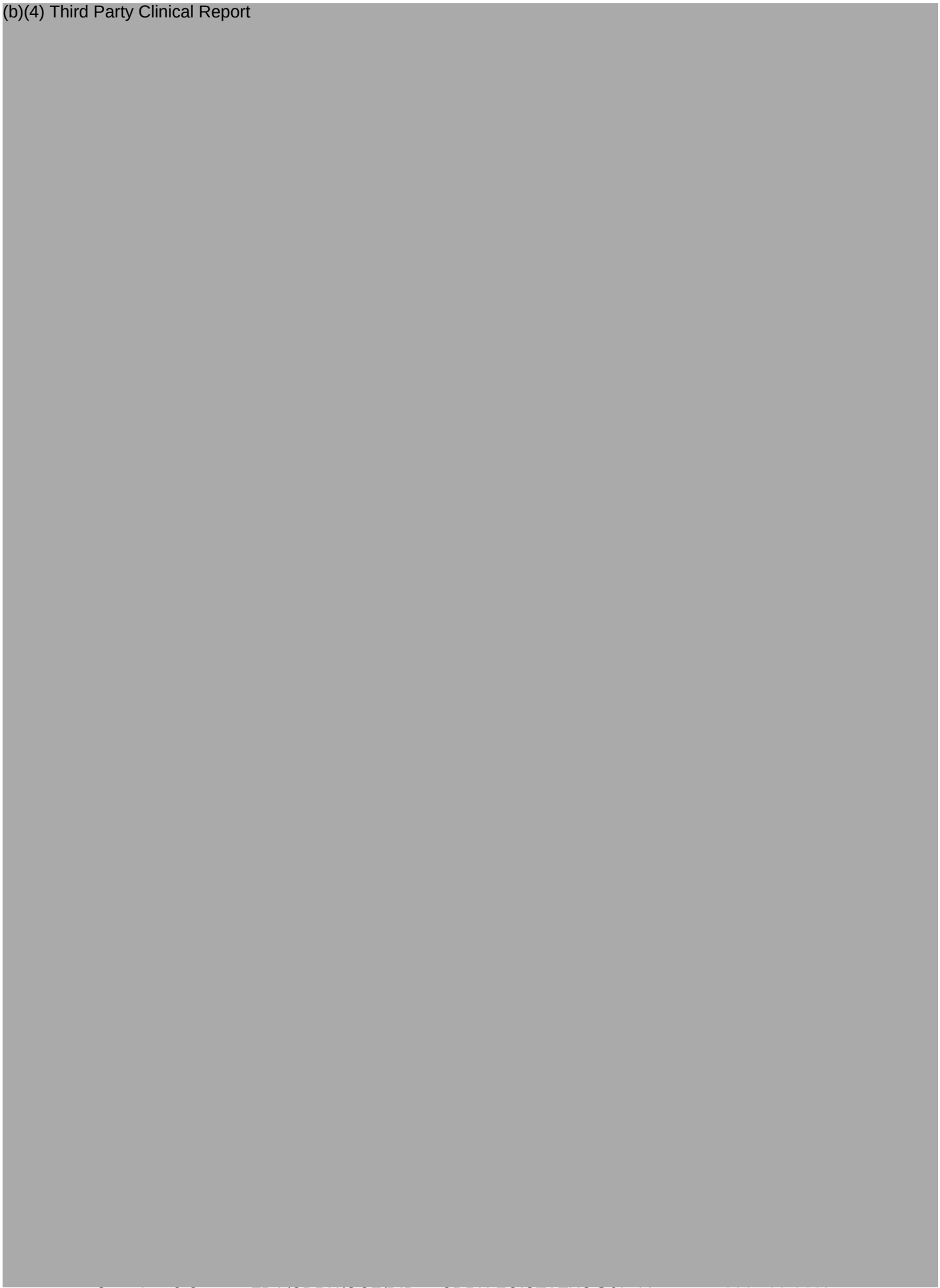
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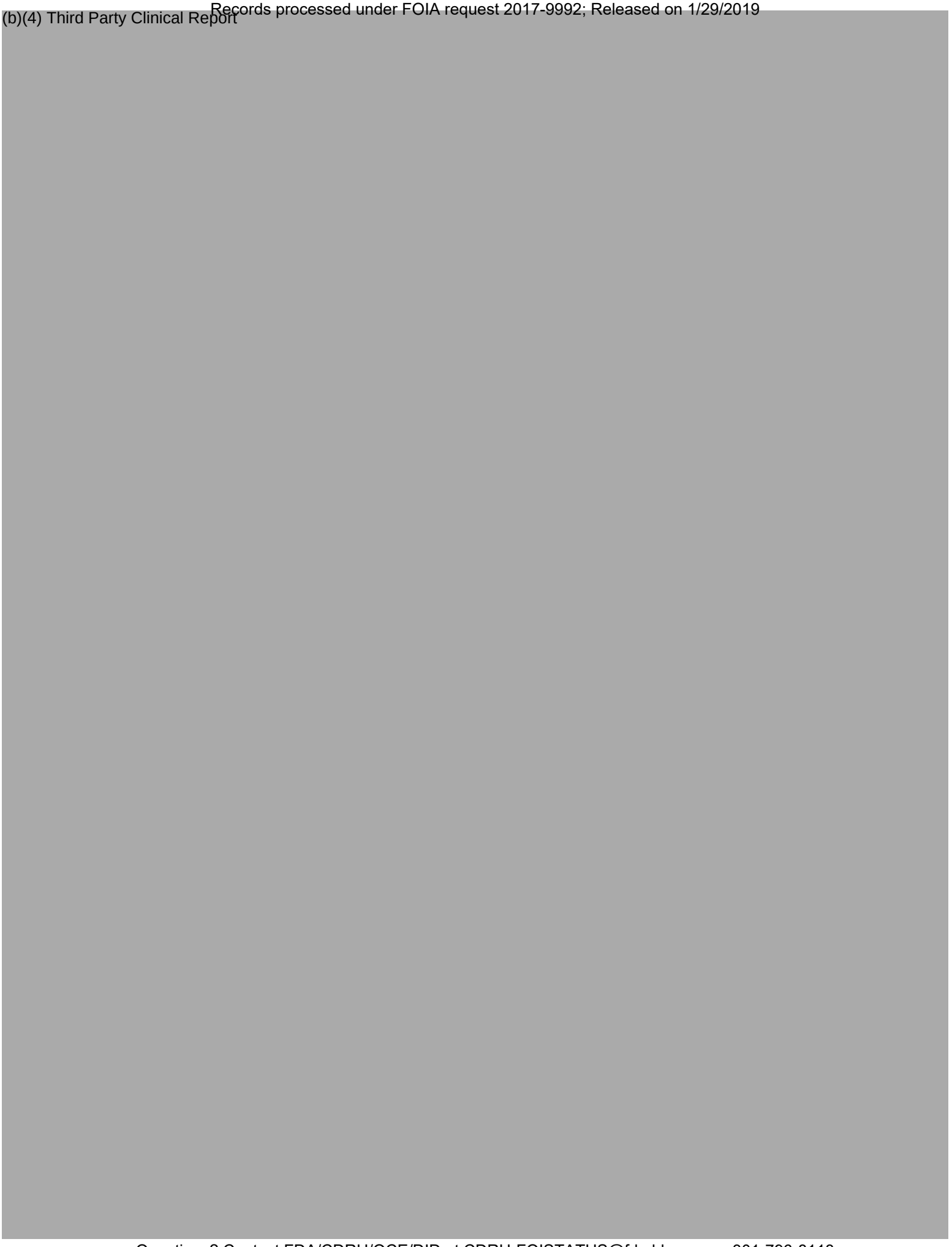
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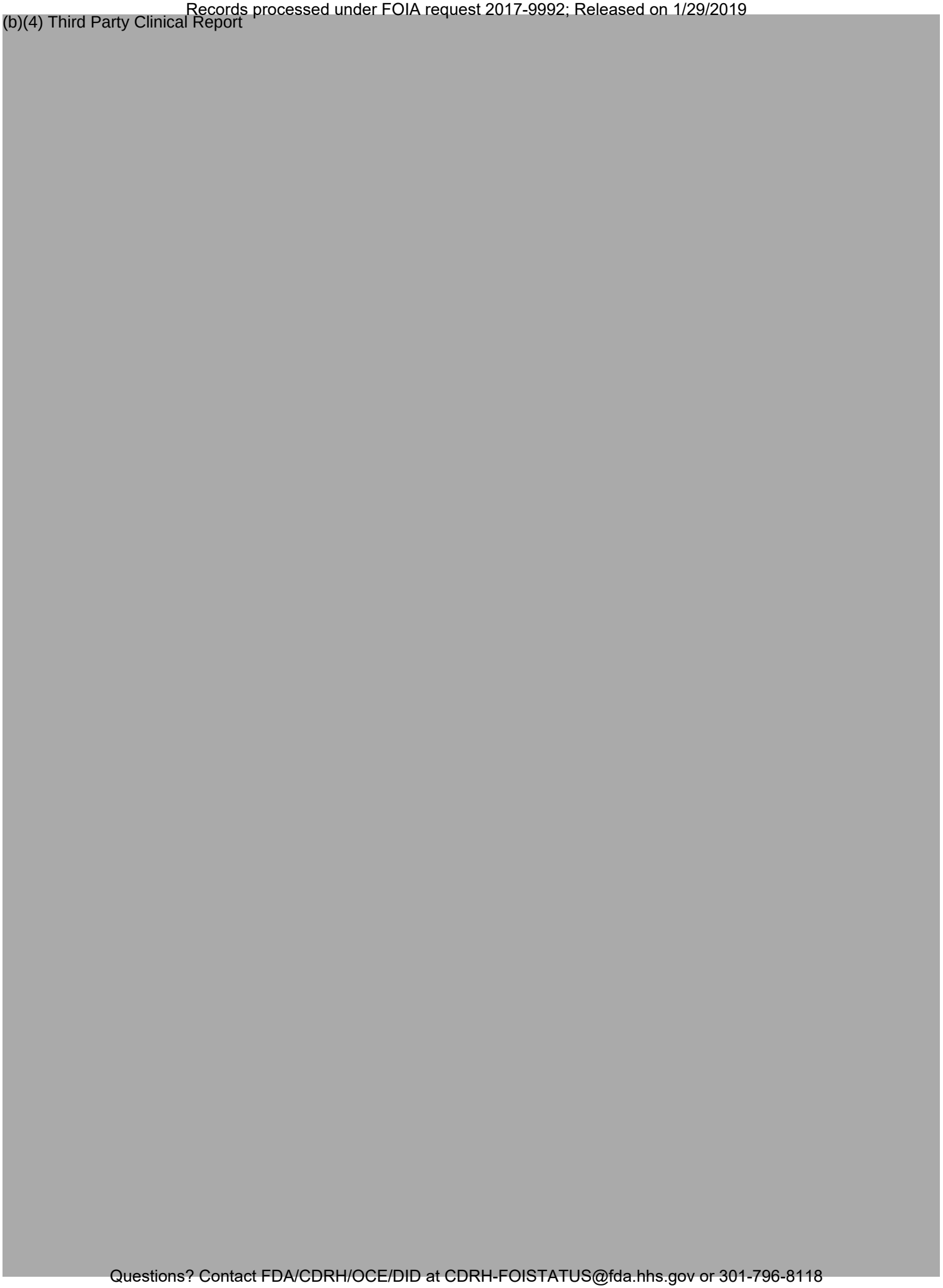
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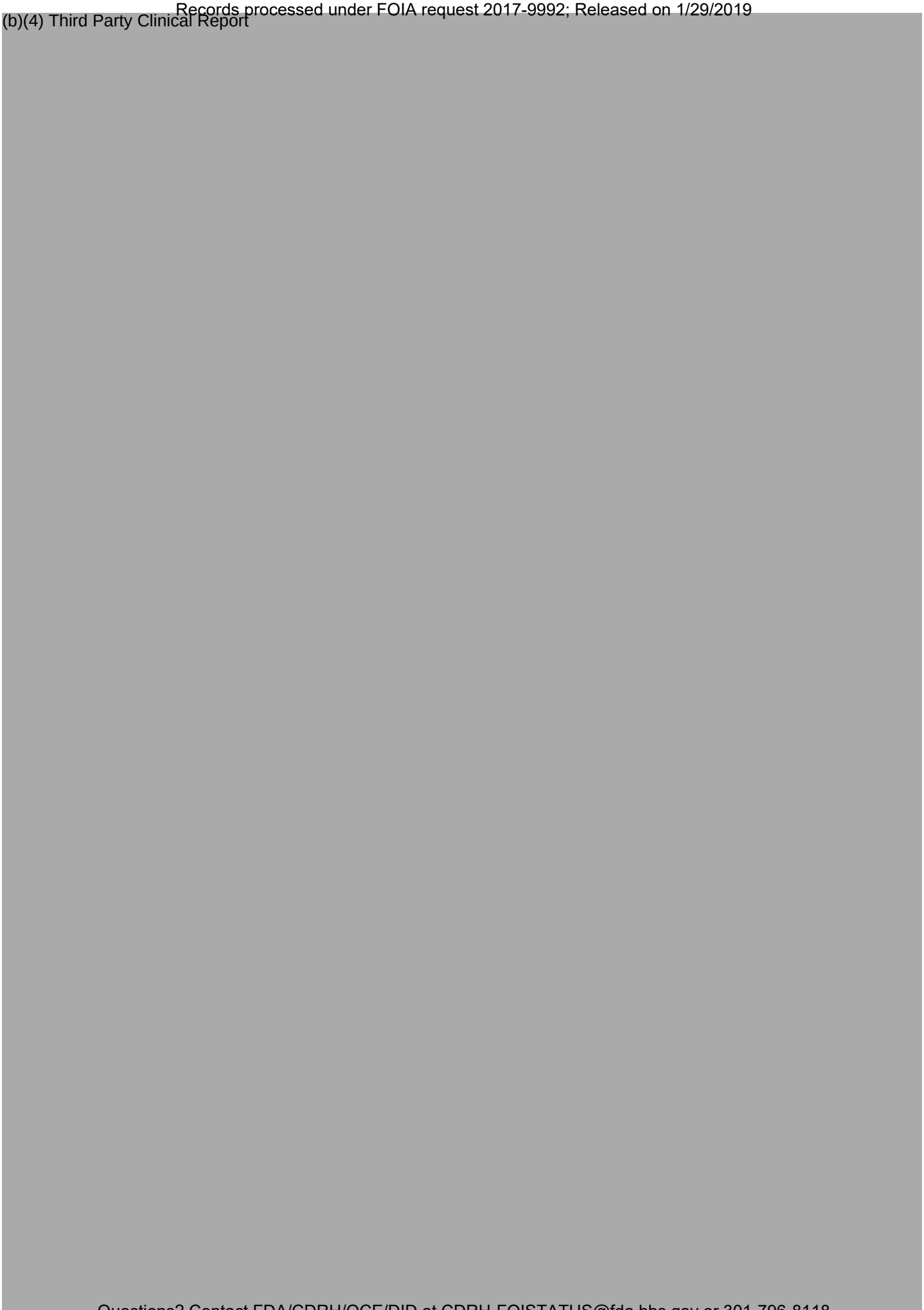
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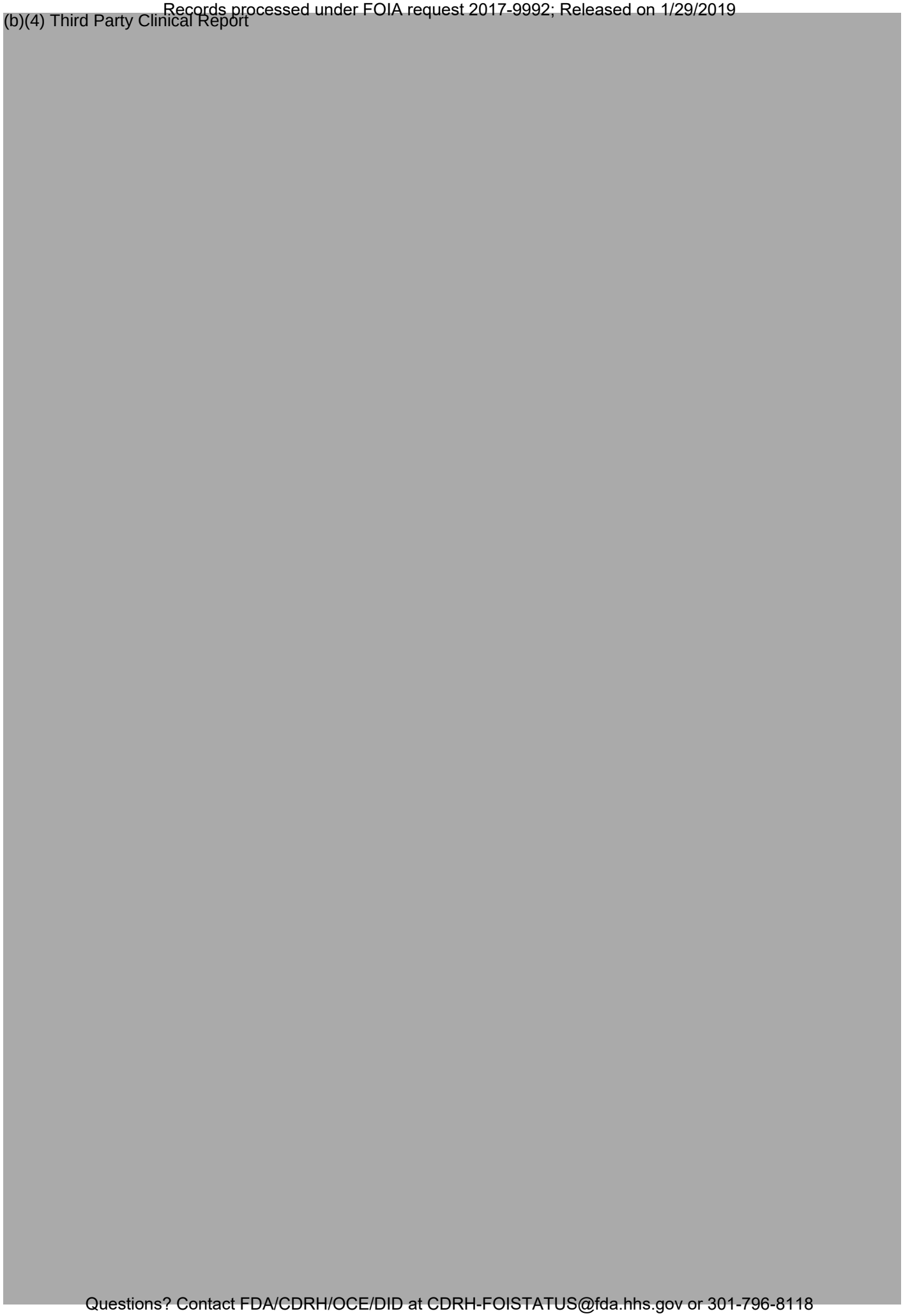
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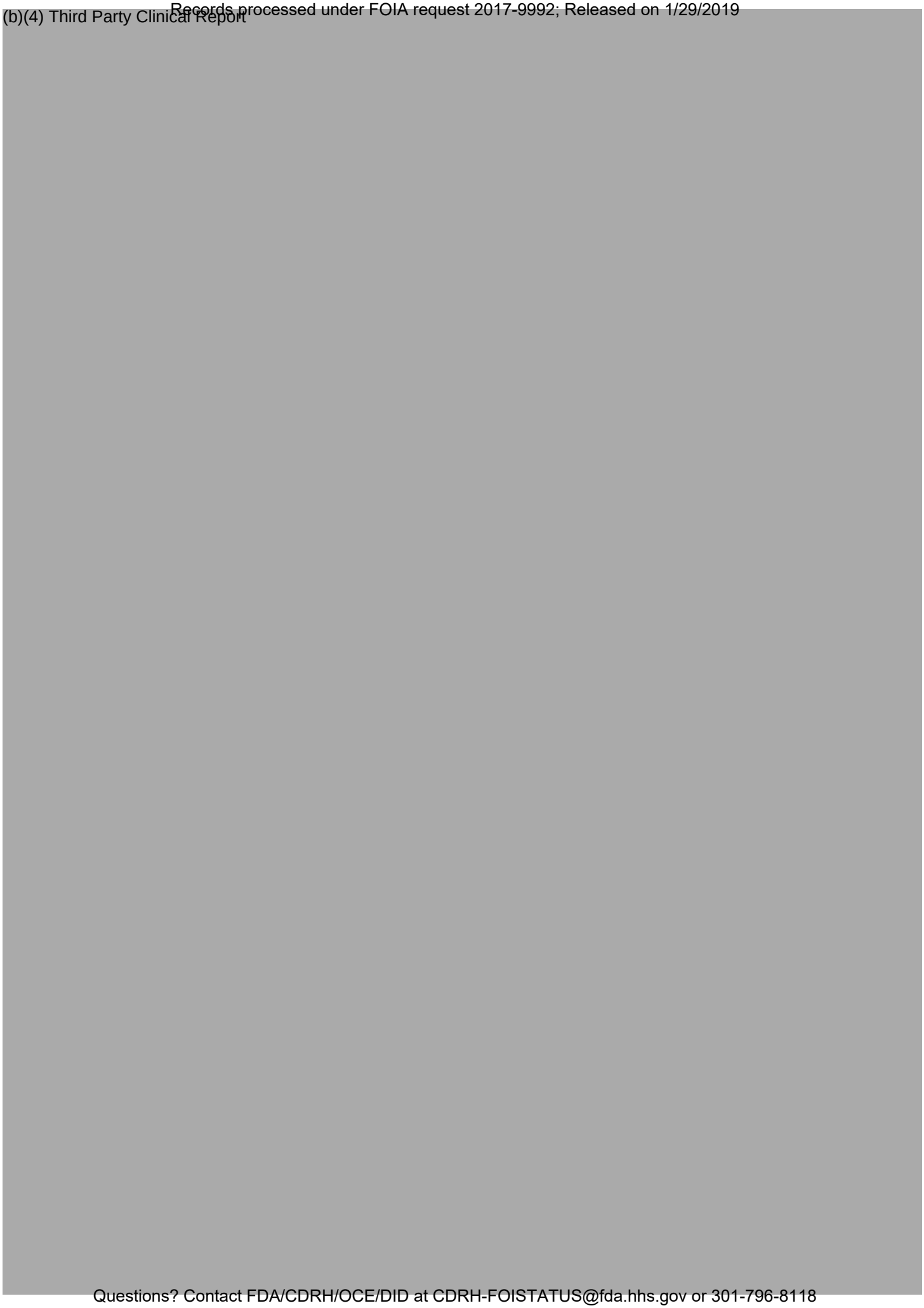
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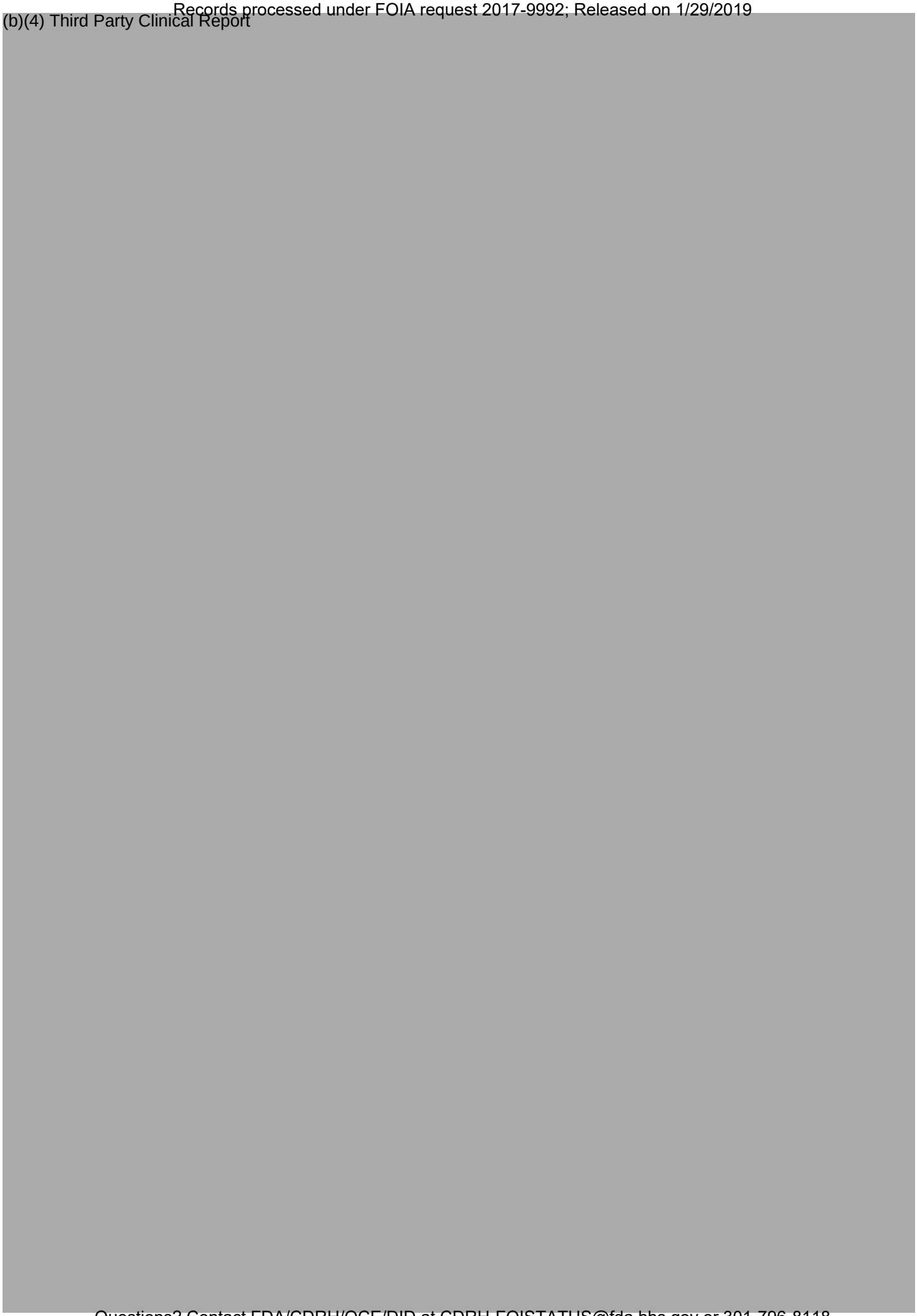
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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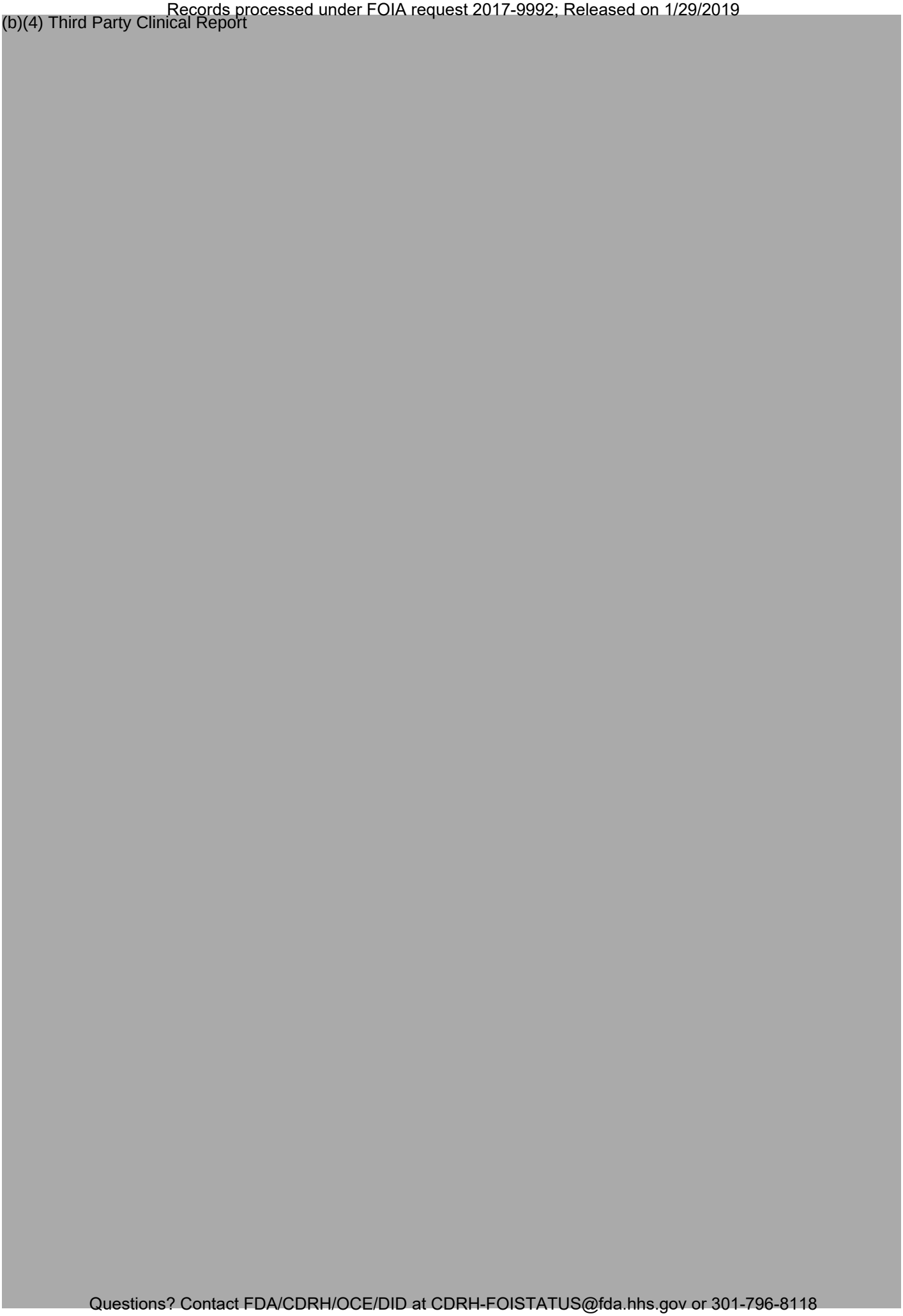
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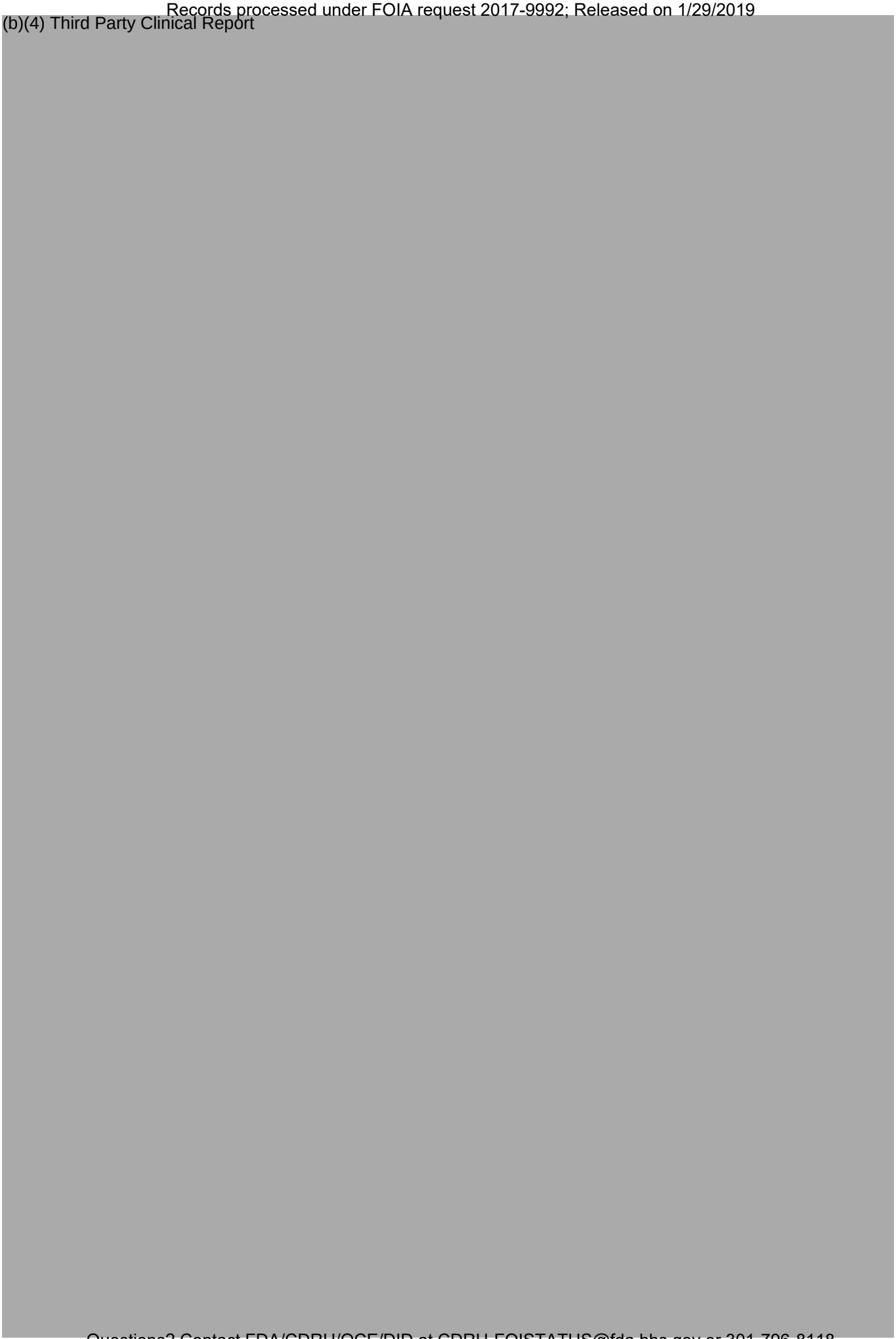
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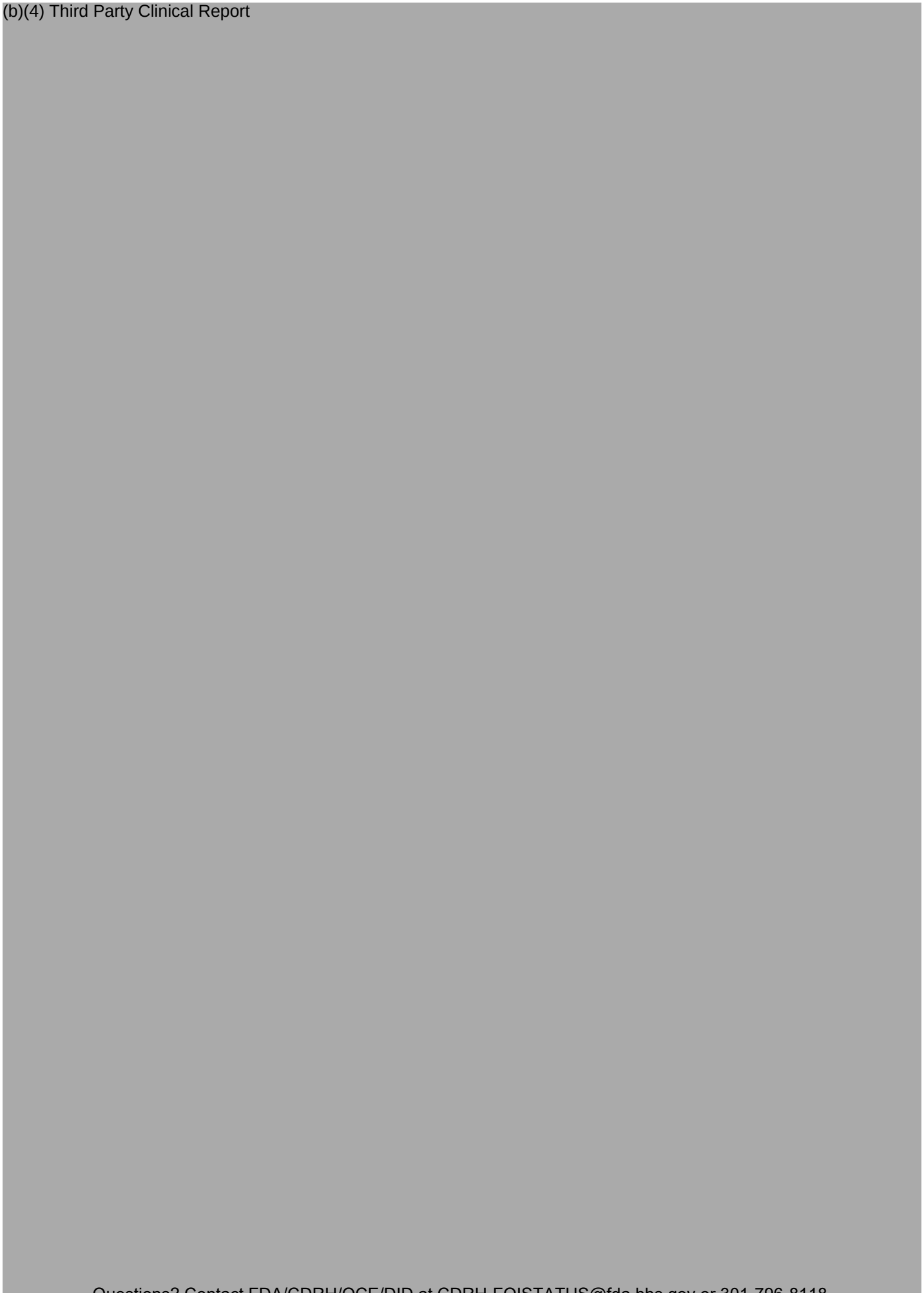
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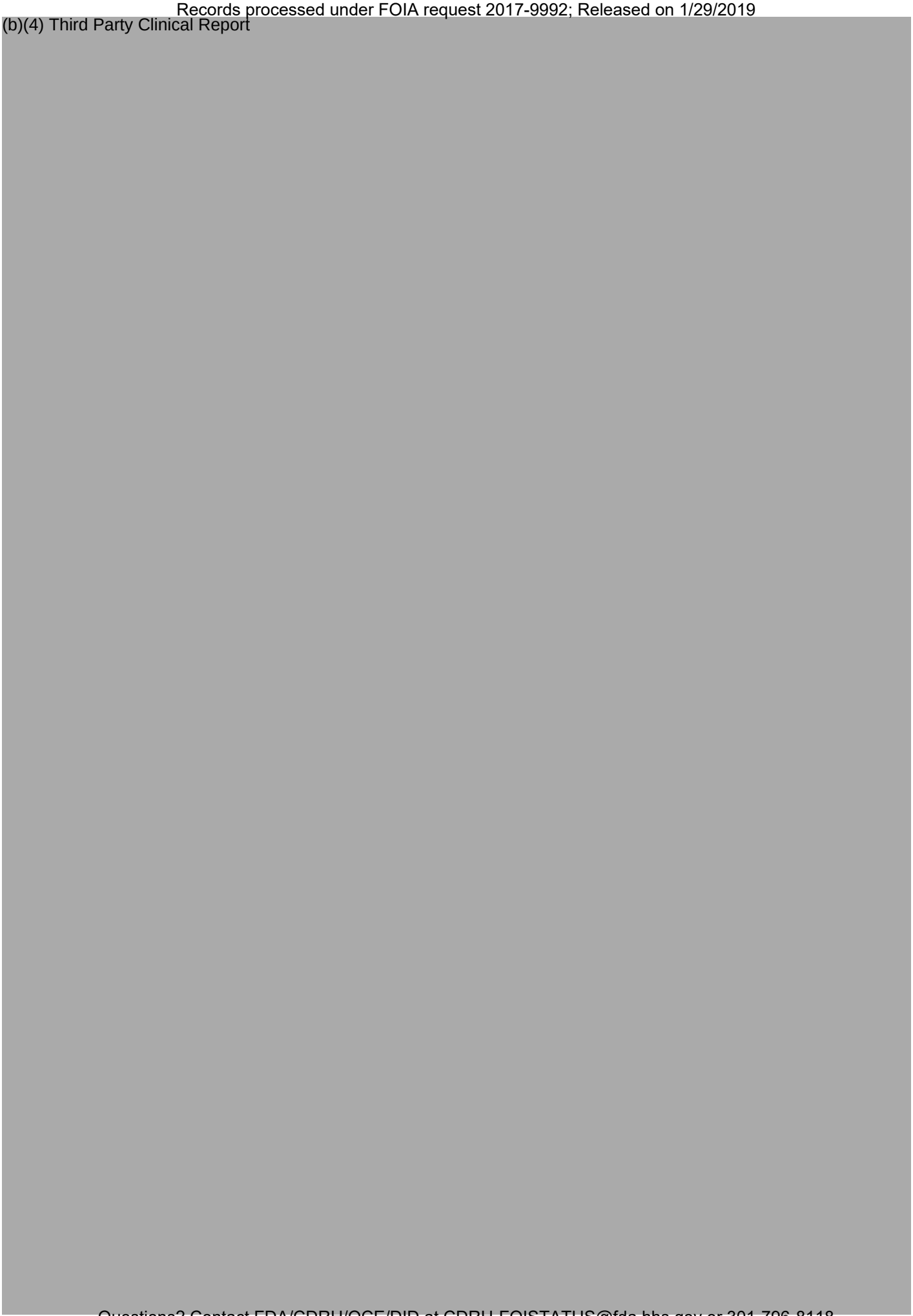
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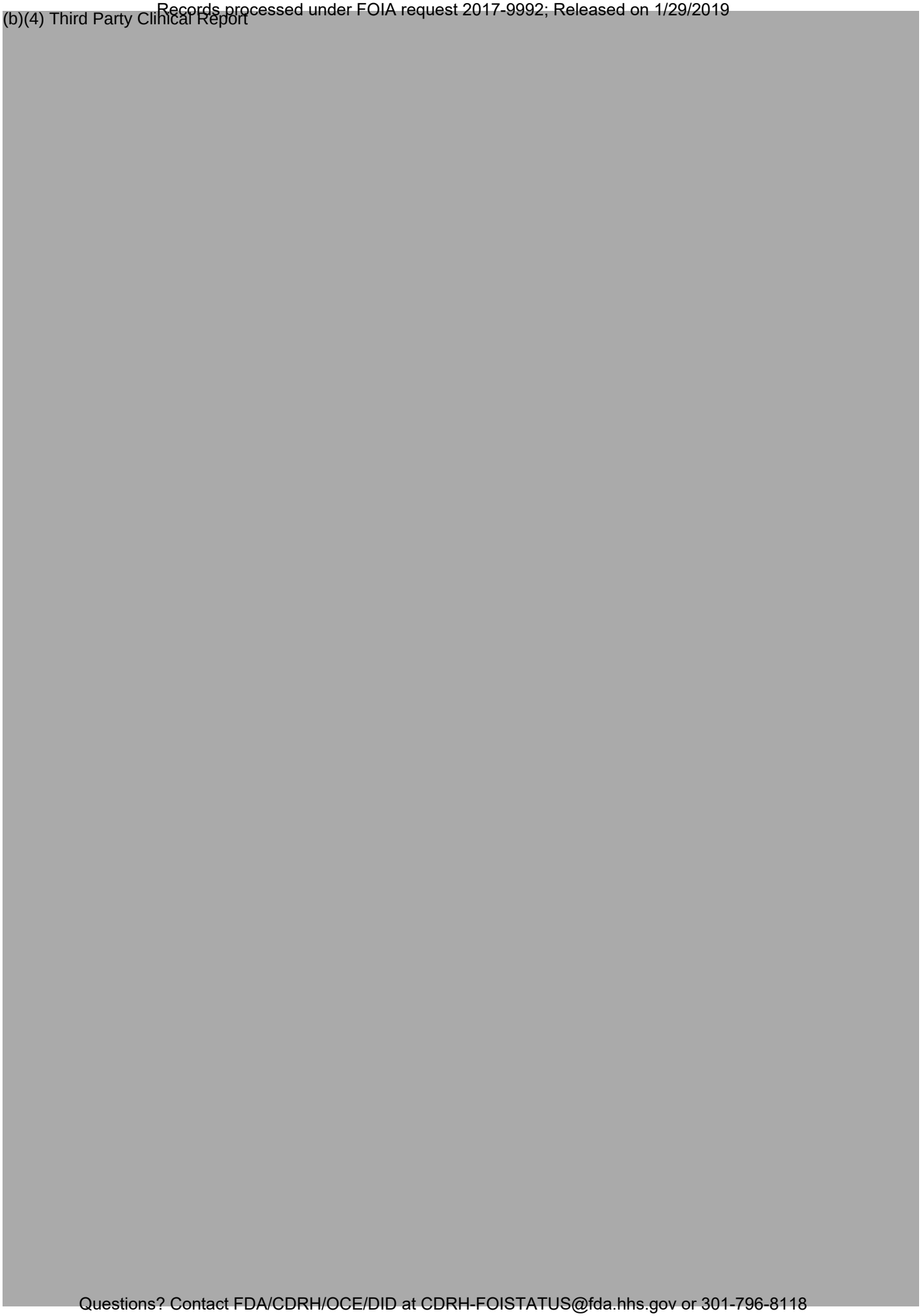
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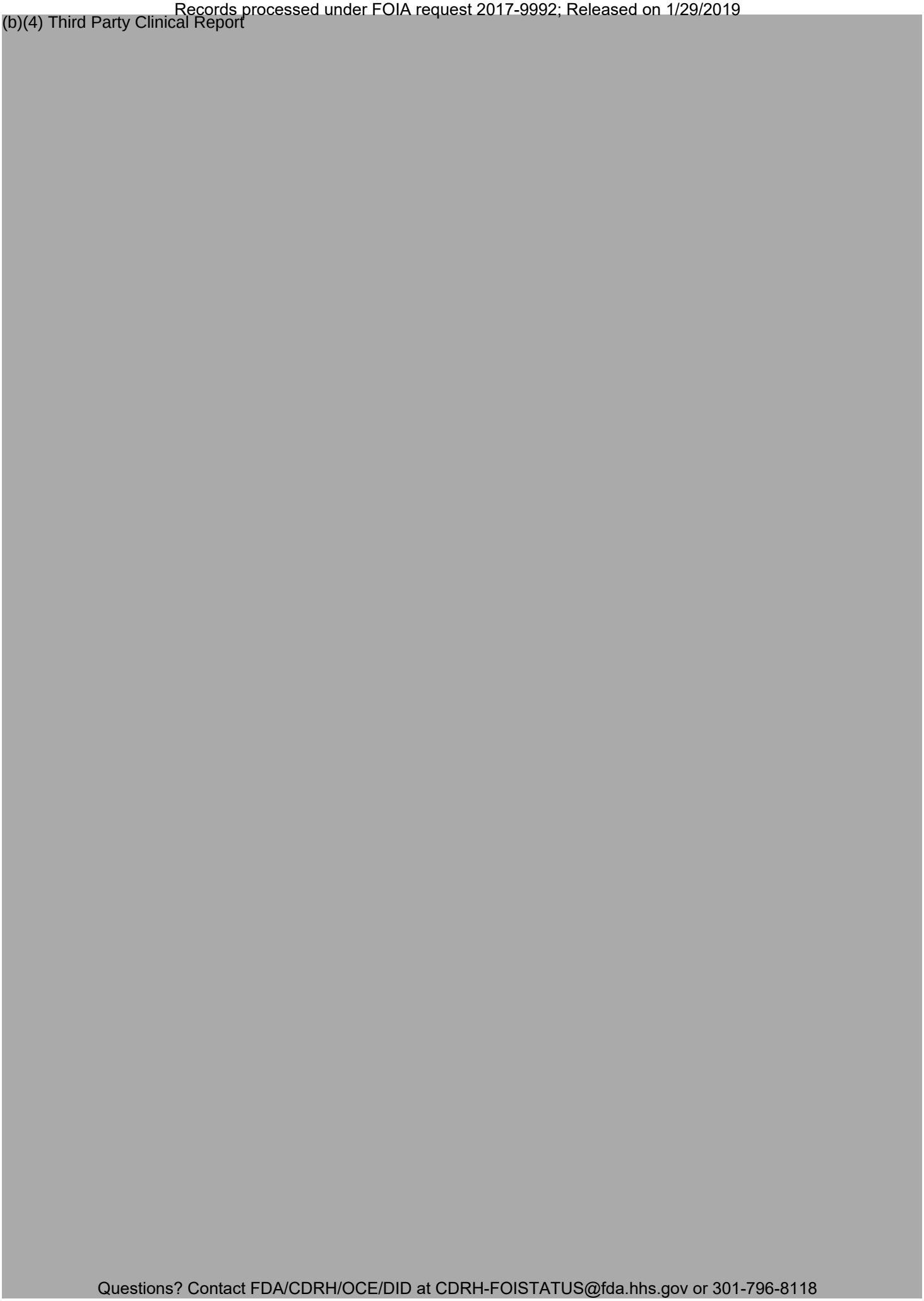
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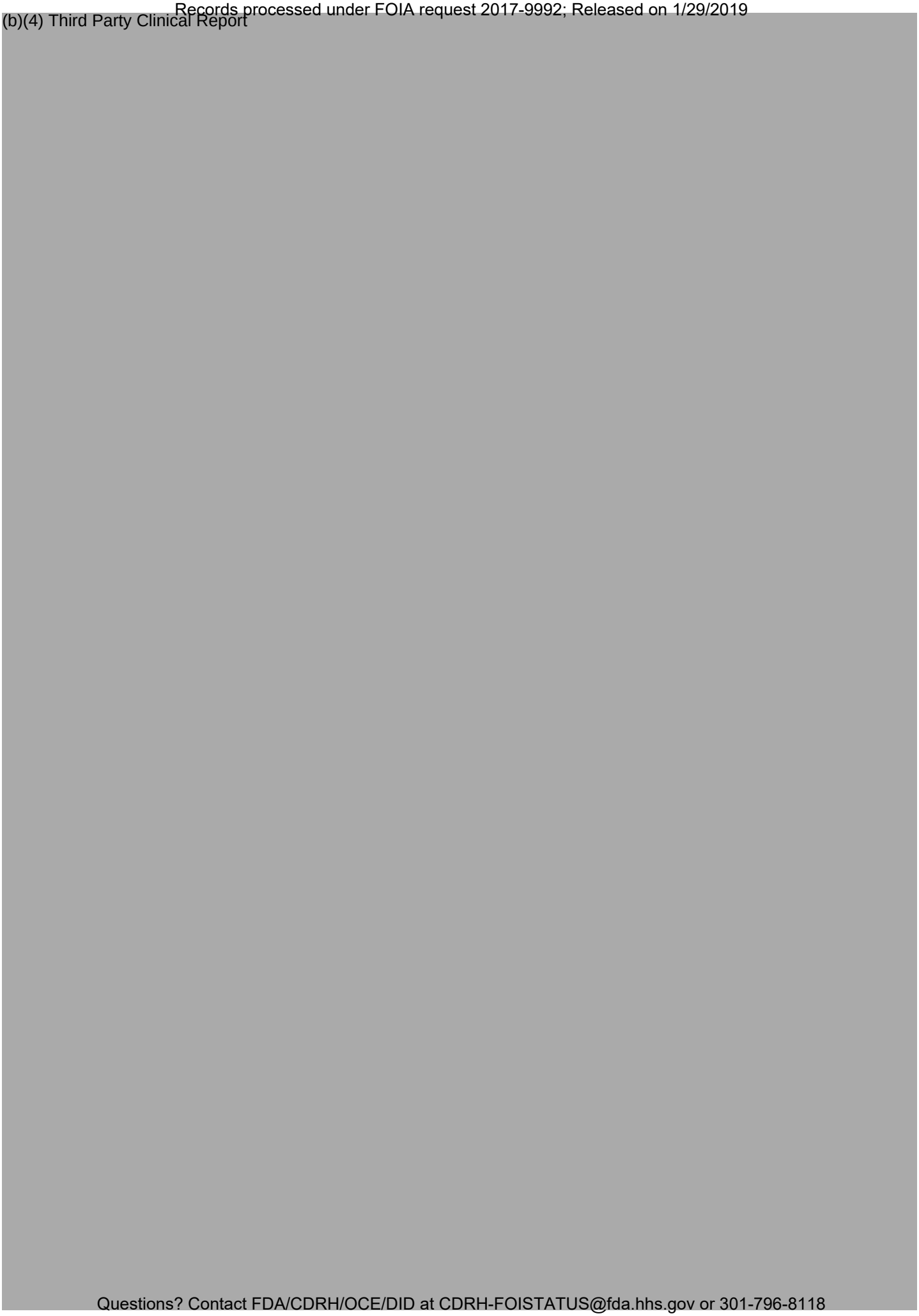


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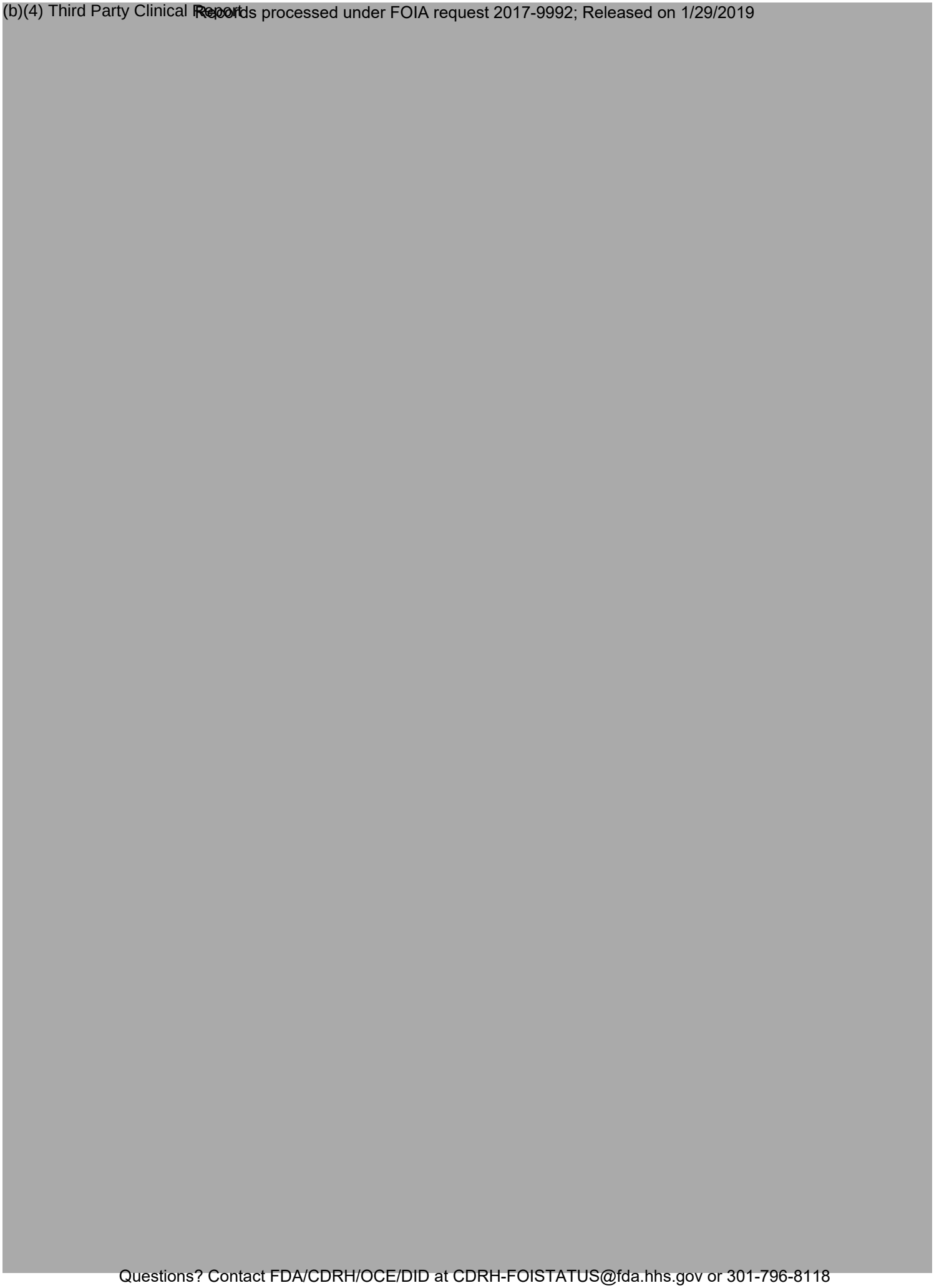


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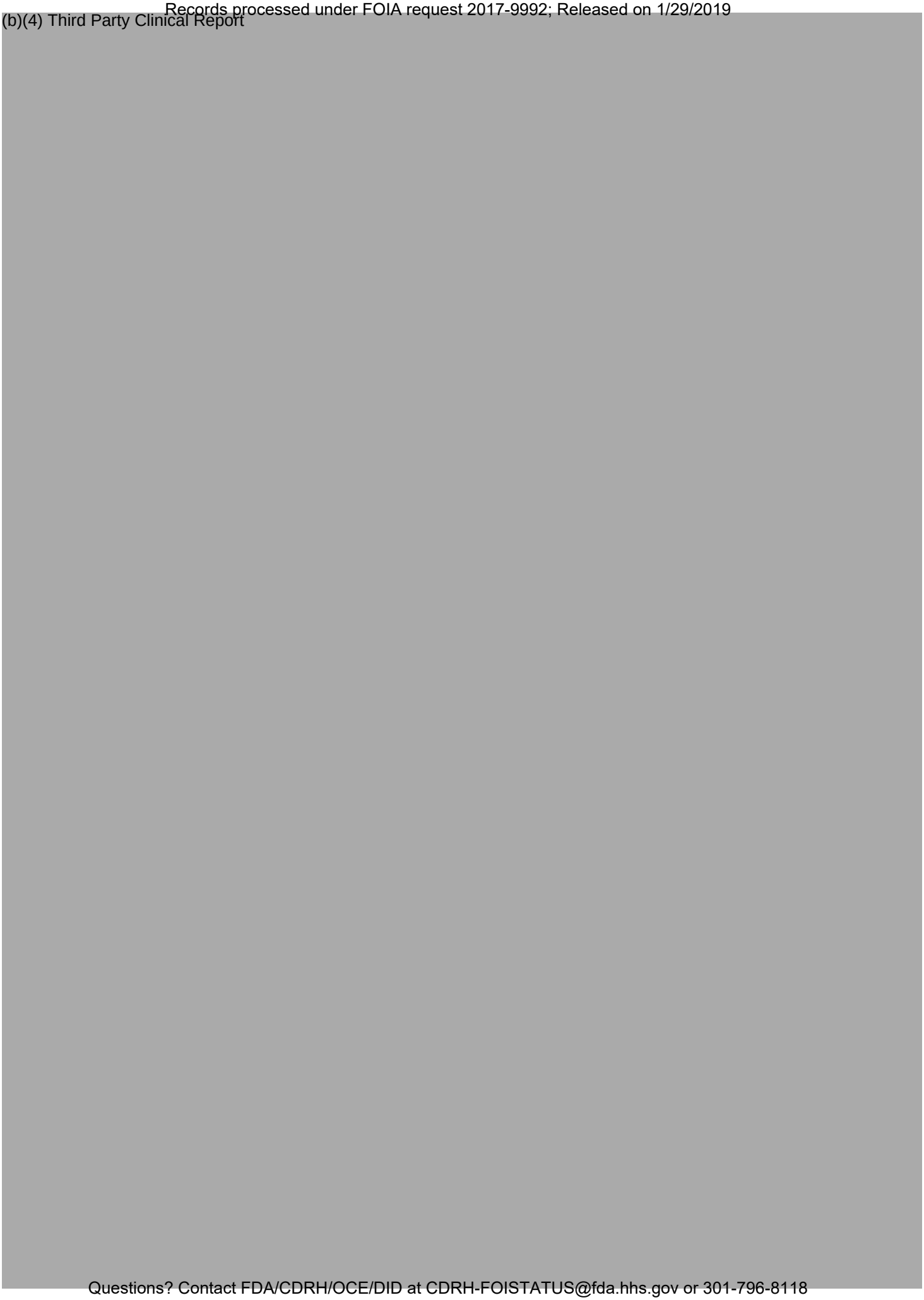
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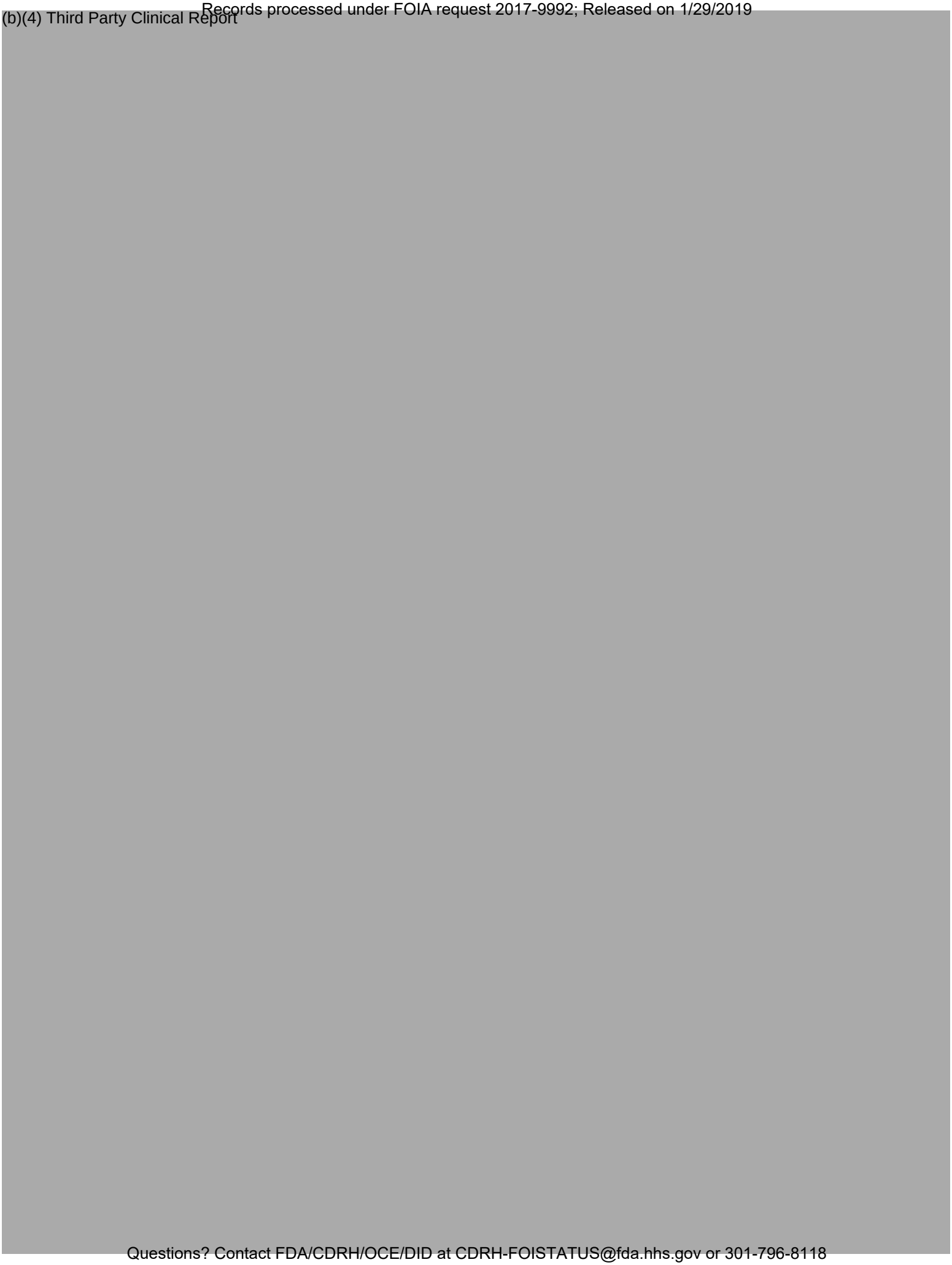
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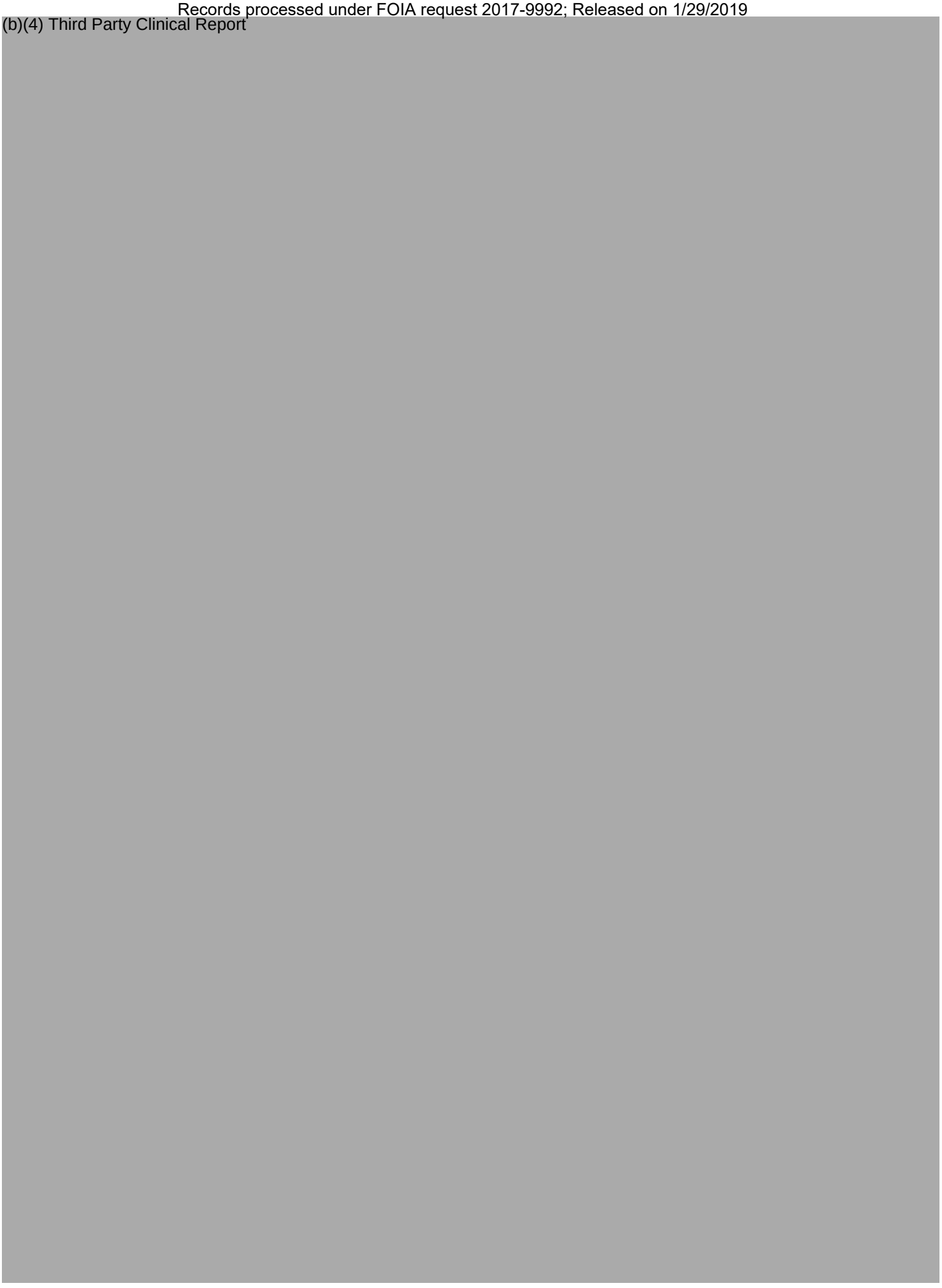
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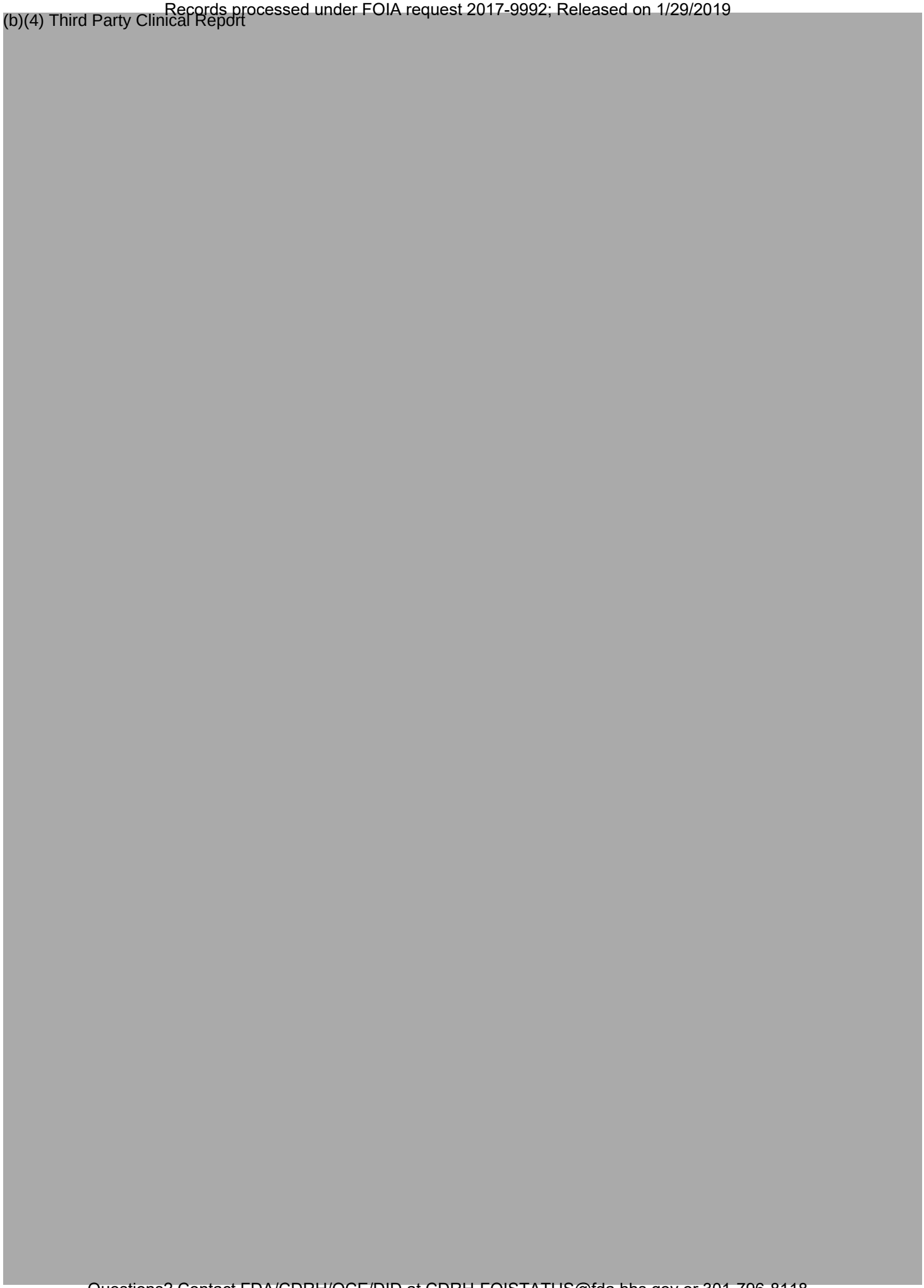
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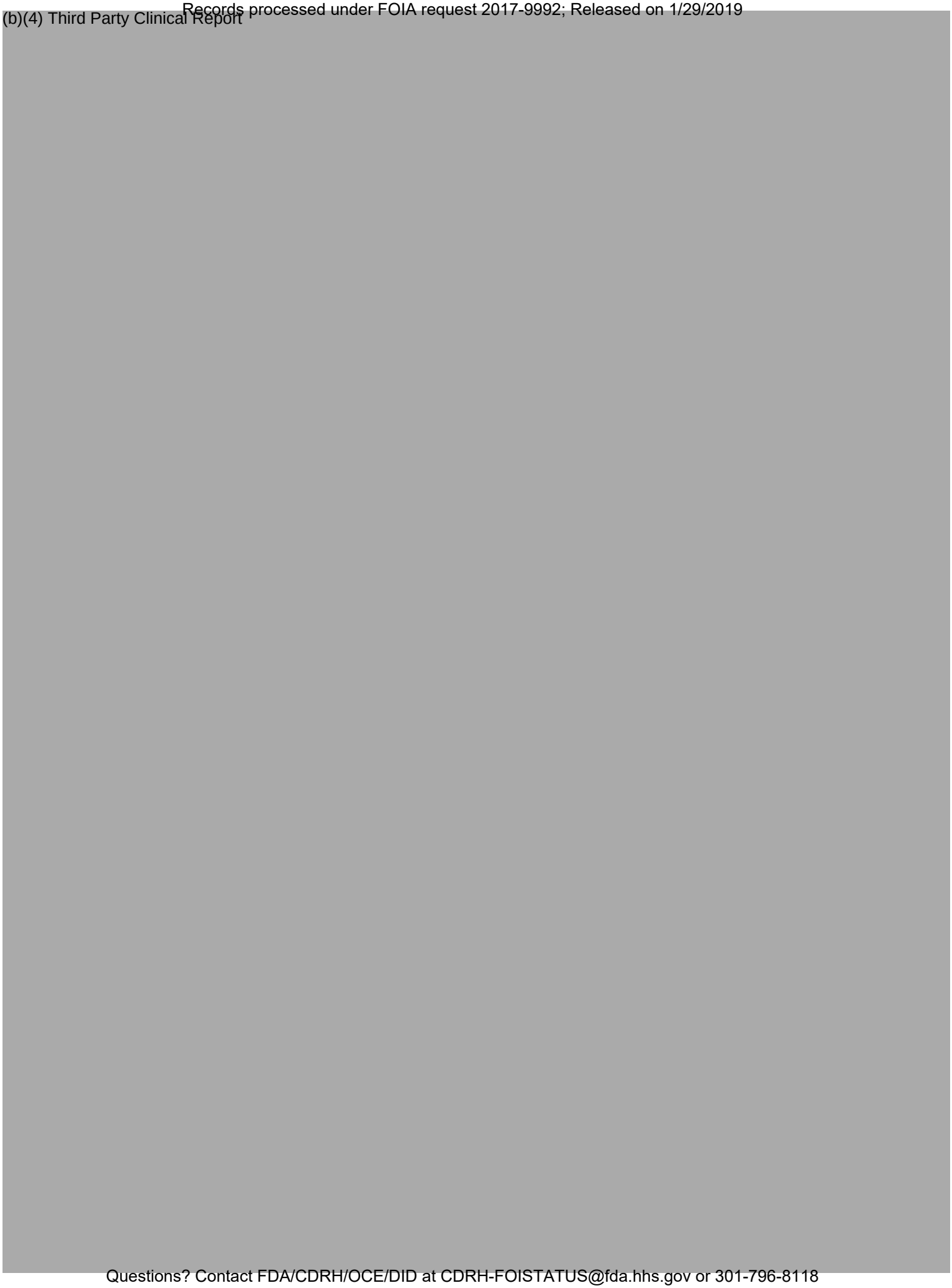
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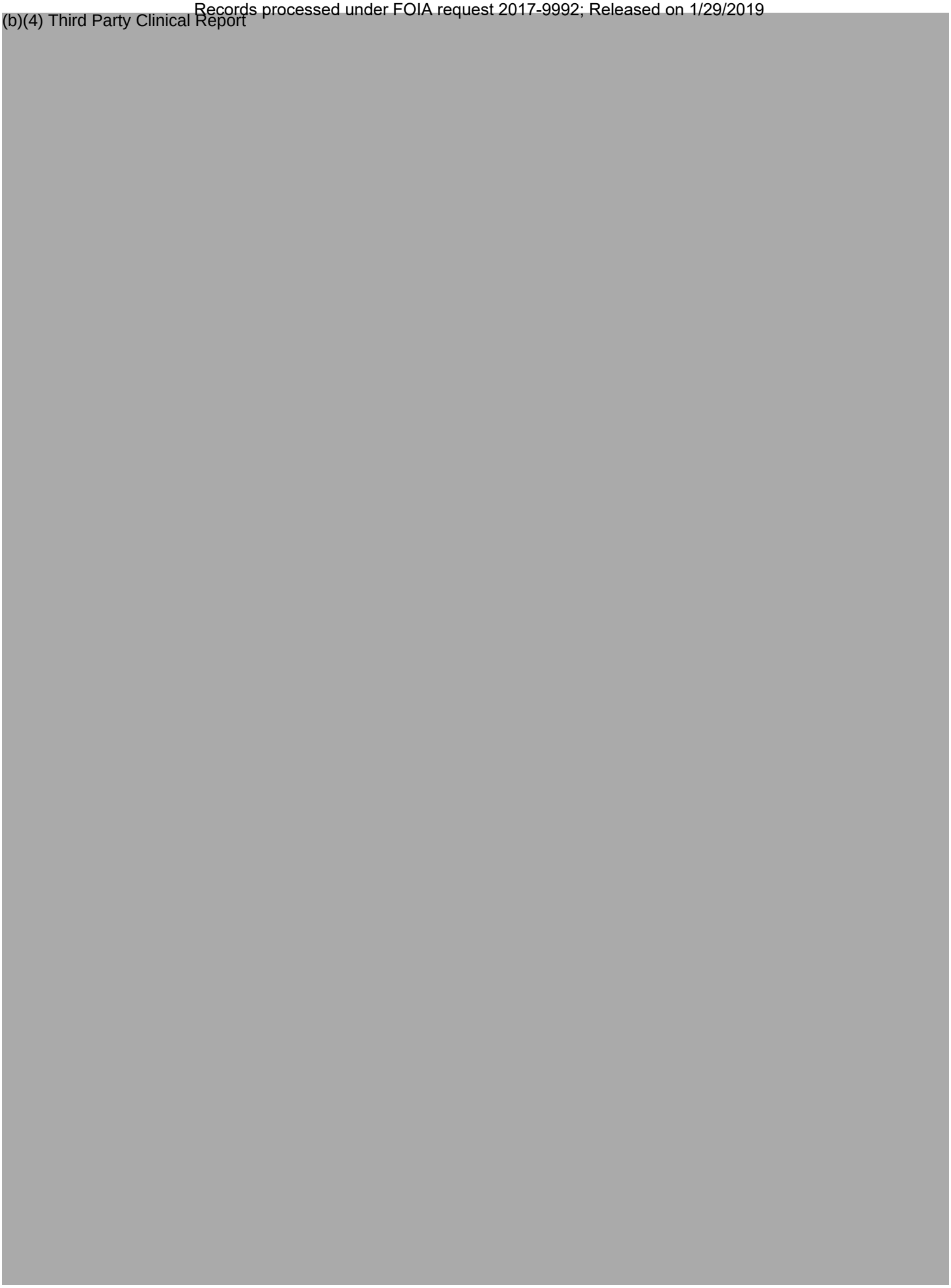
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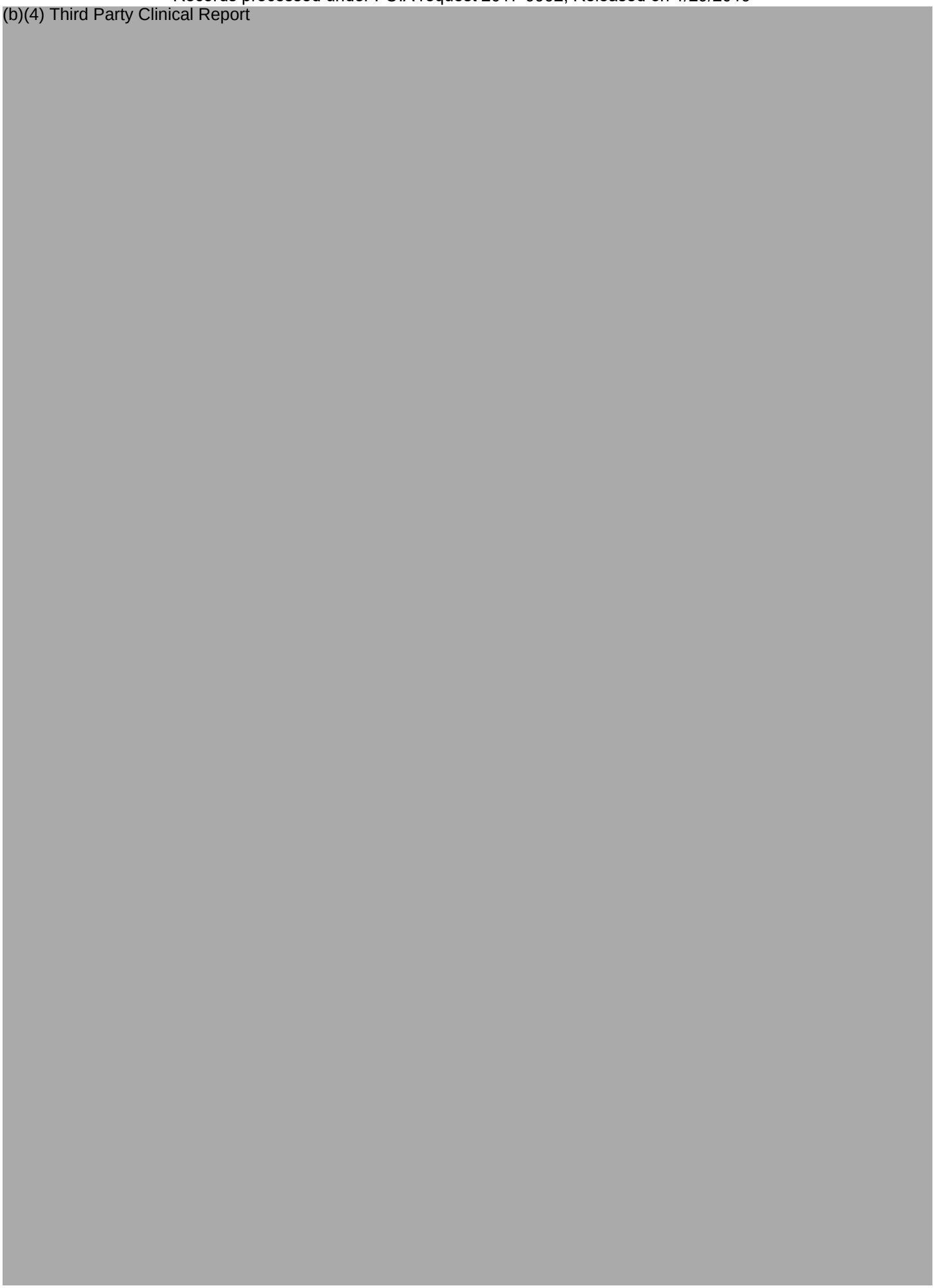
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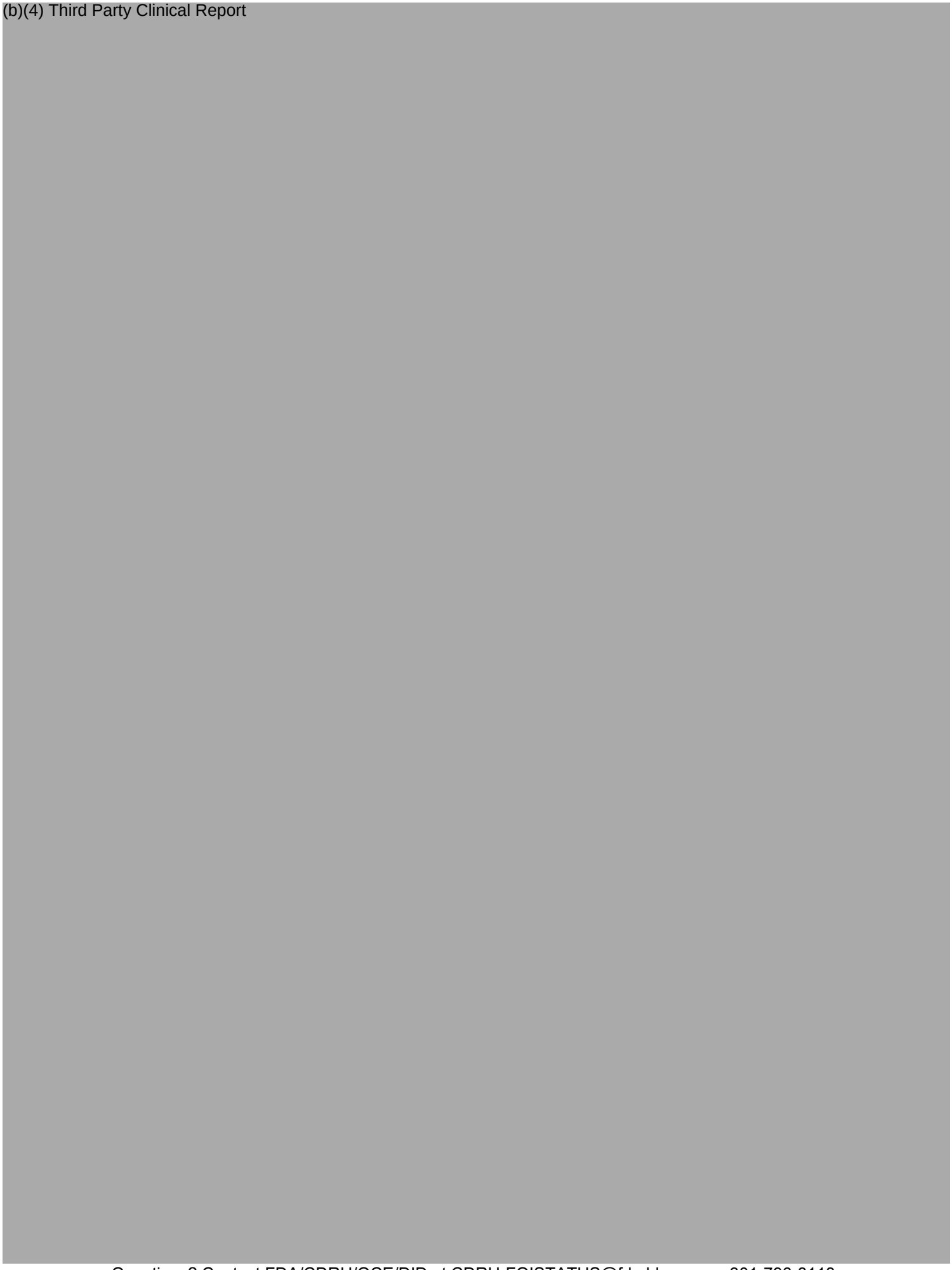
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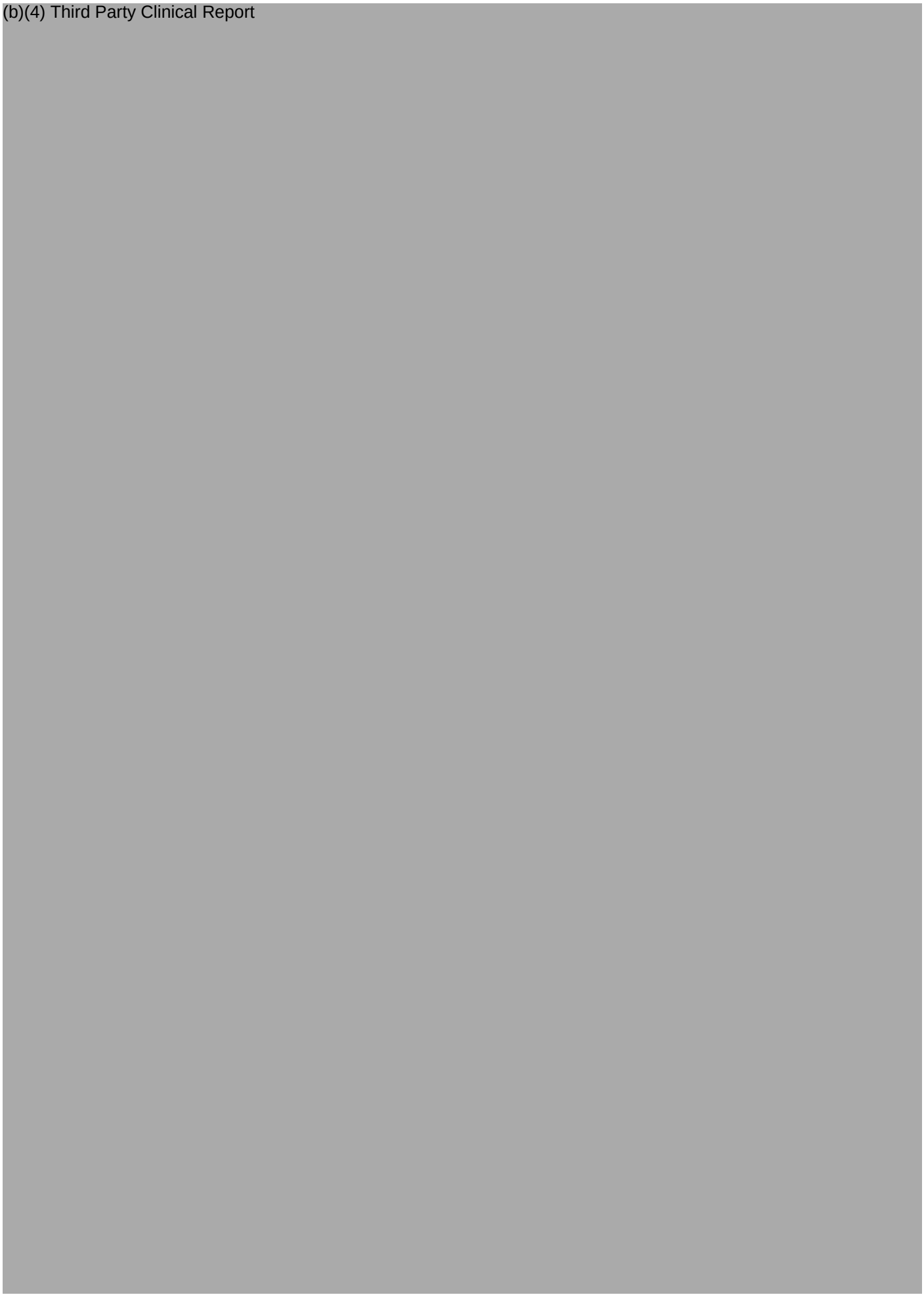
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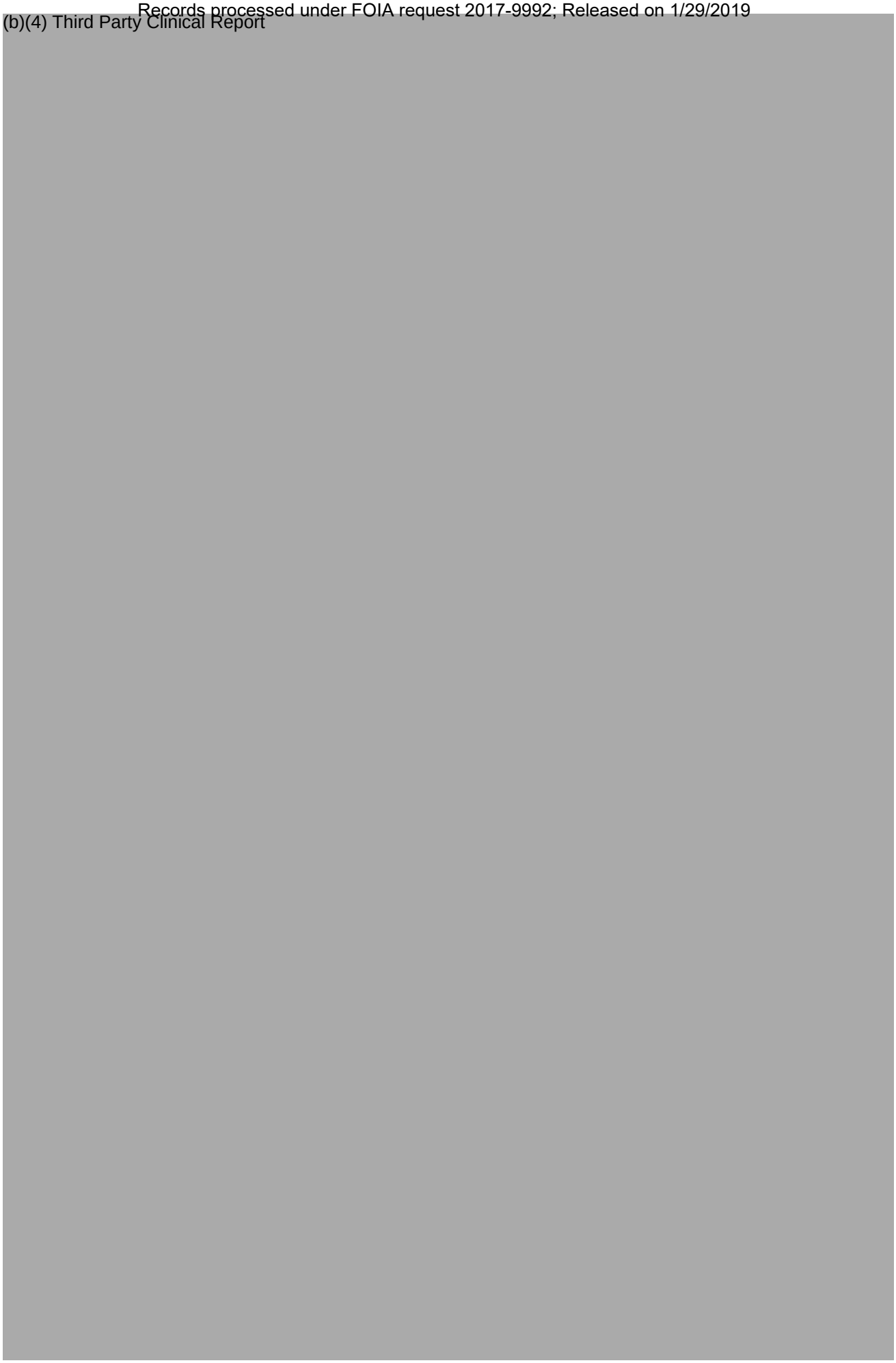
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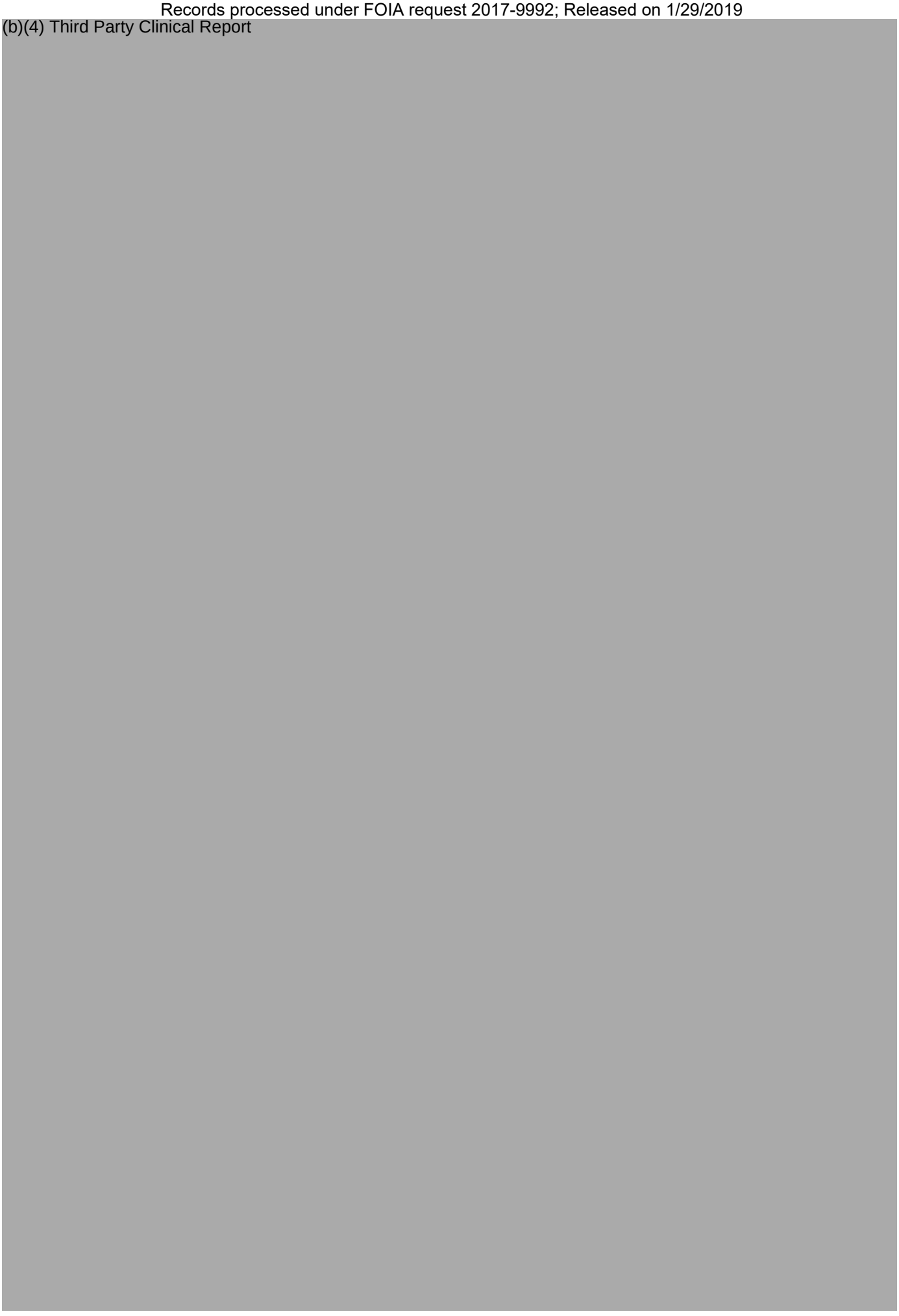
Appendix A: Instructions for Use

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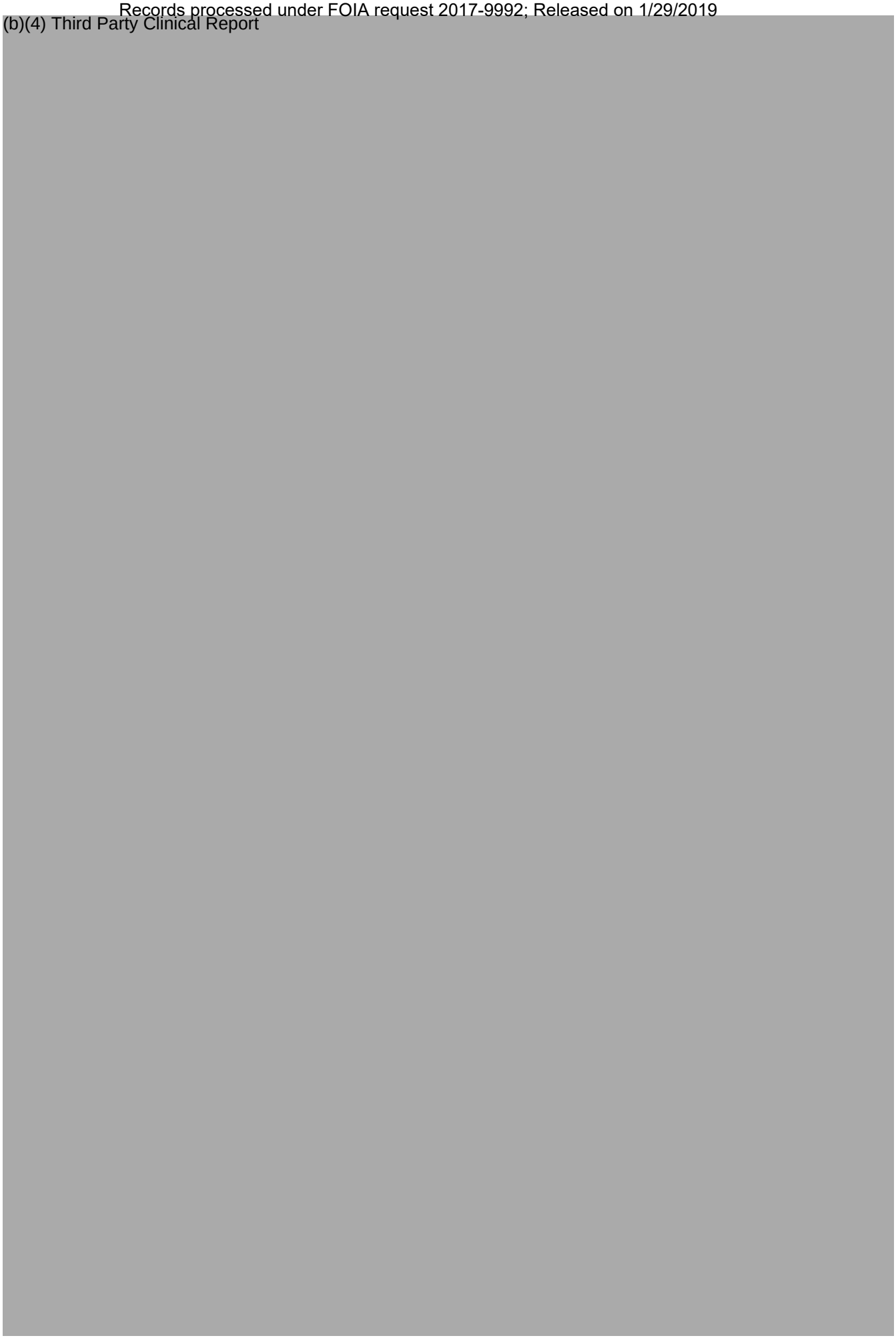


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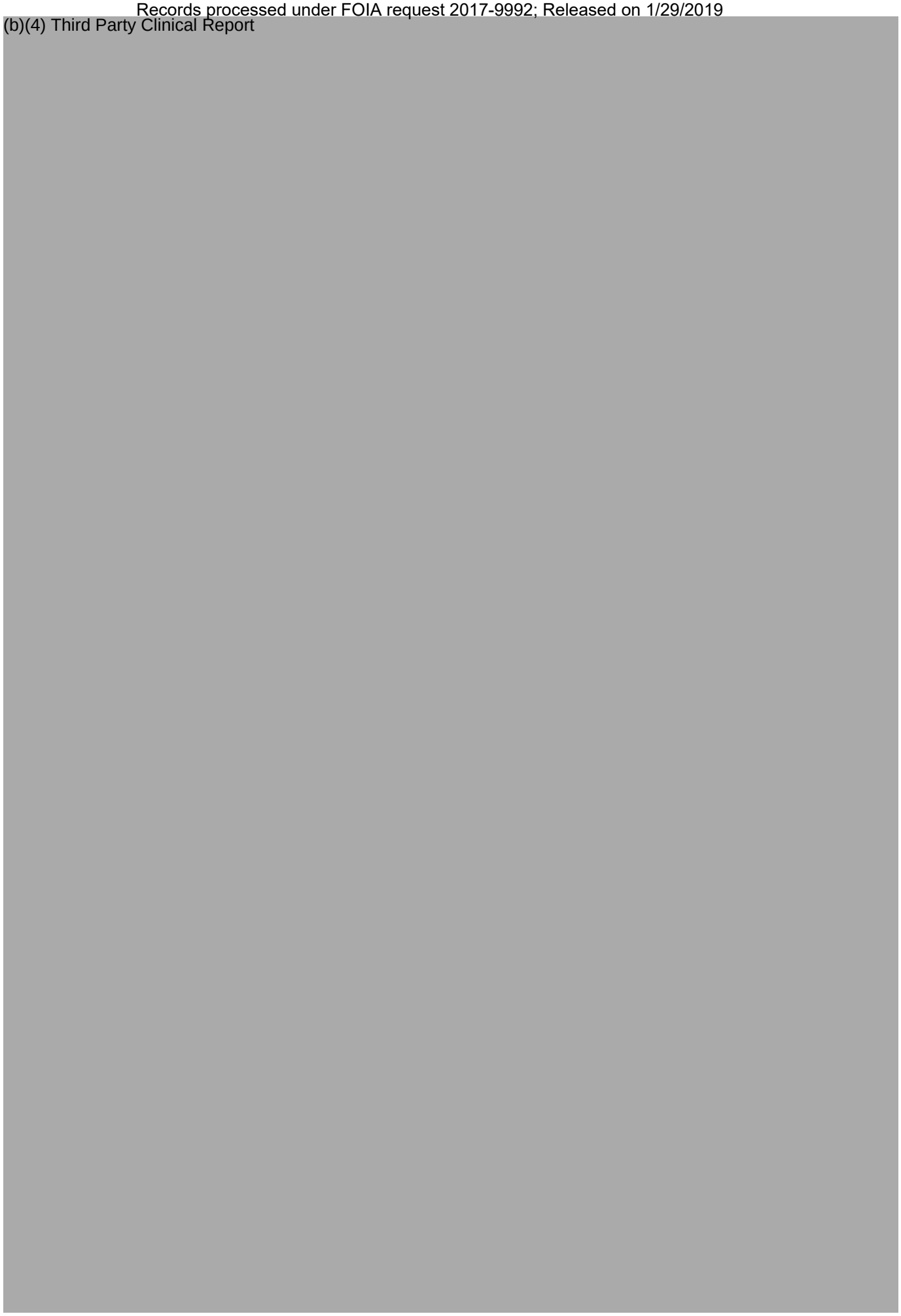
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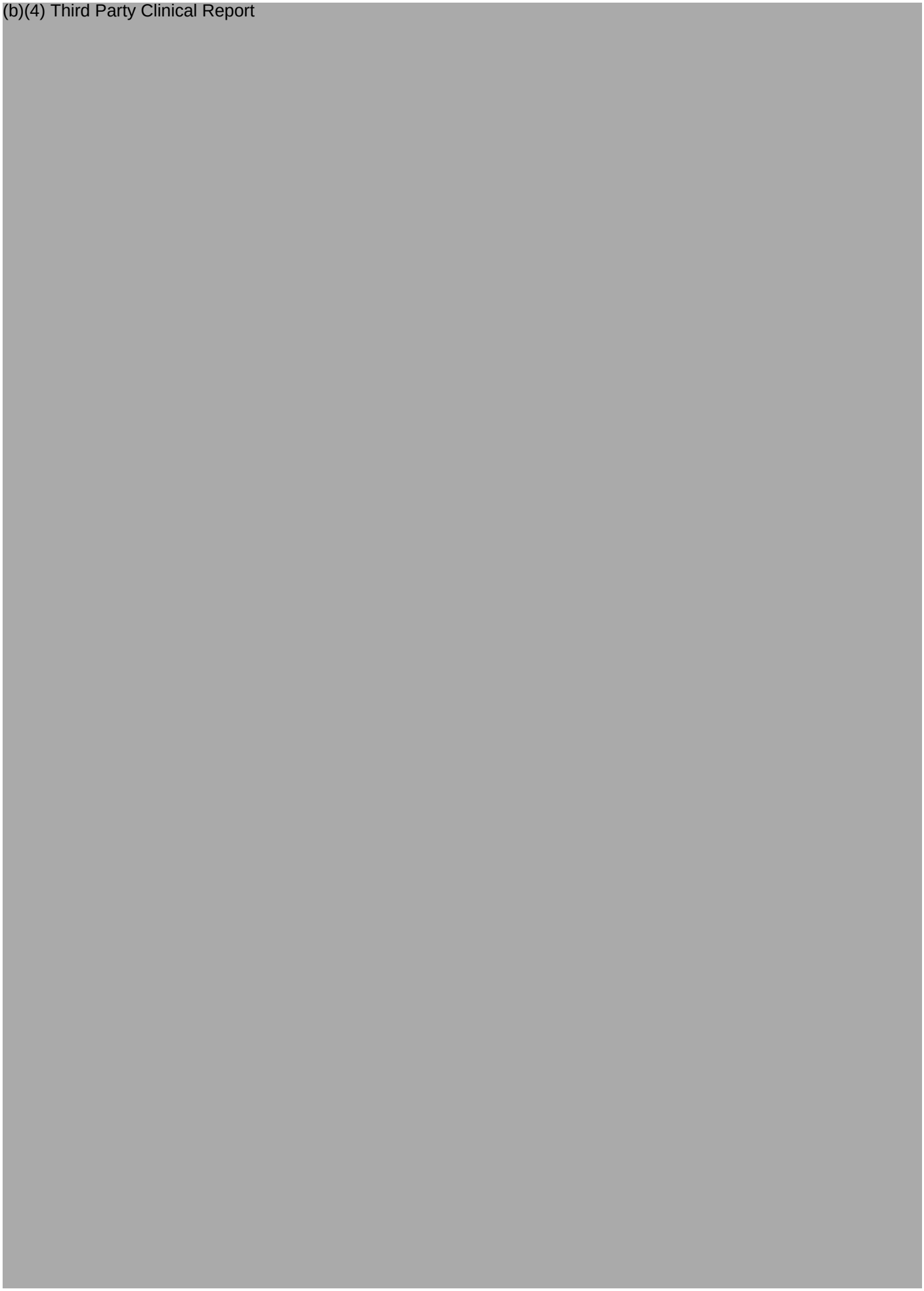
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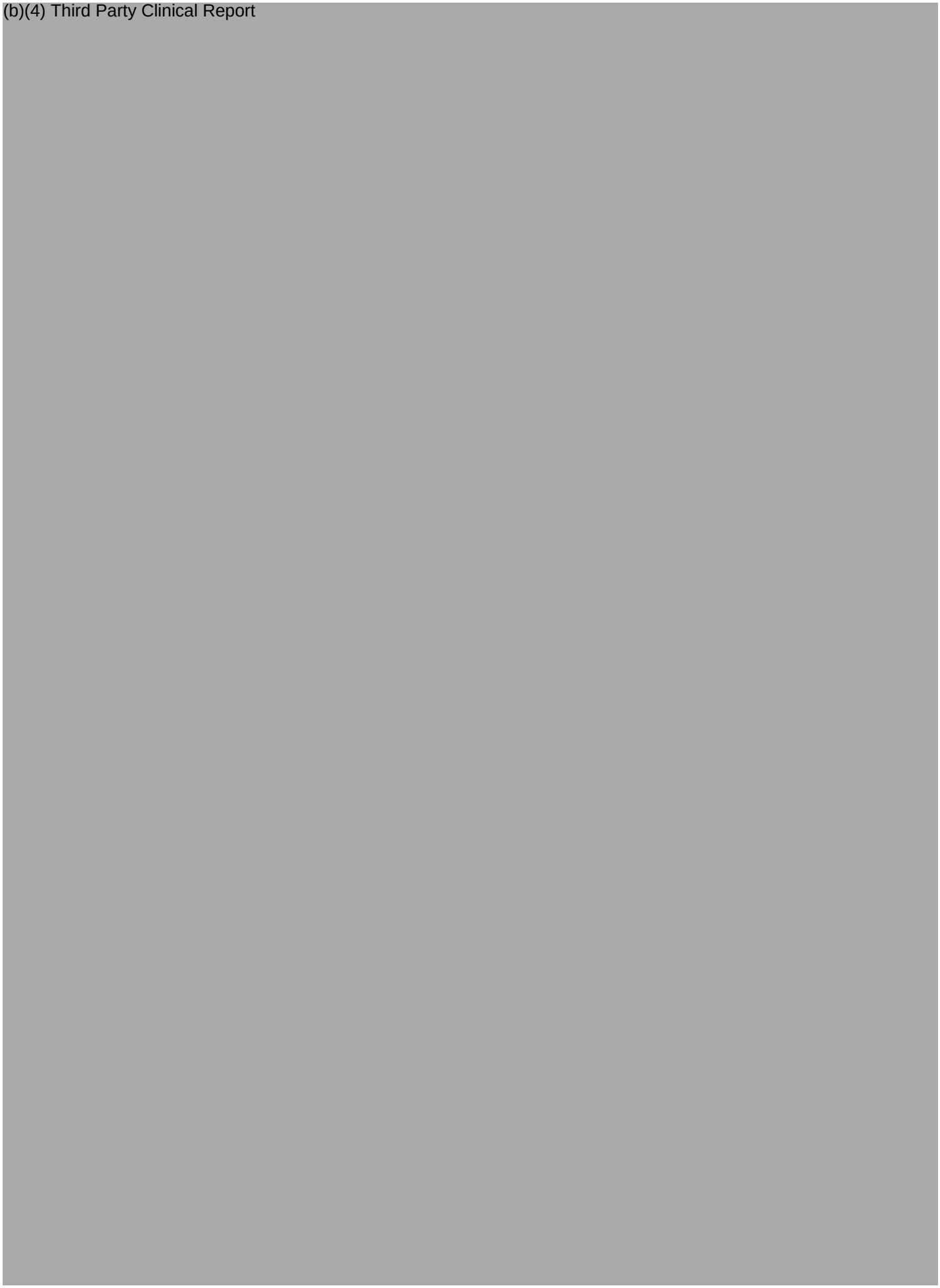
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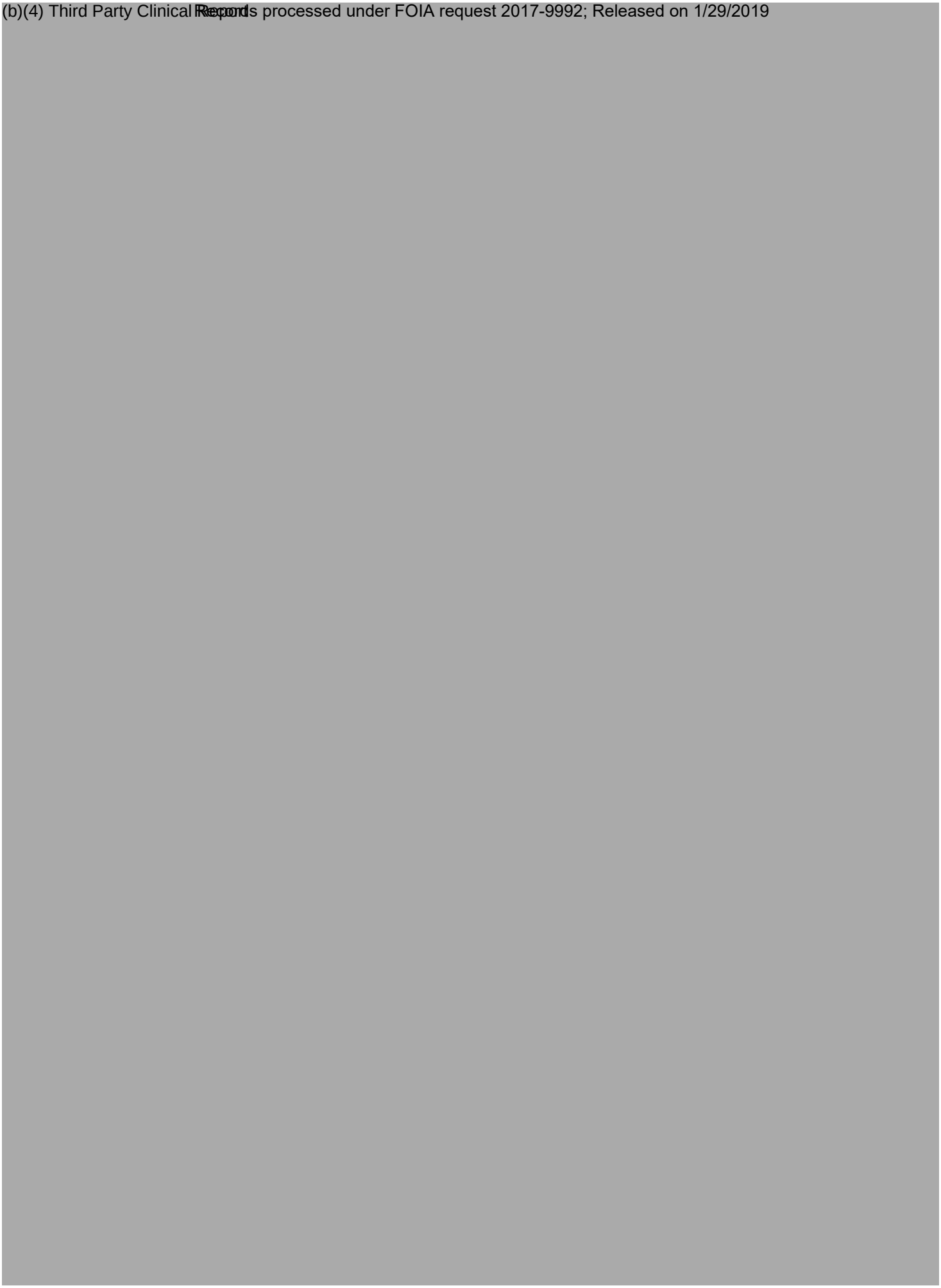
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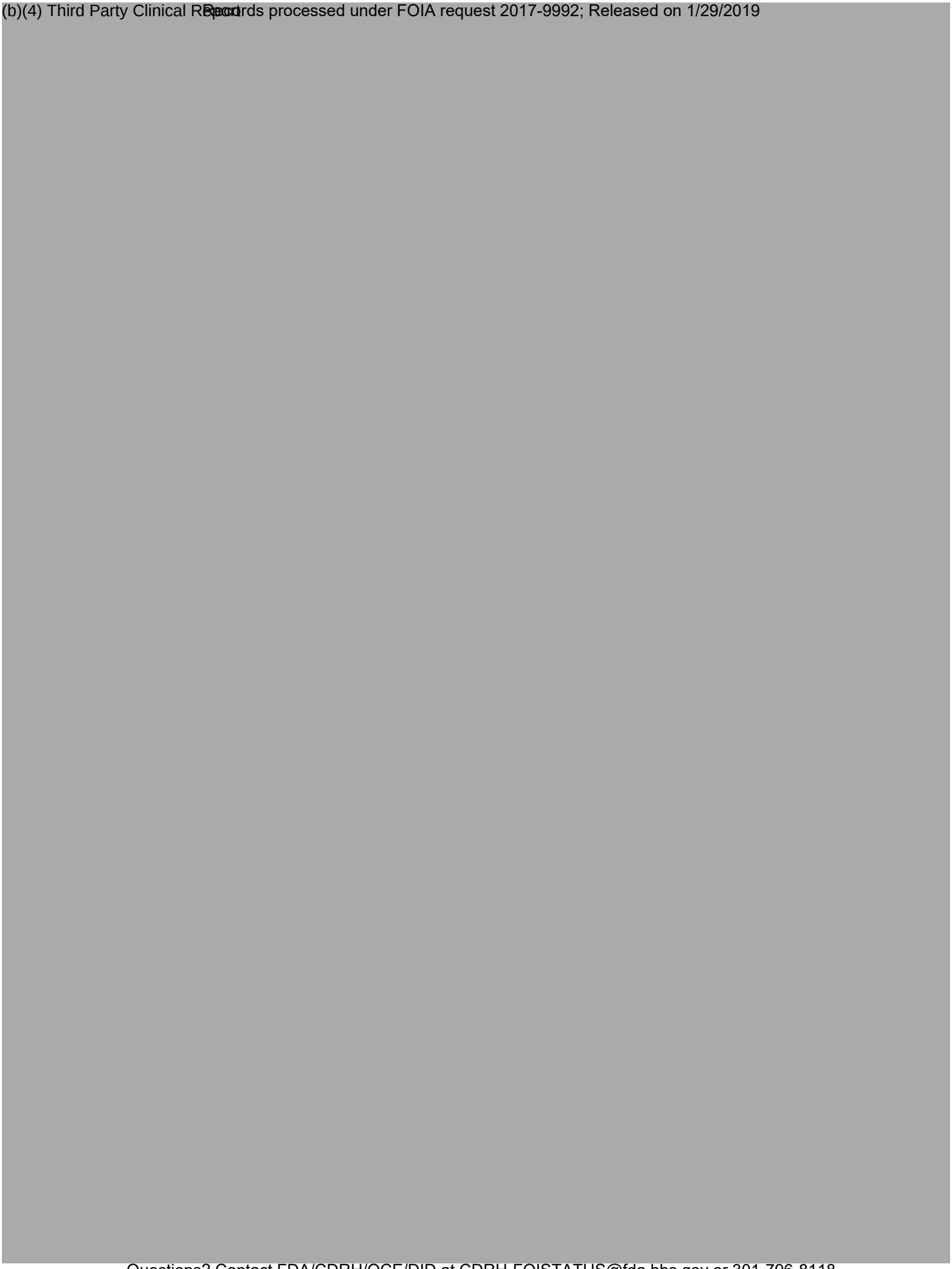
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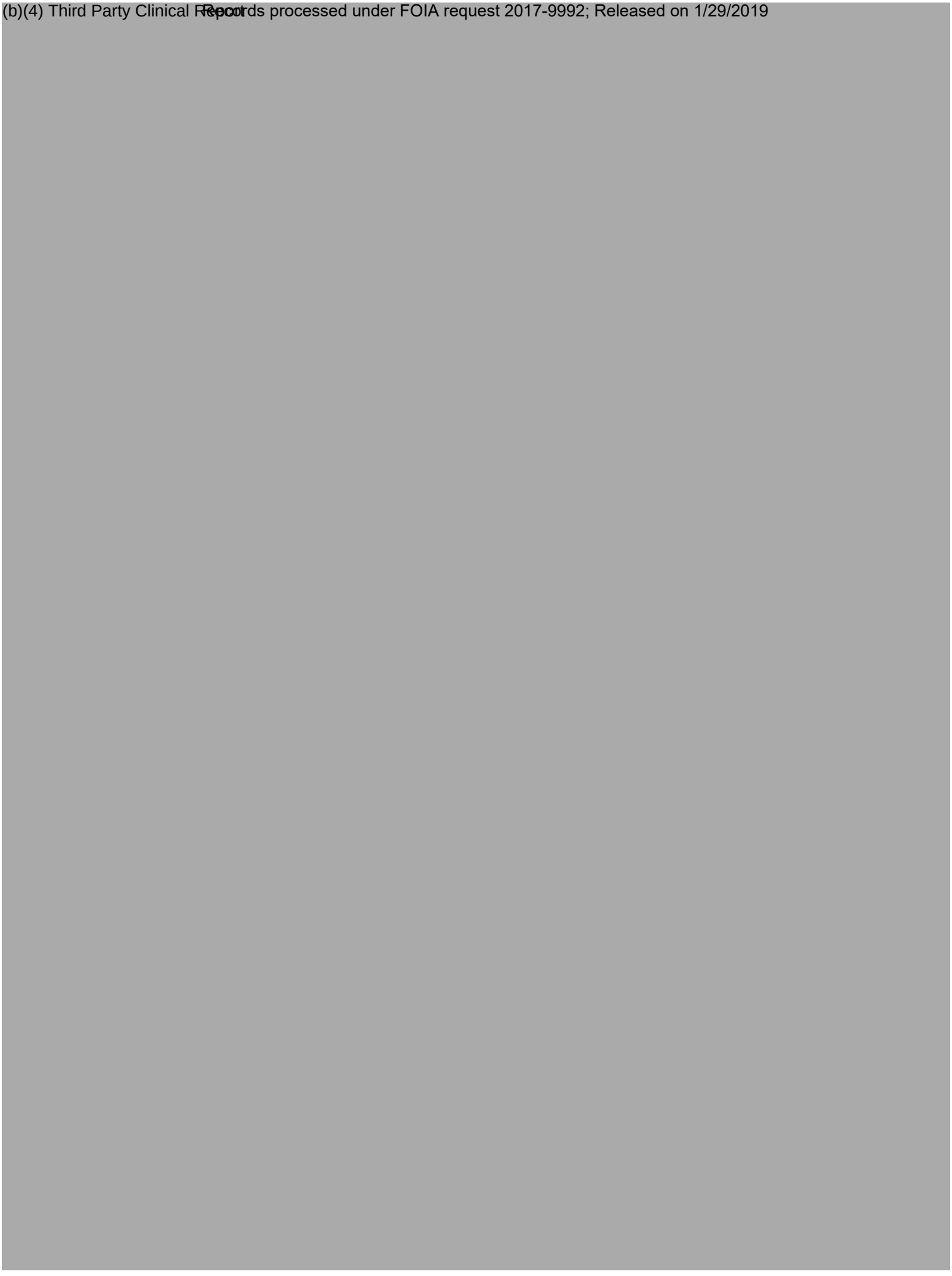
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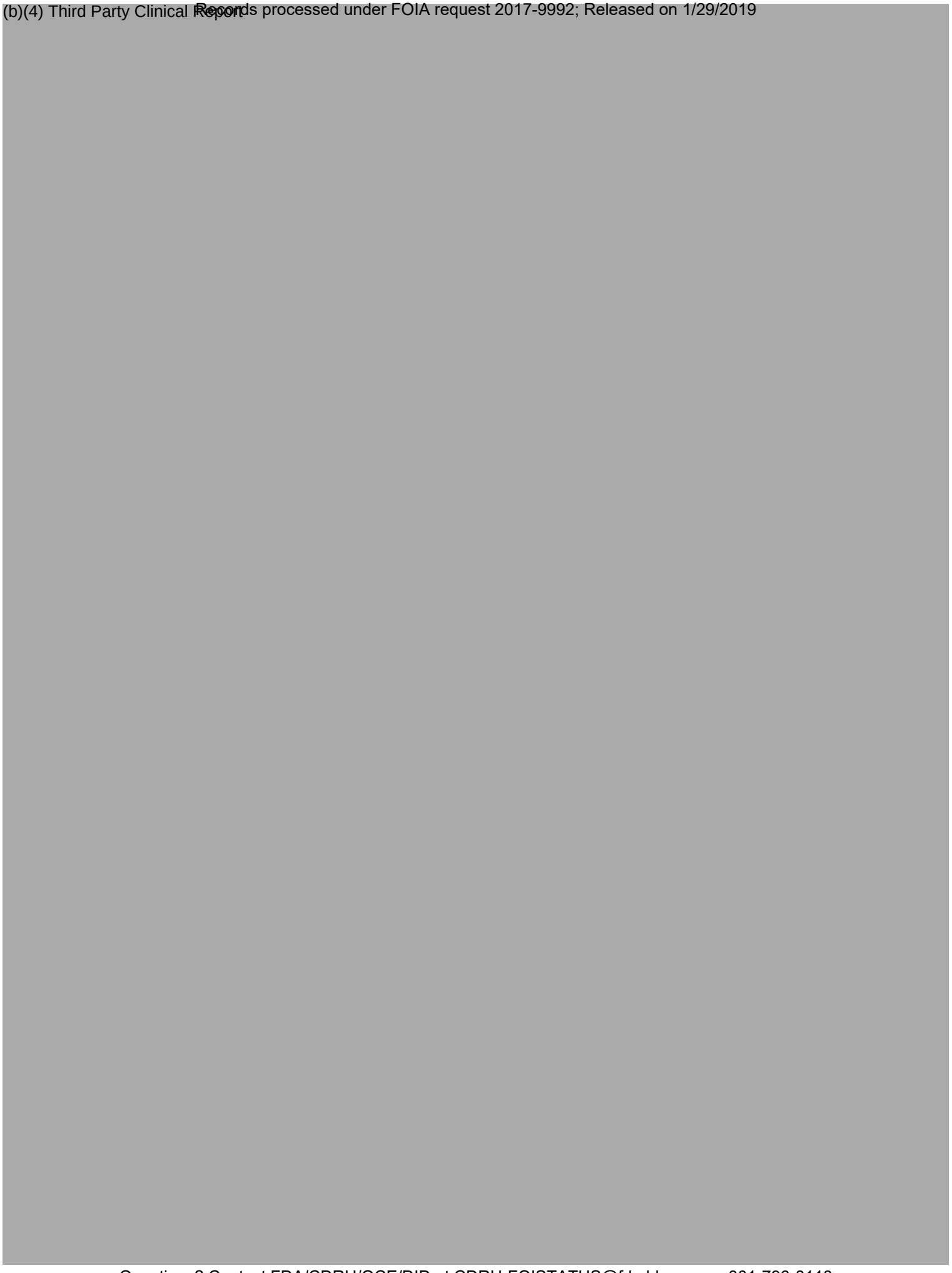
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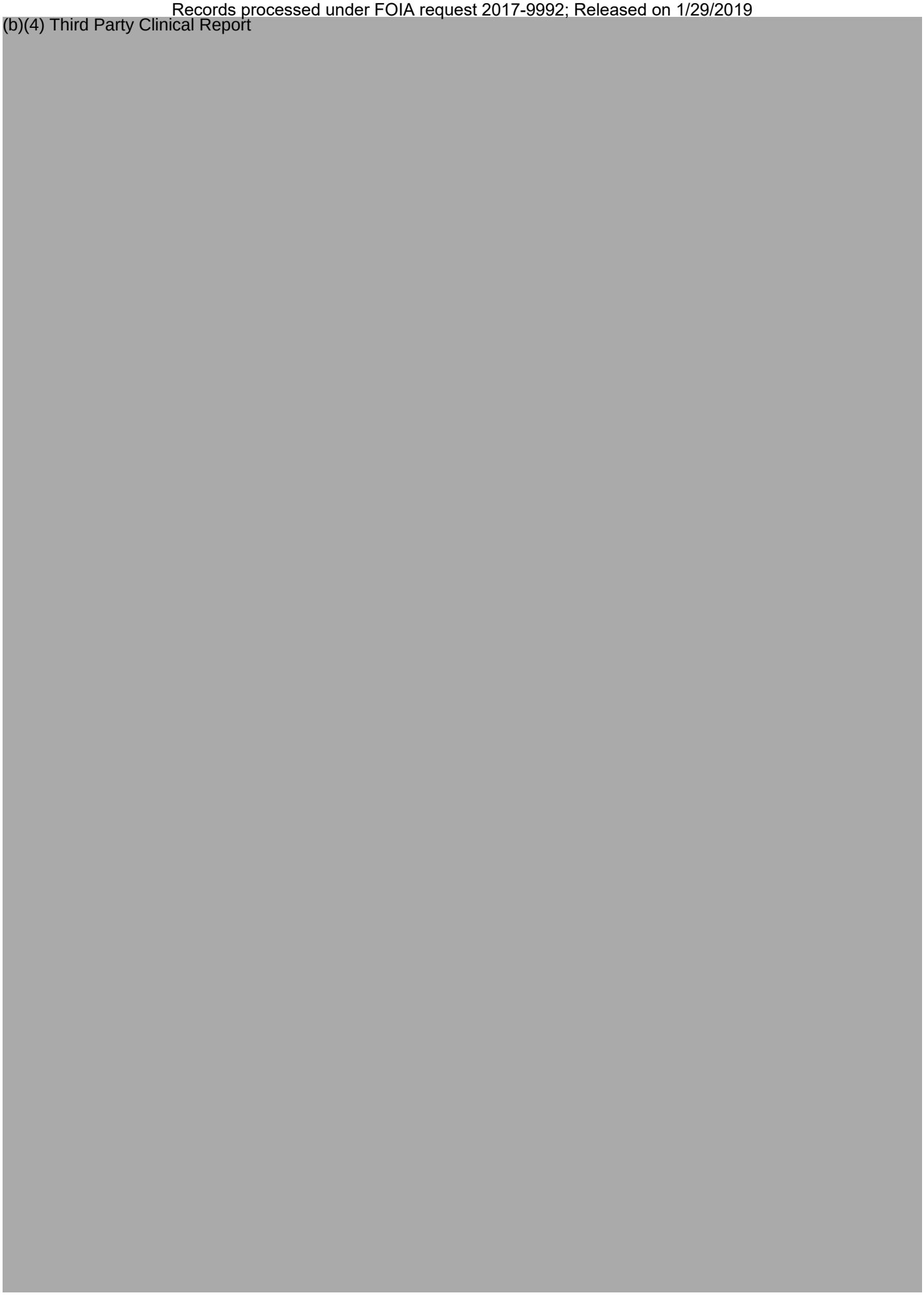
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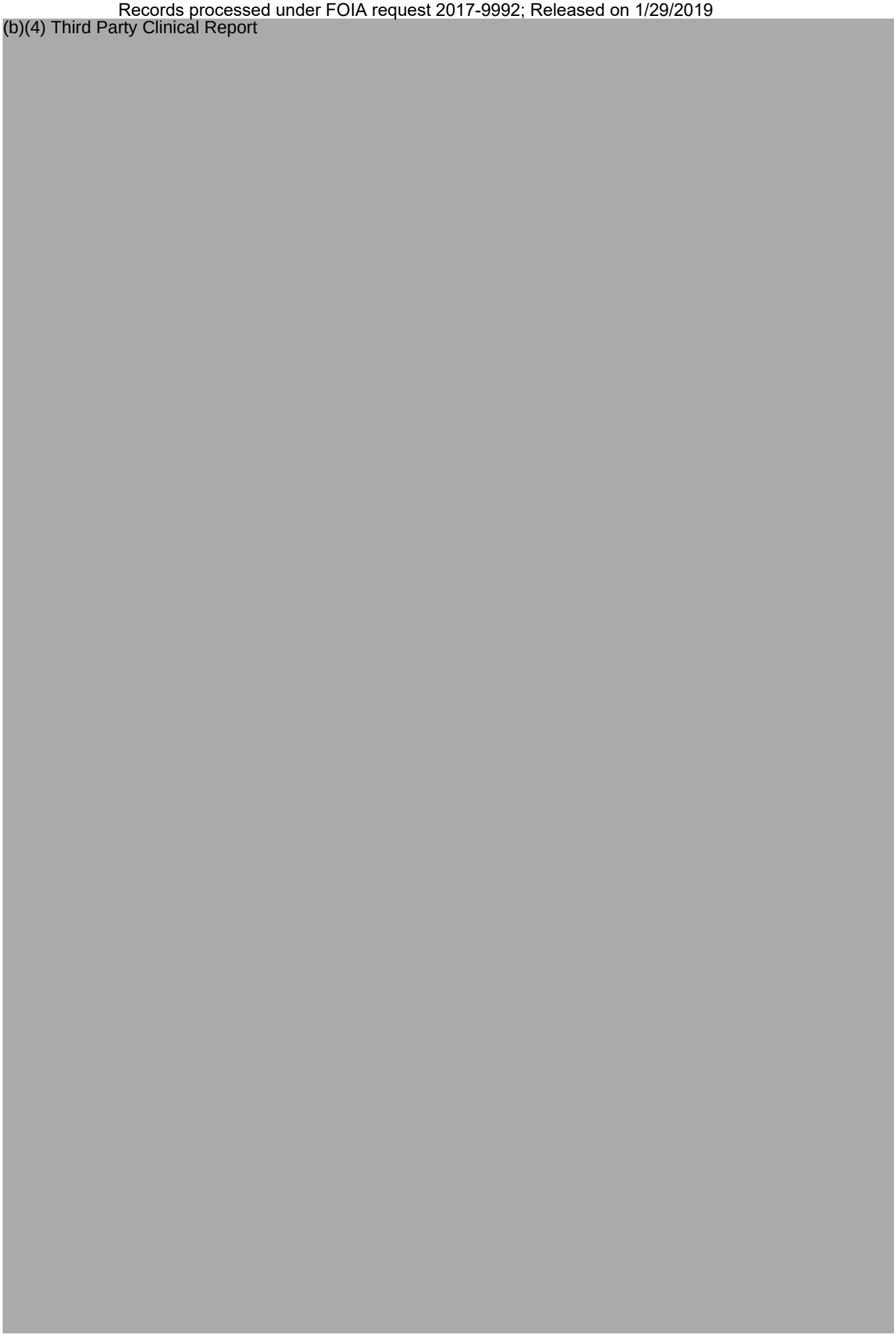
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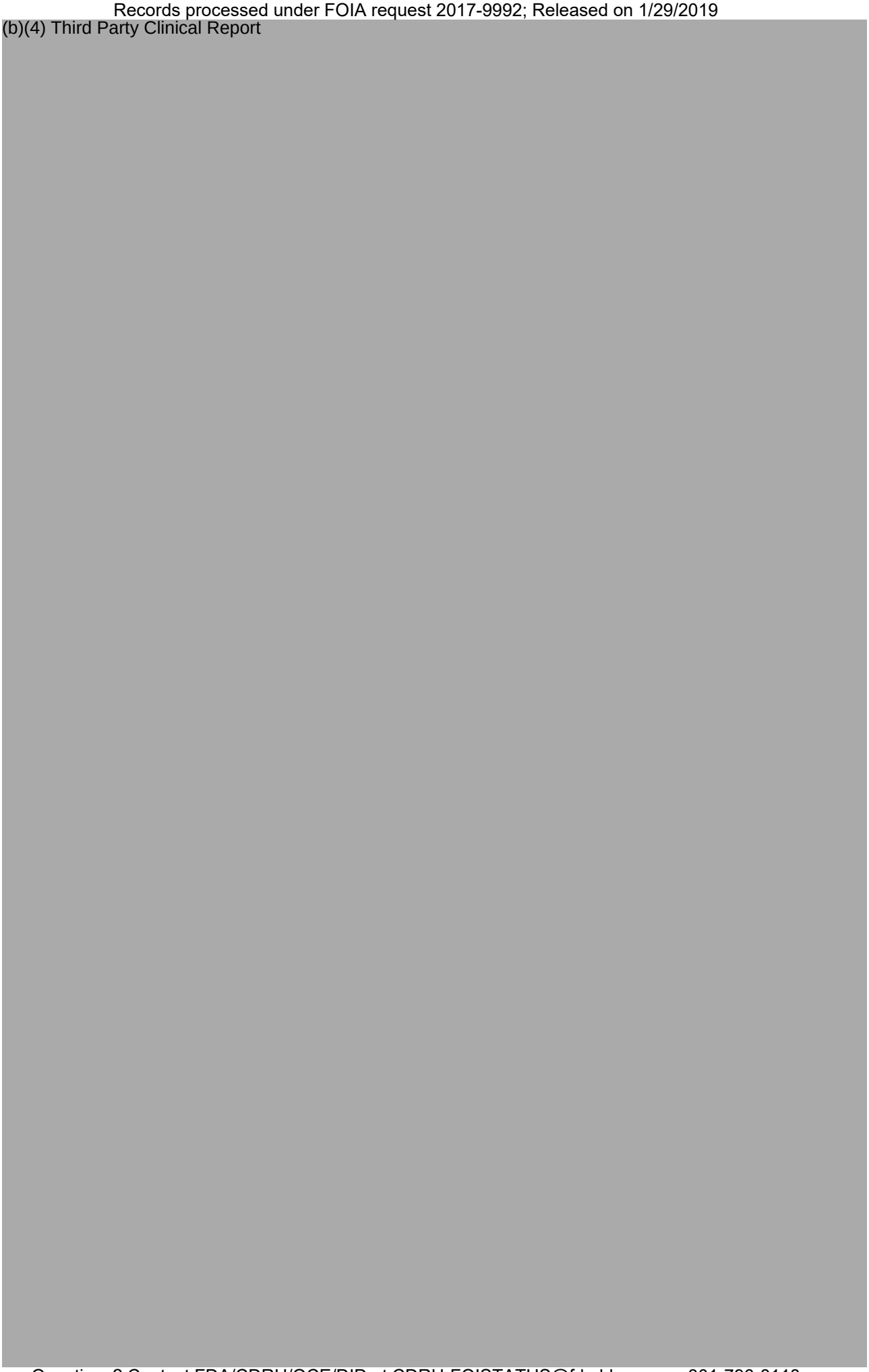
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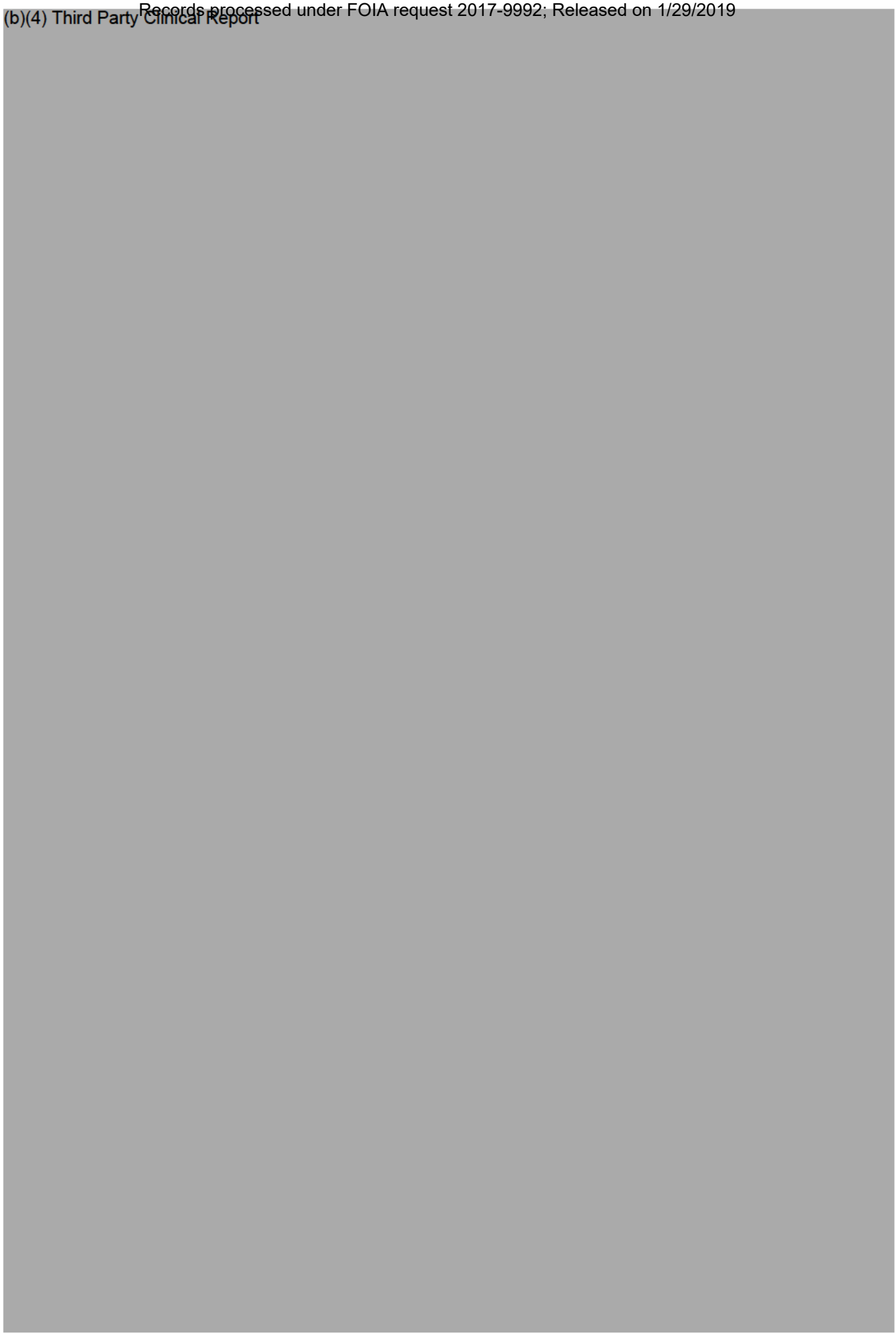
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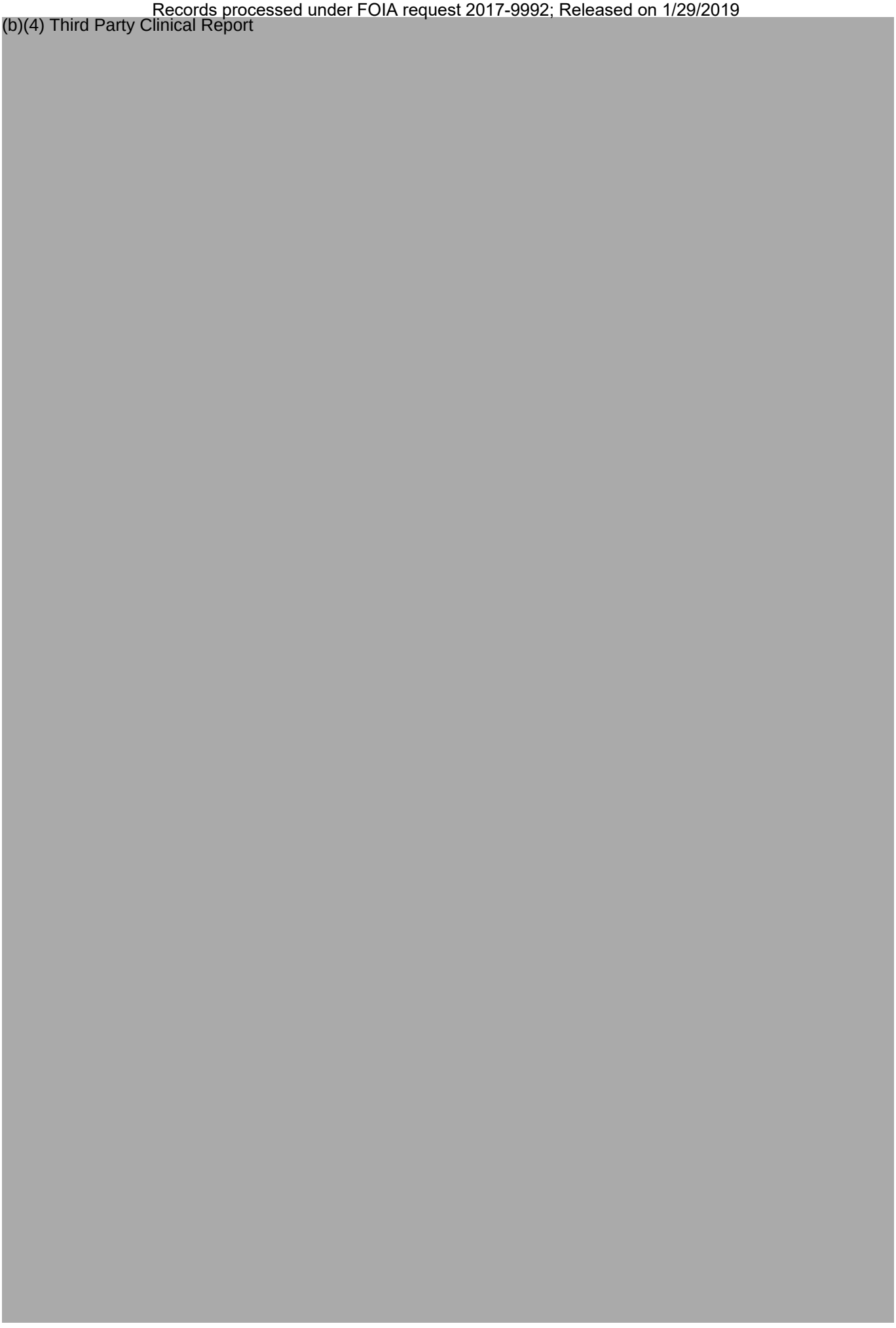
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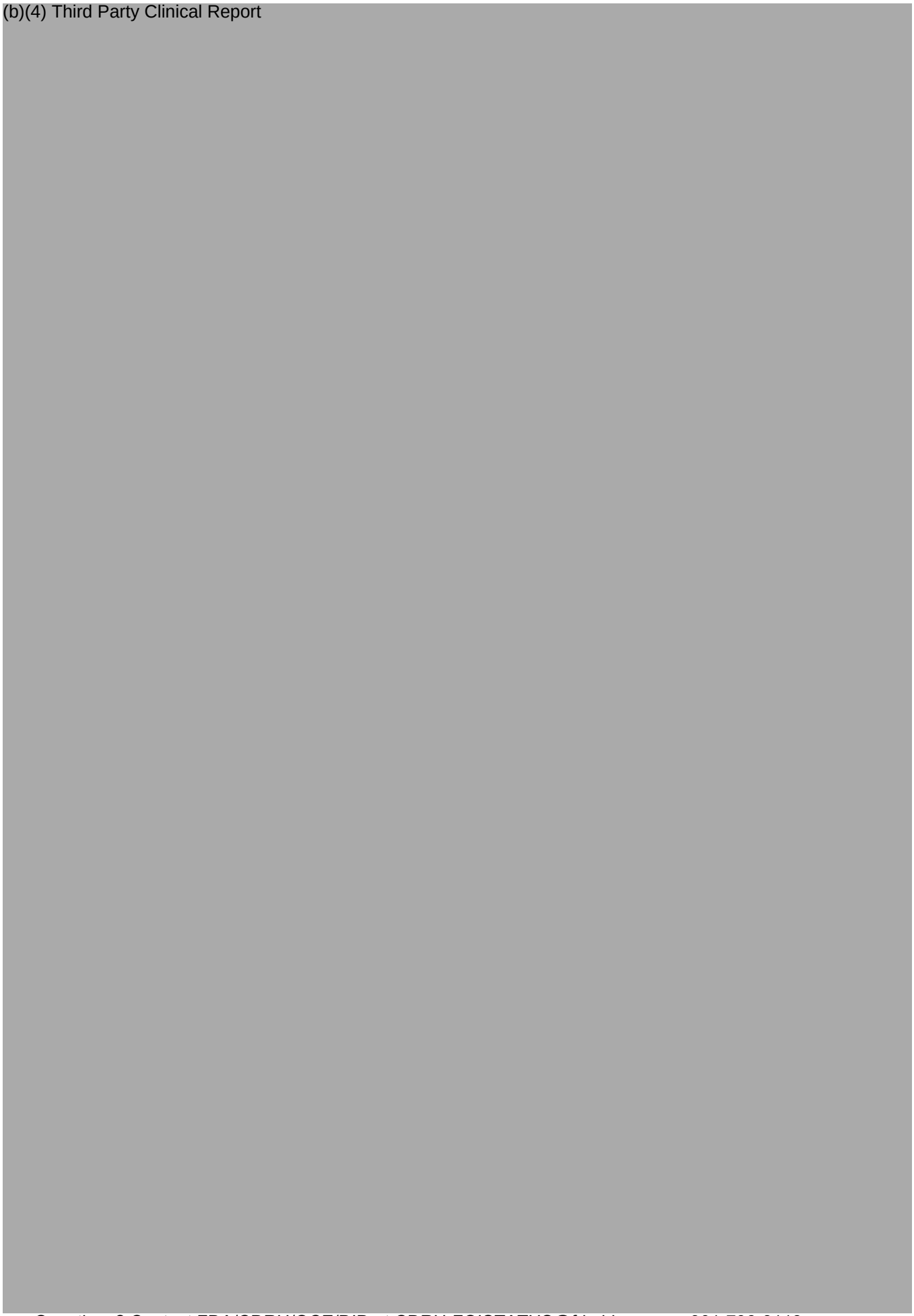
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Appendix B: Protocol

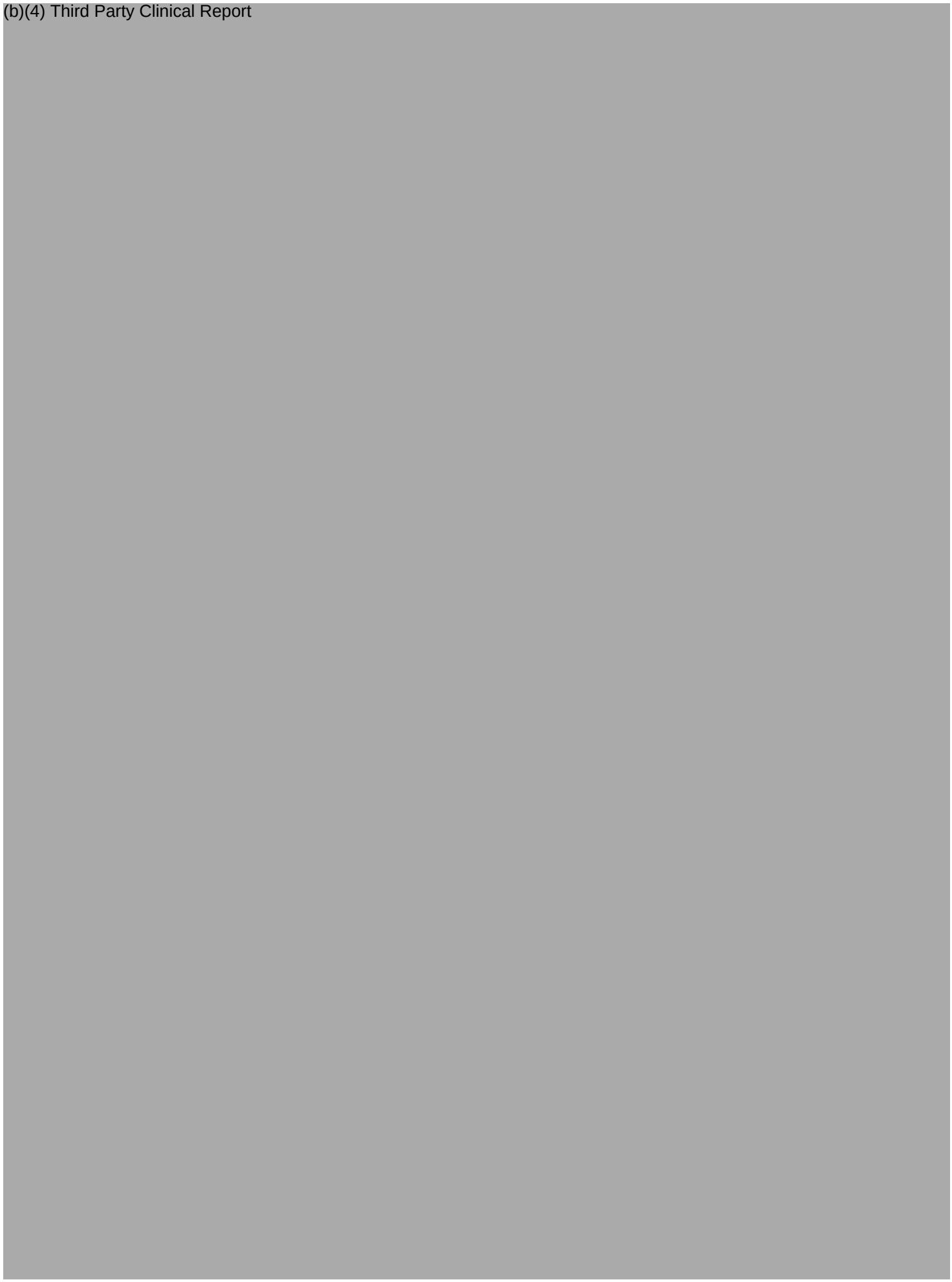
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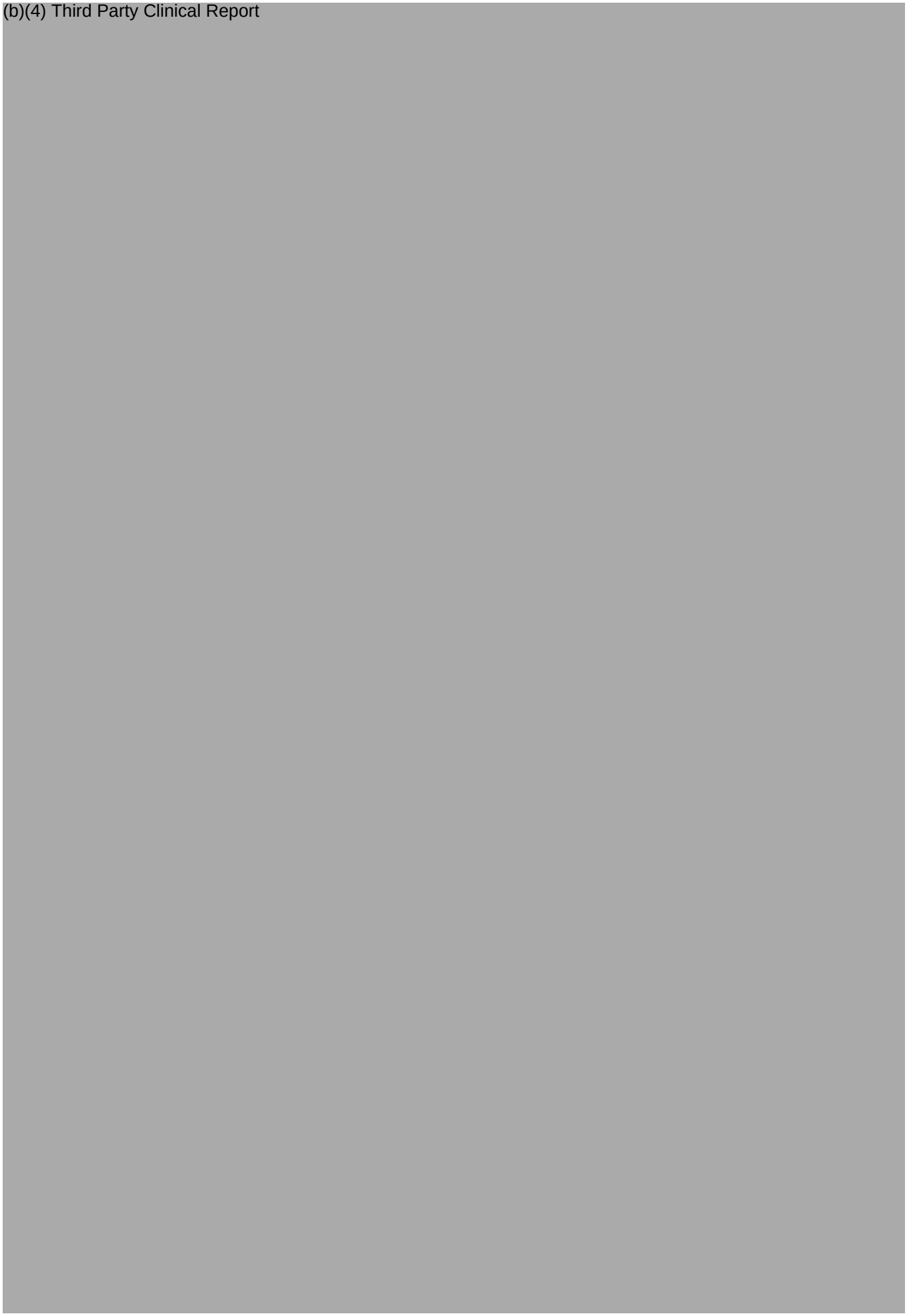
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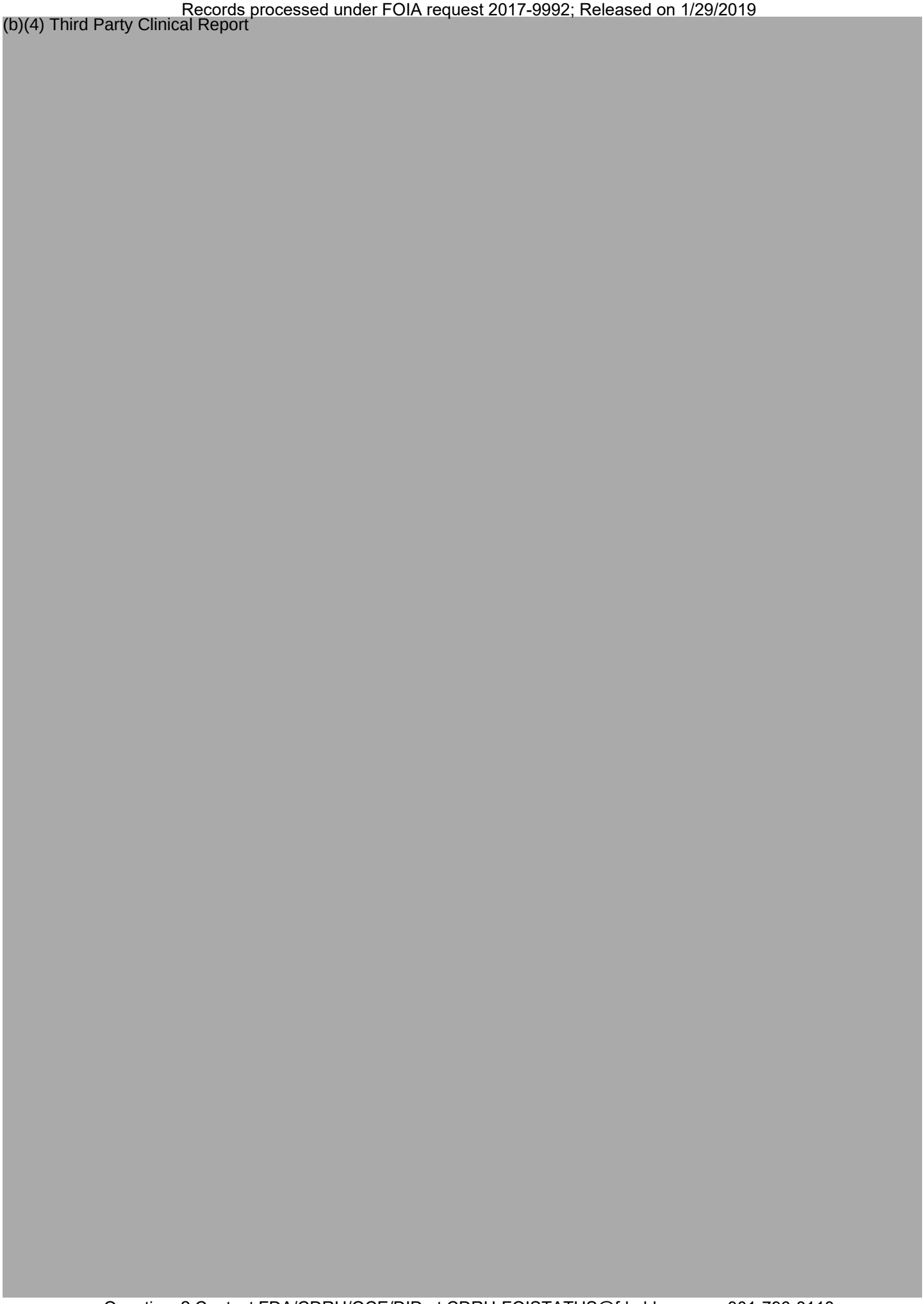
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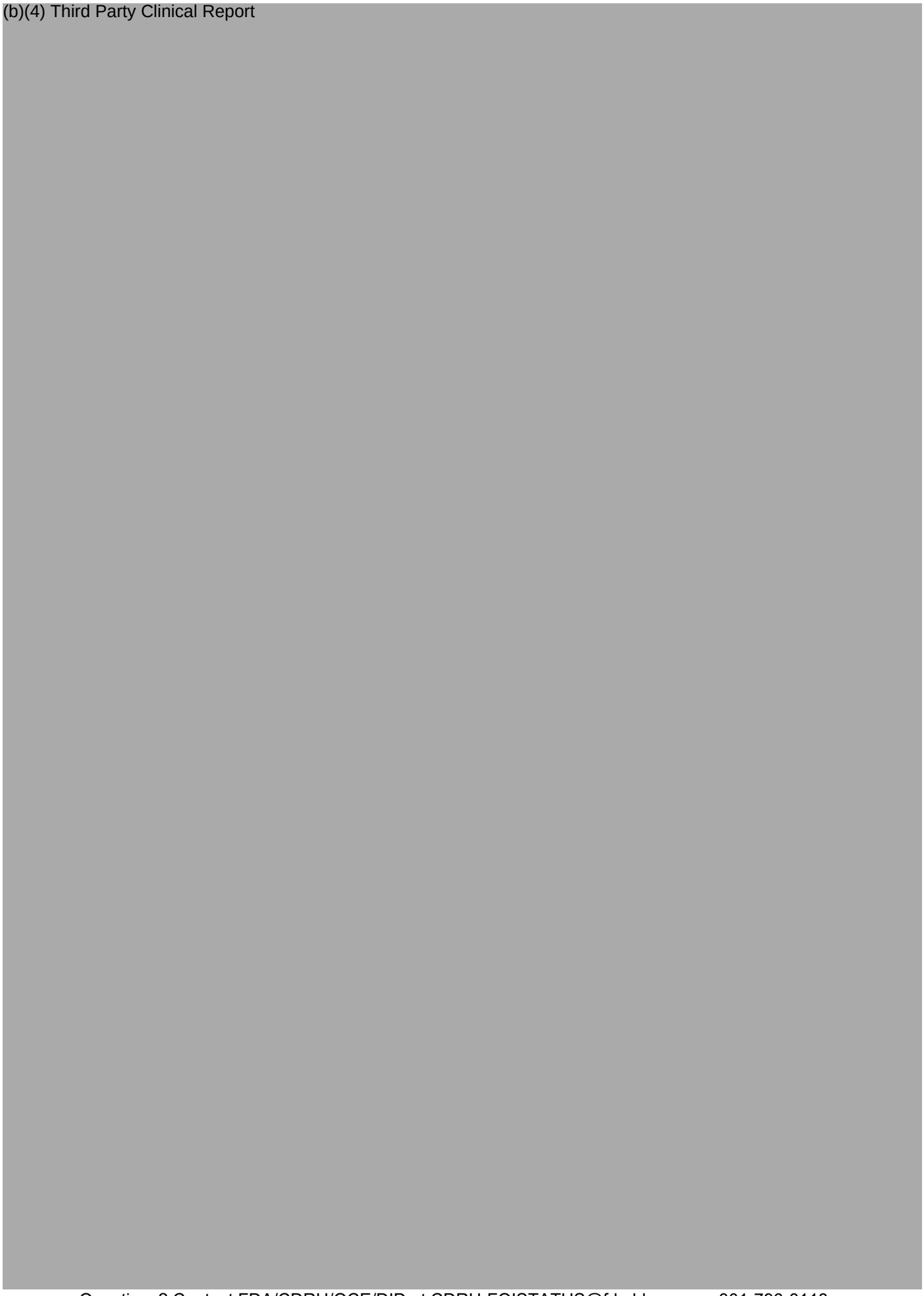
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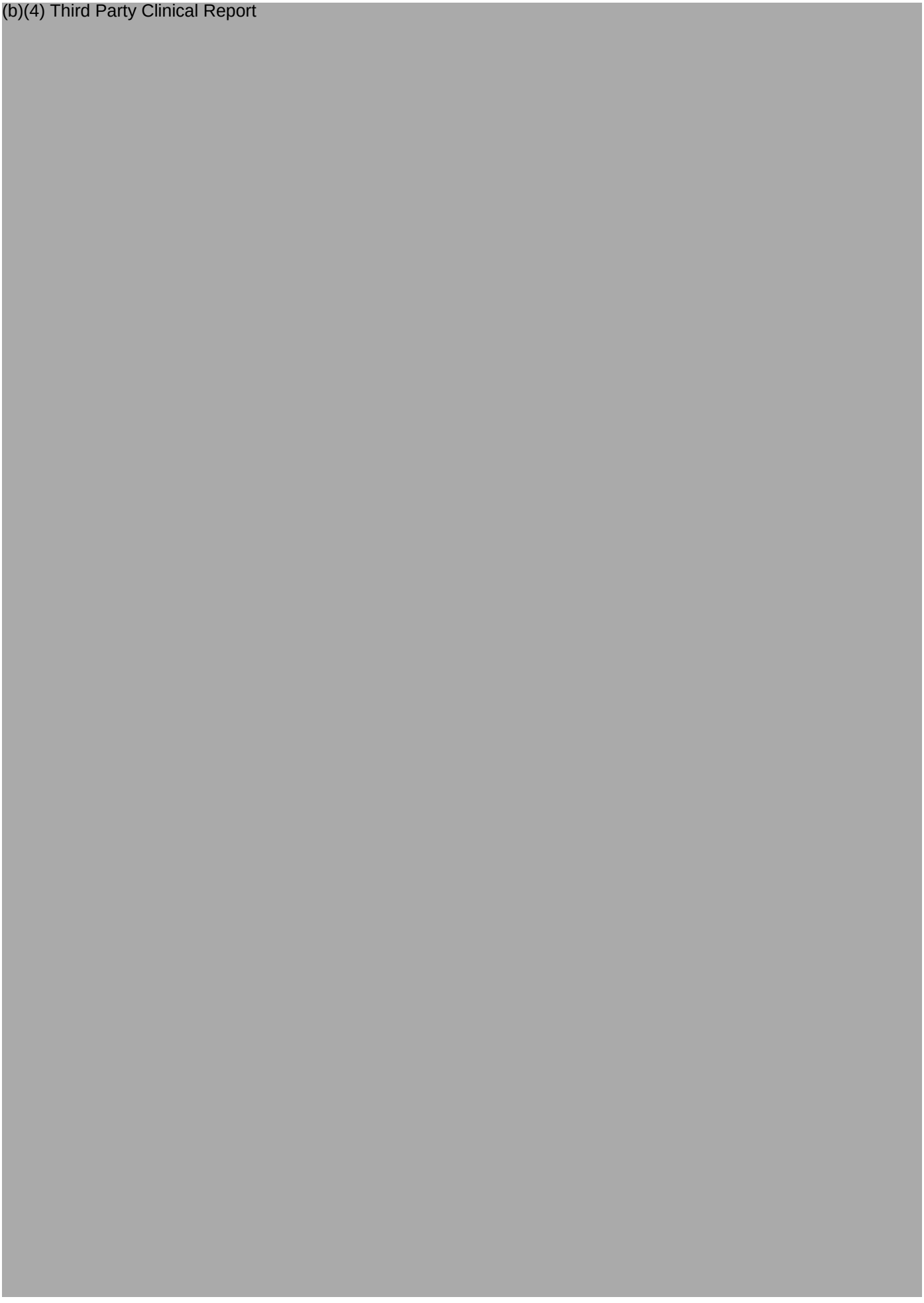
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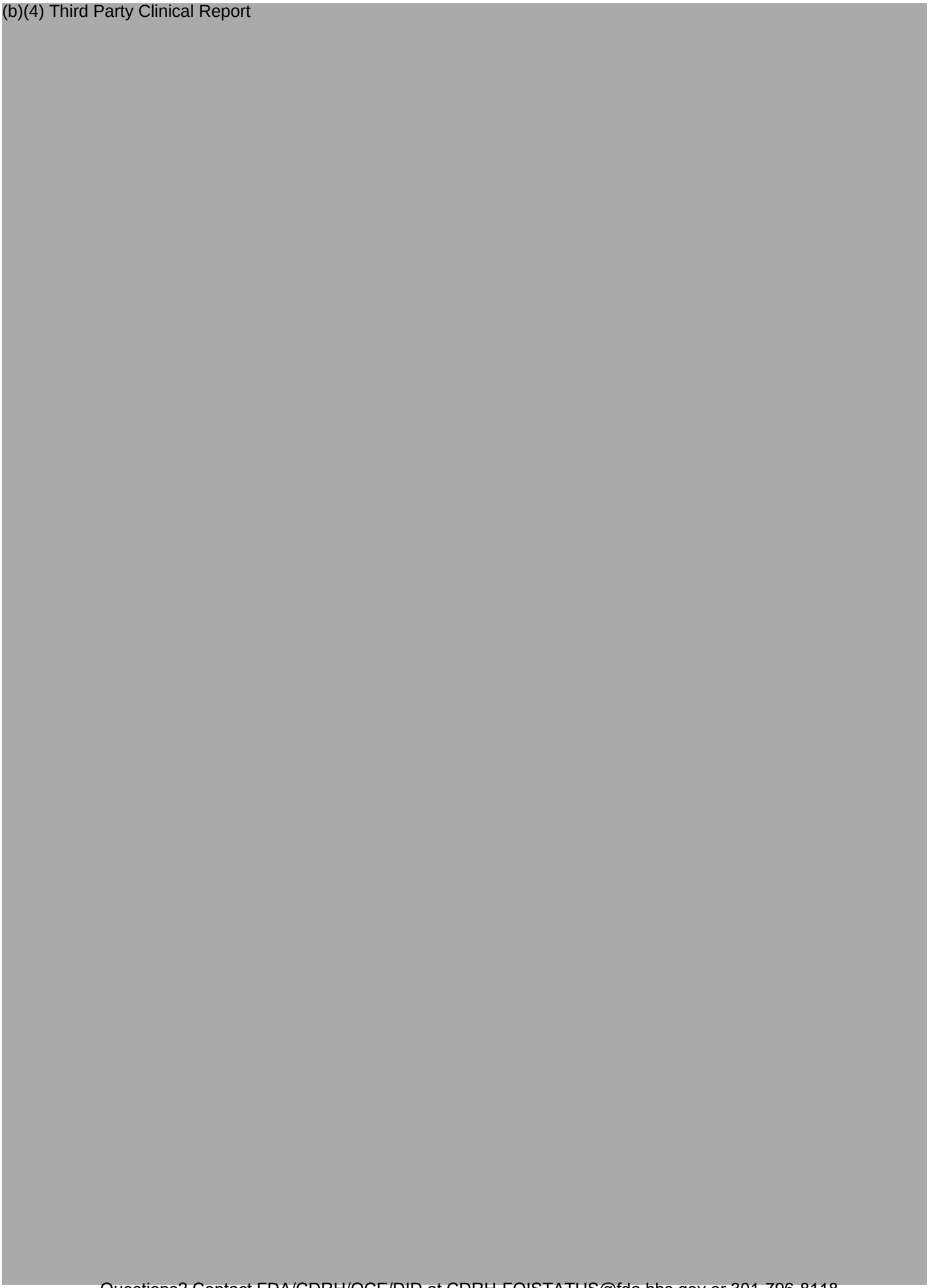
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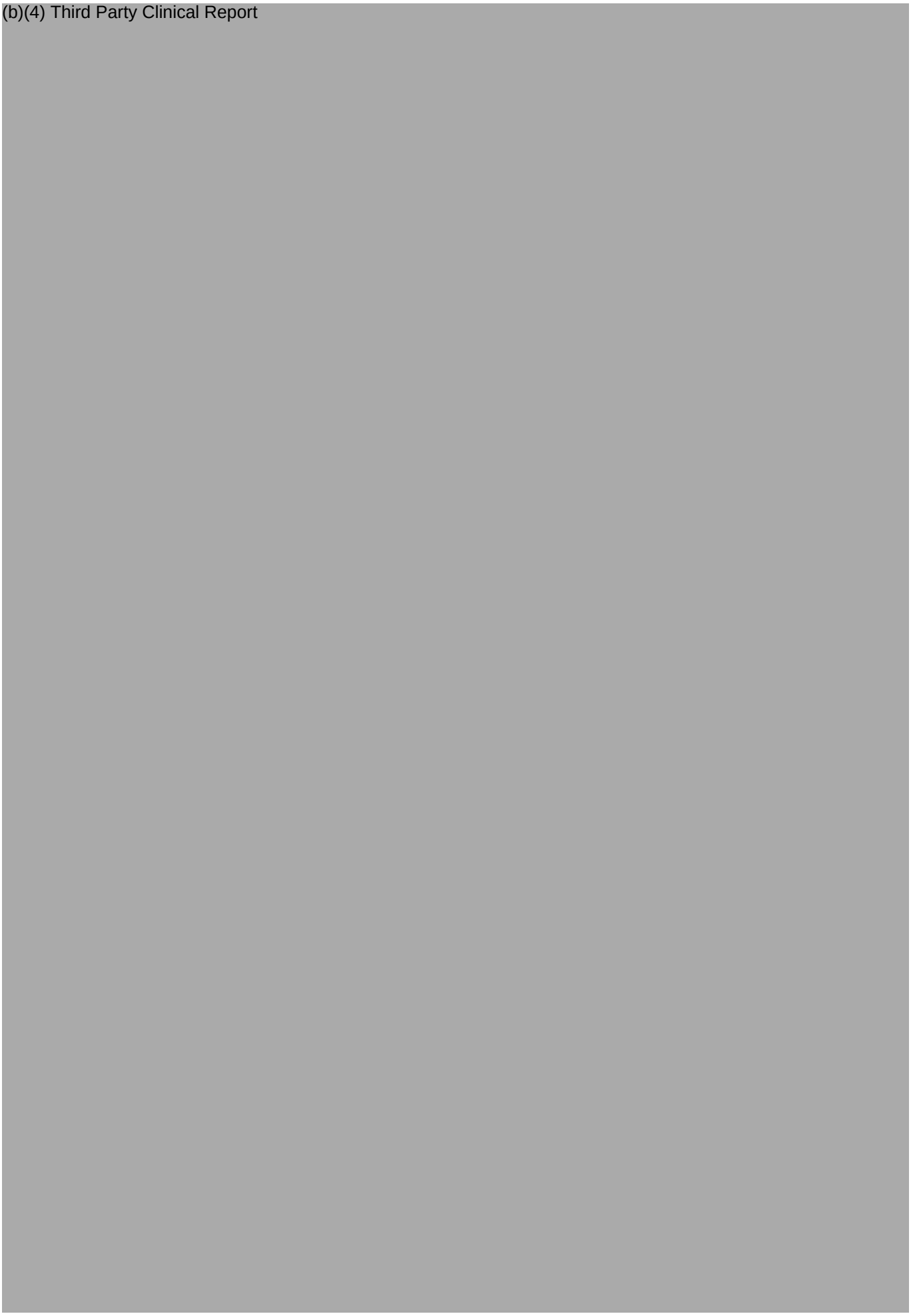
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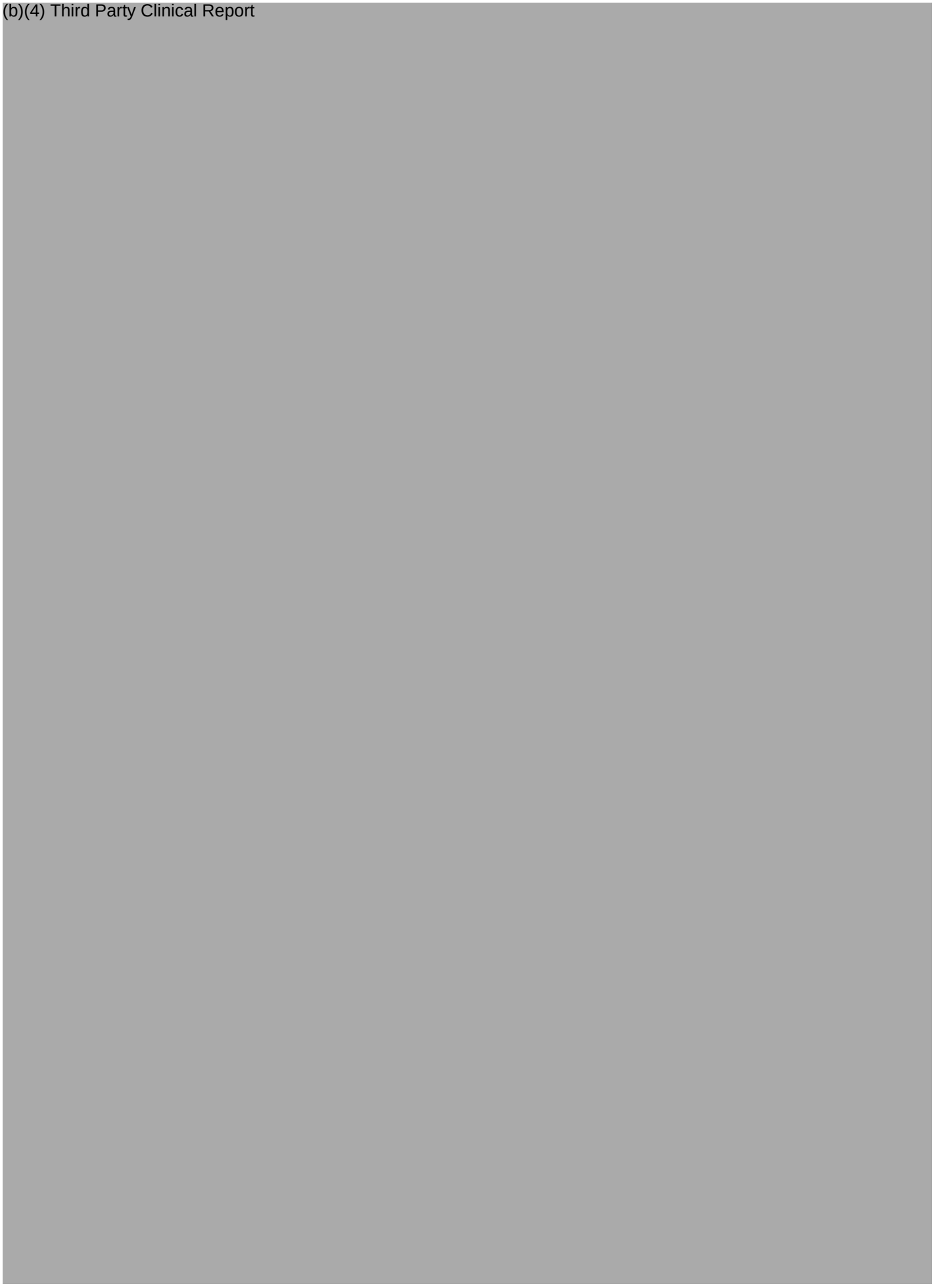
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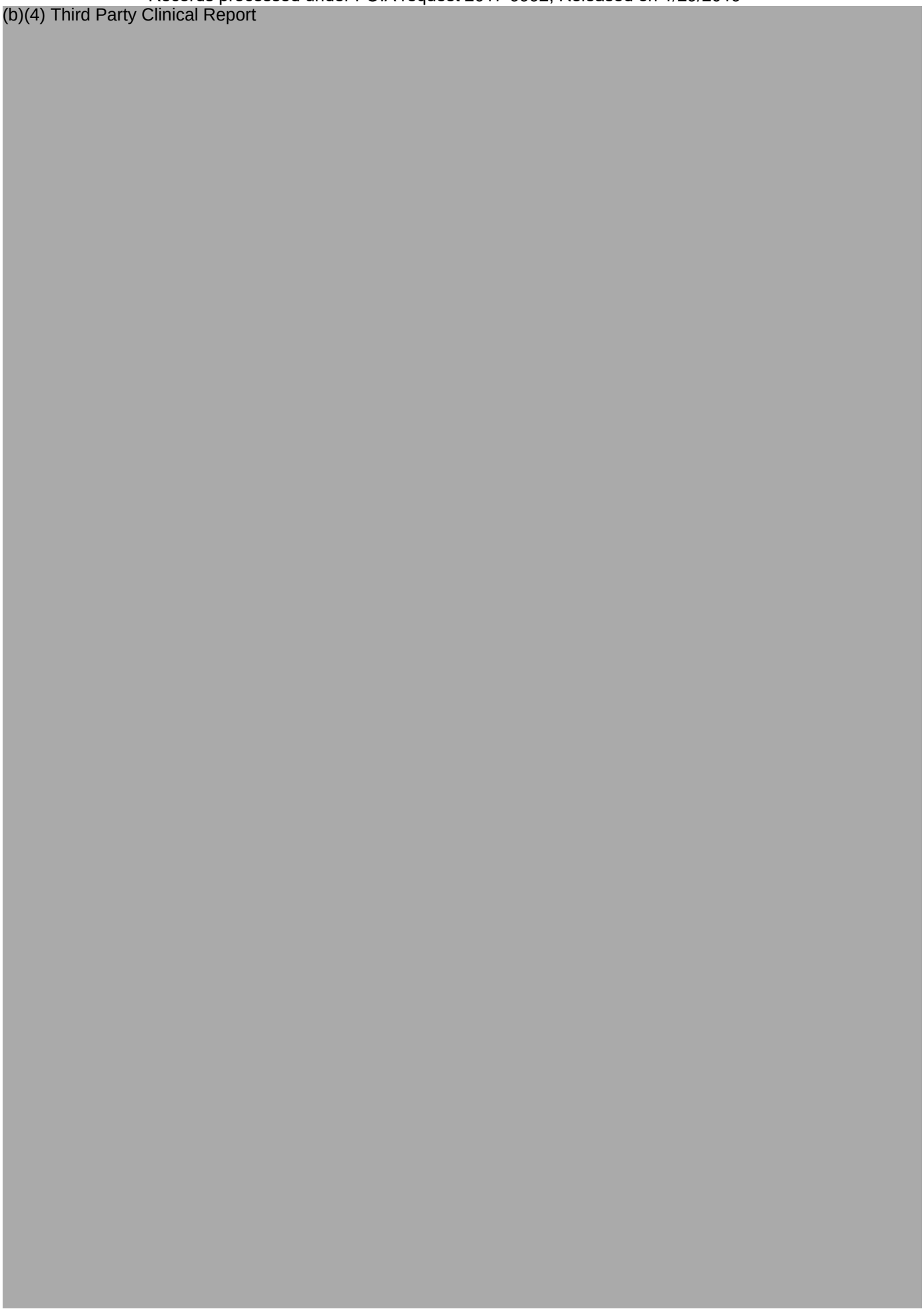
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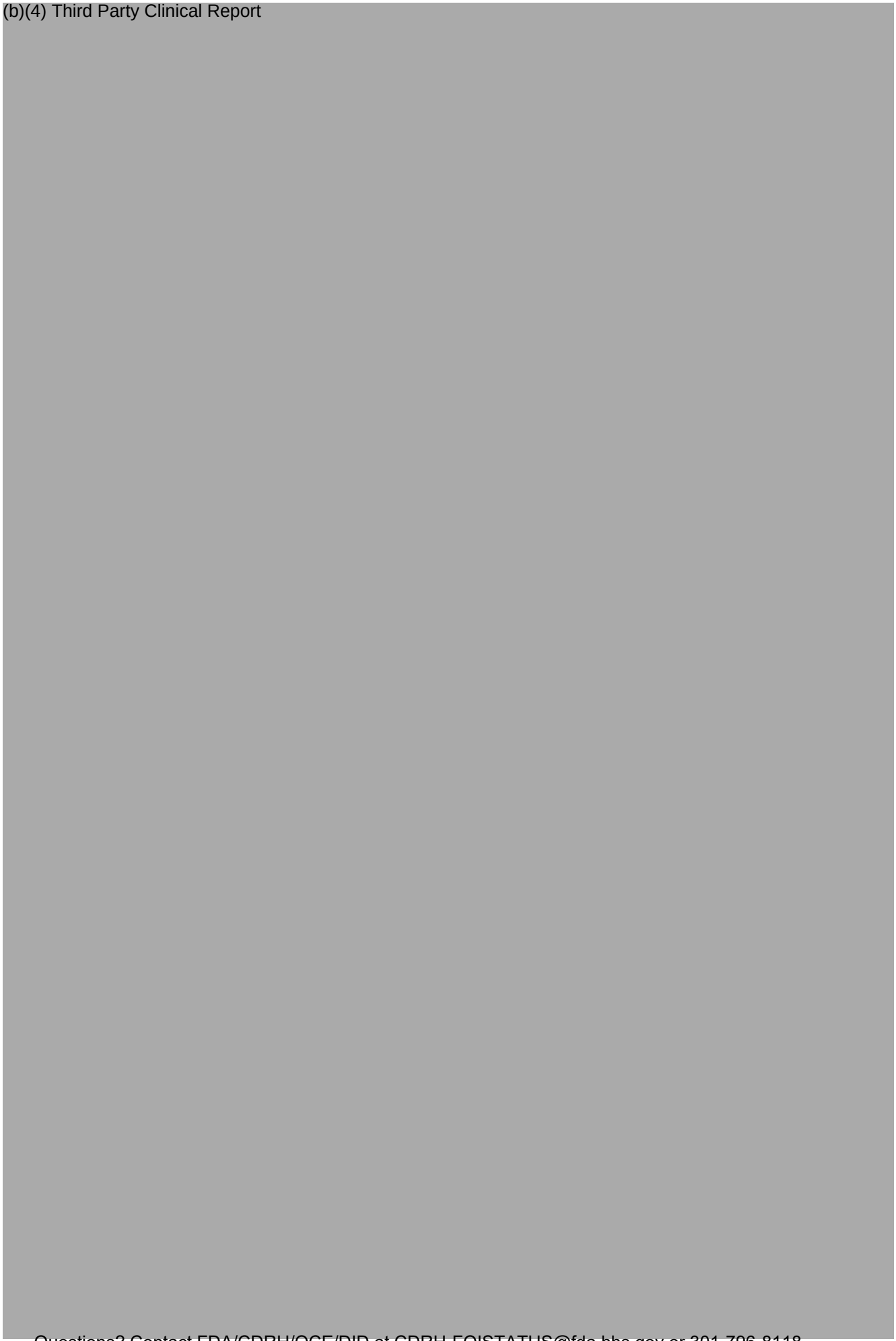
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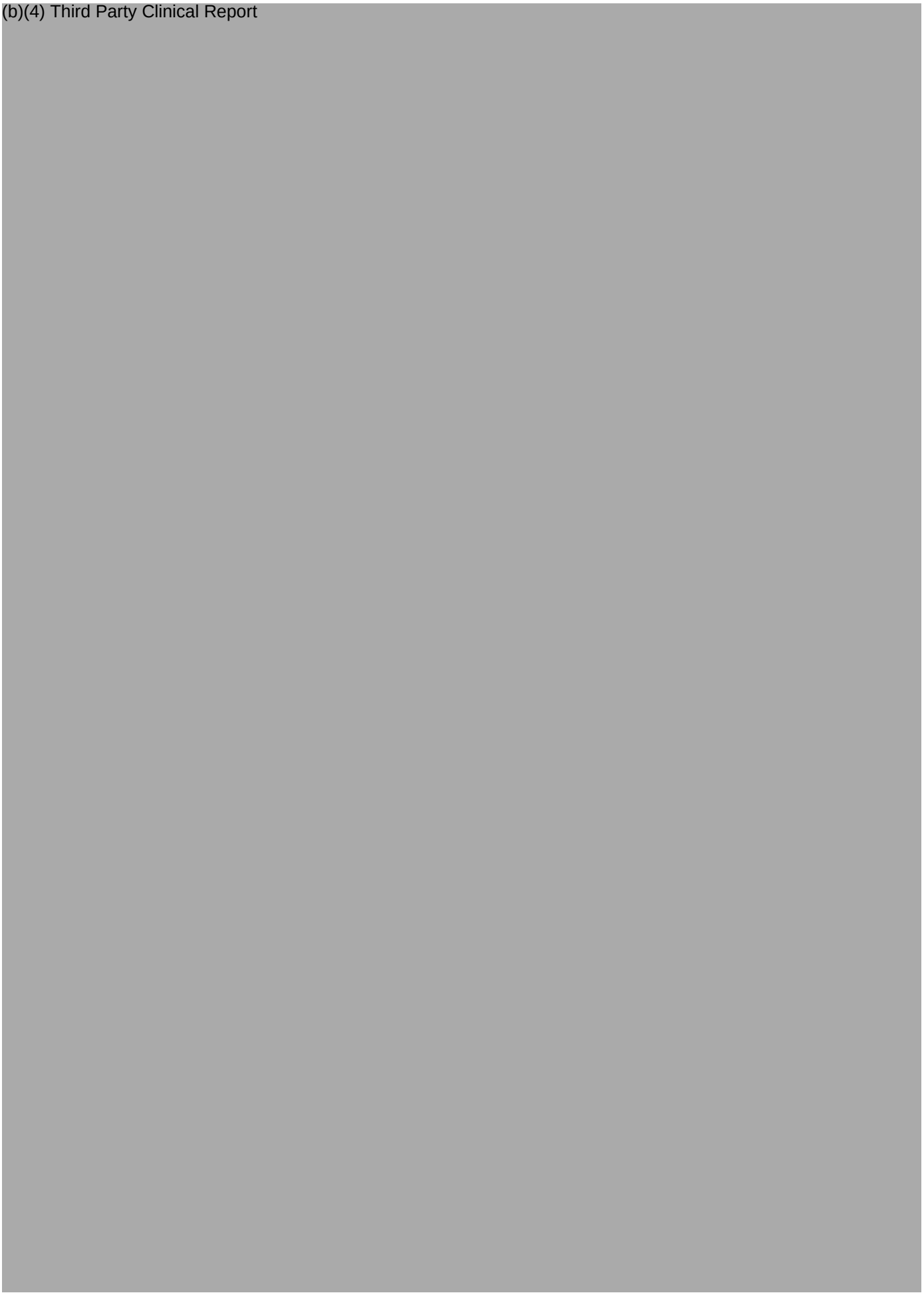
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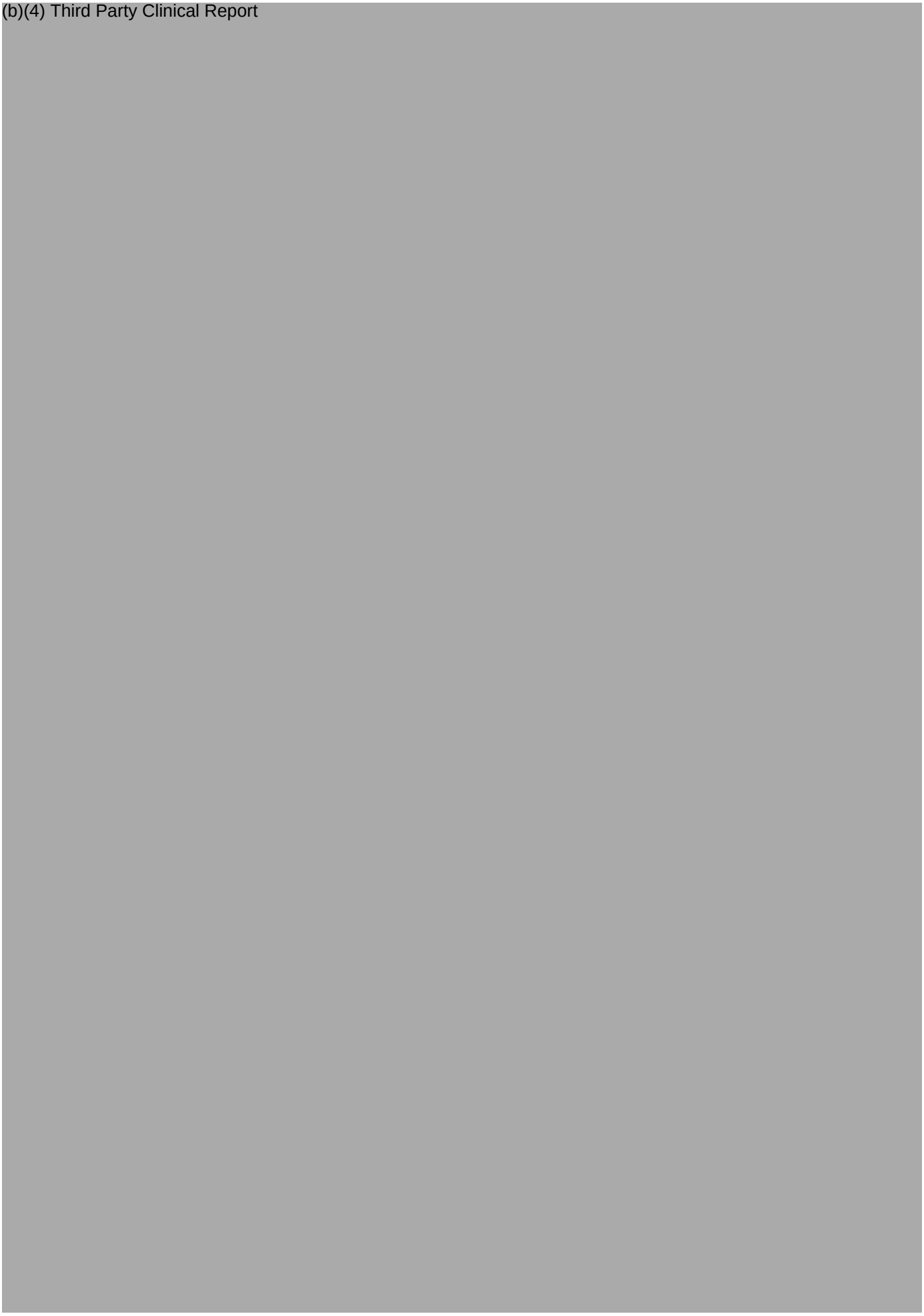
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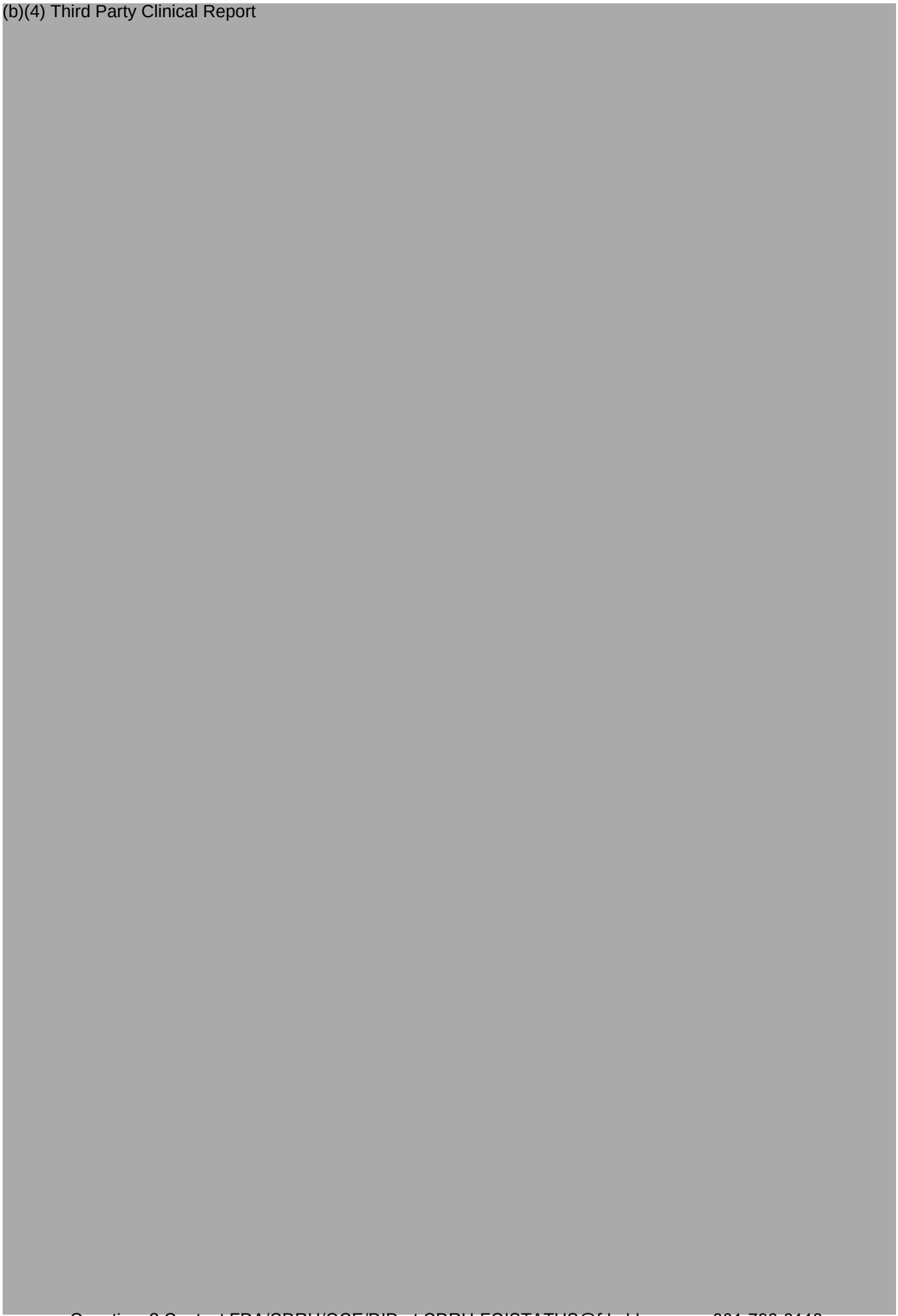
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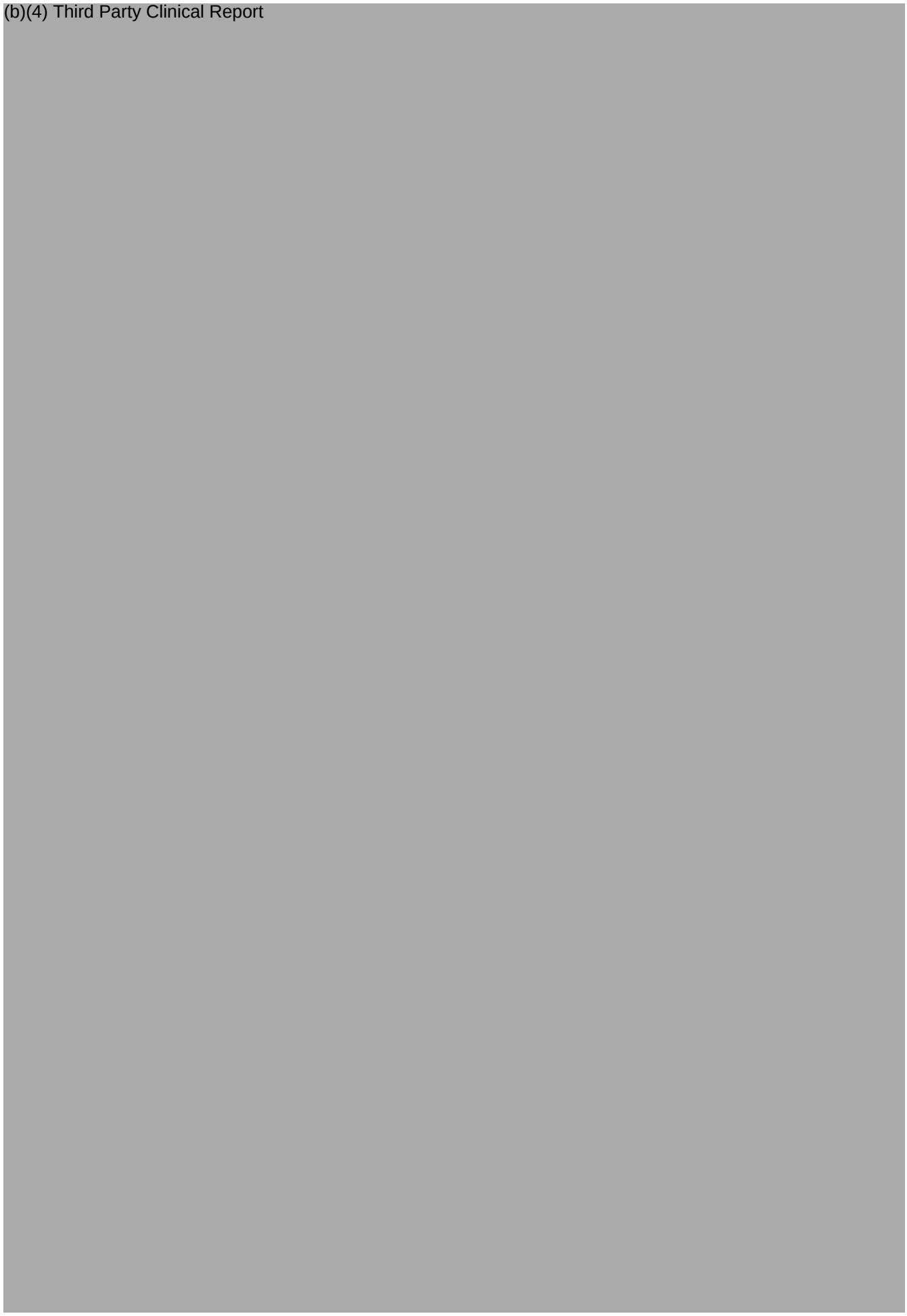
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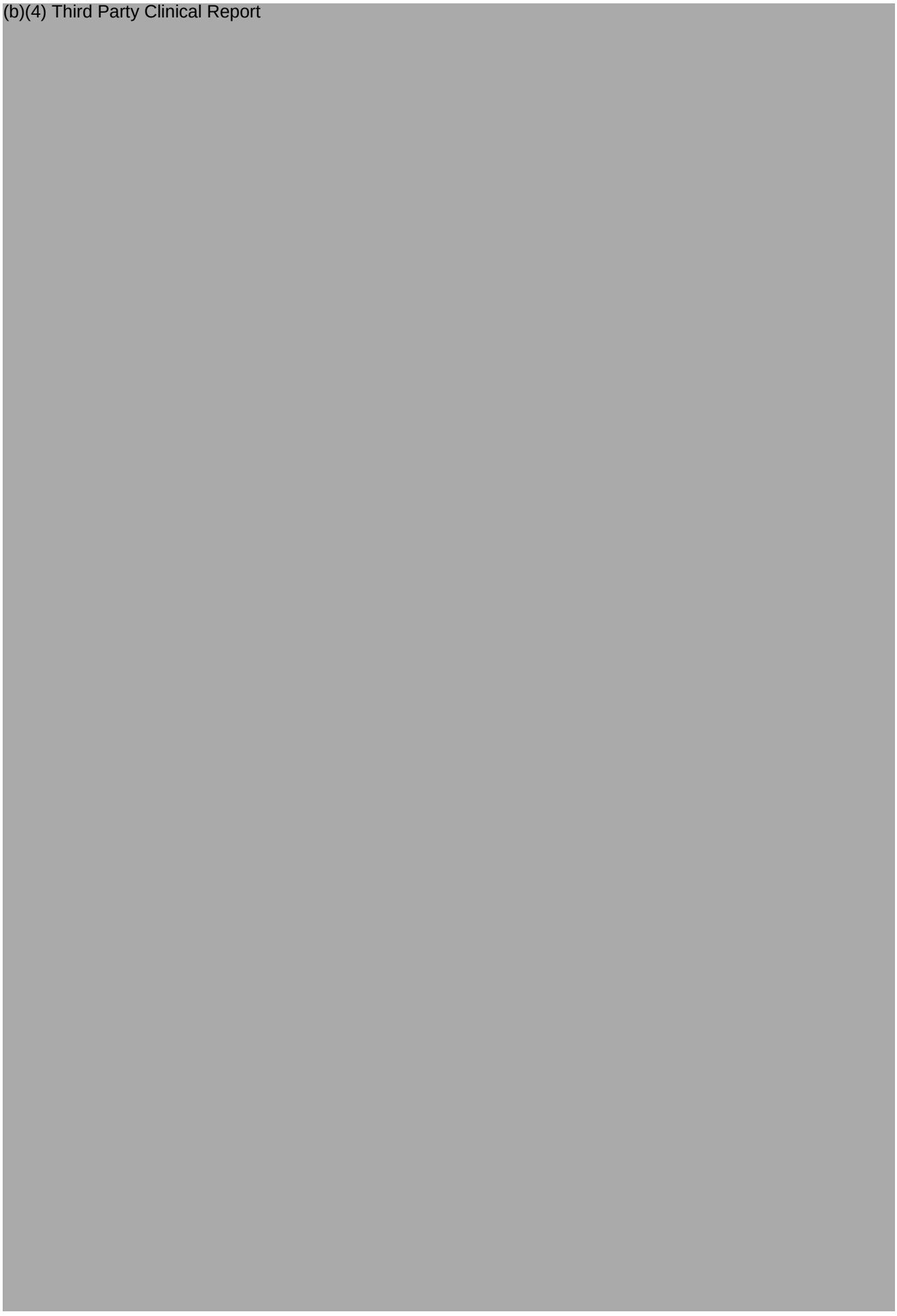
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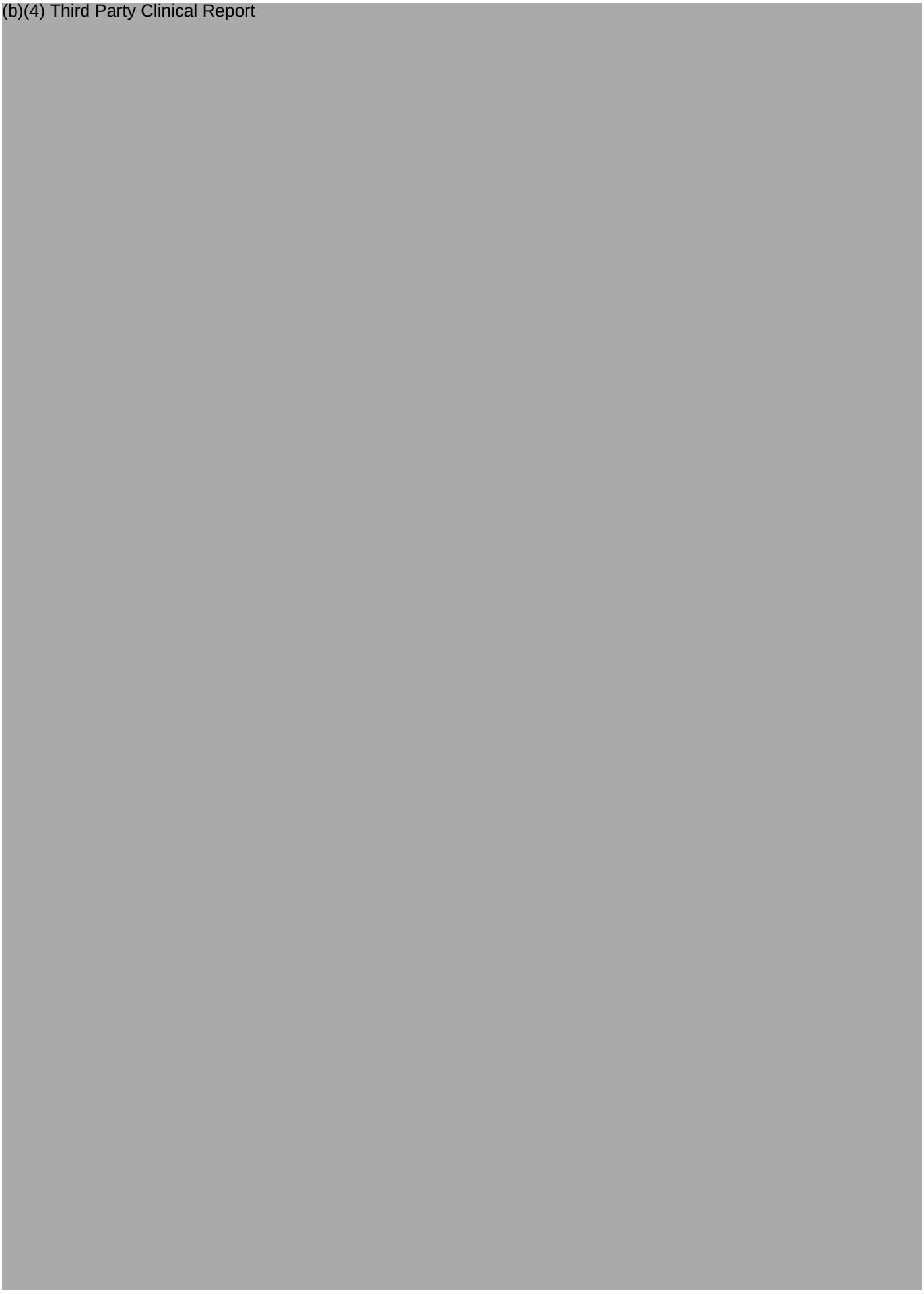
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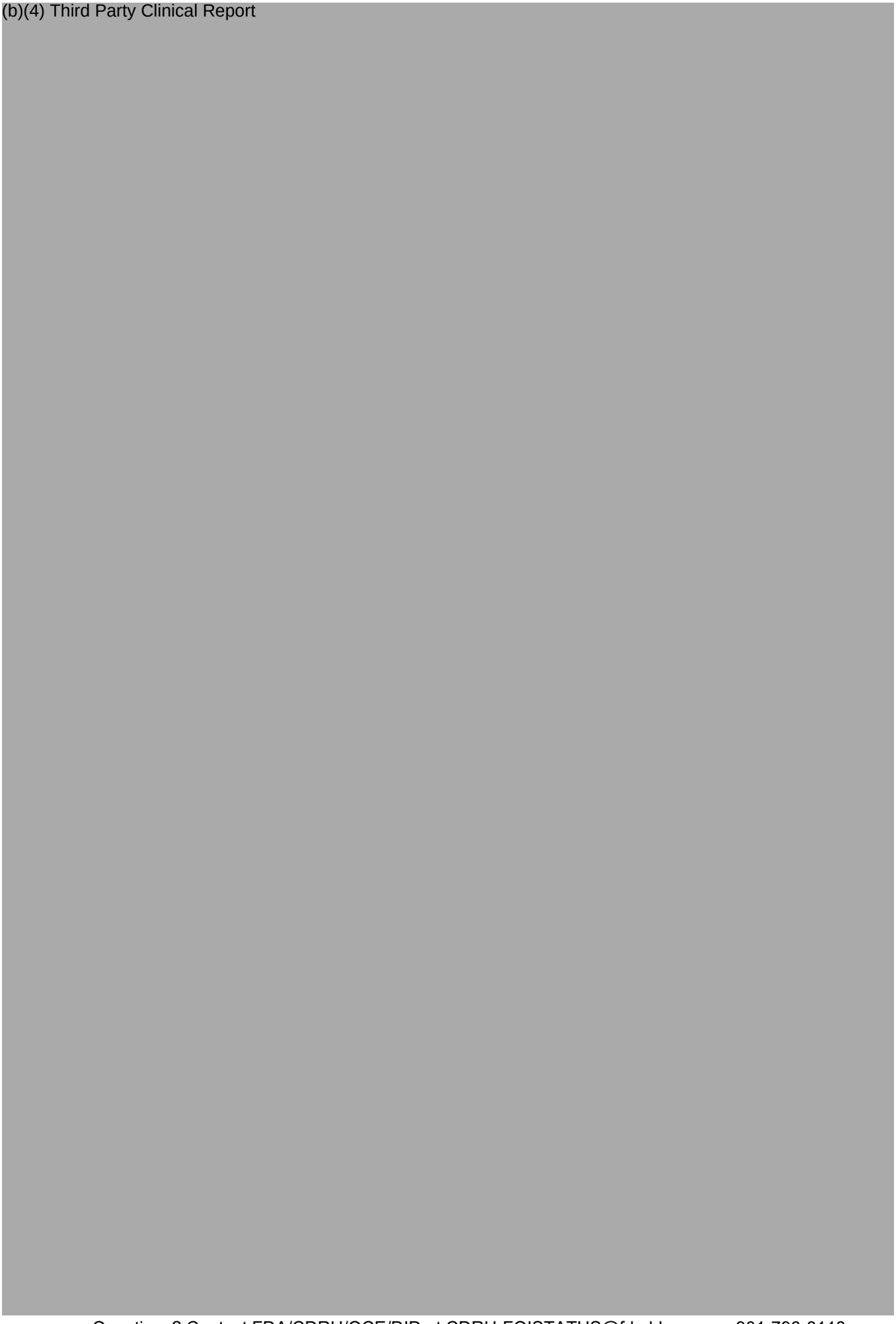
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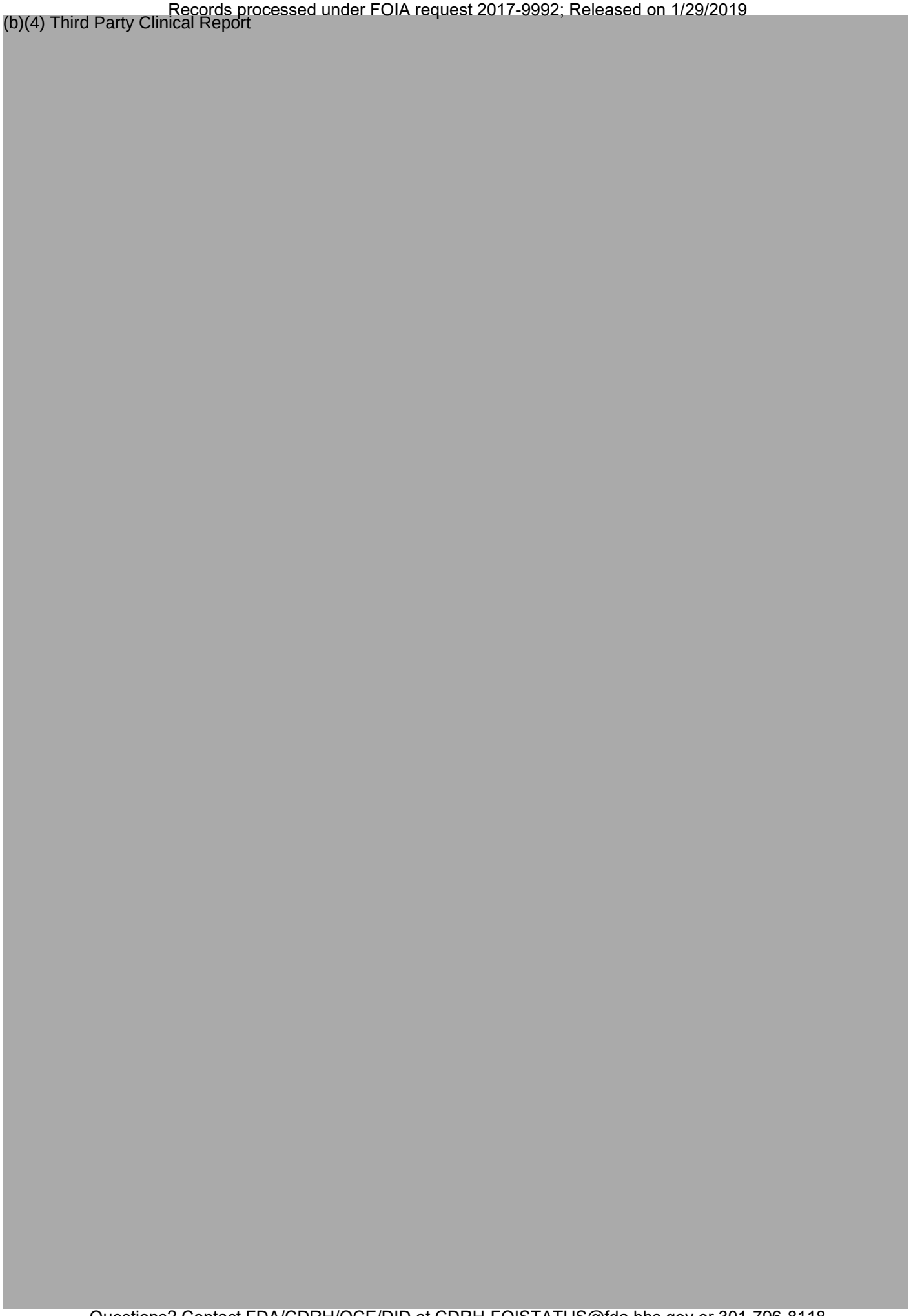
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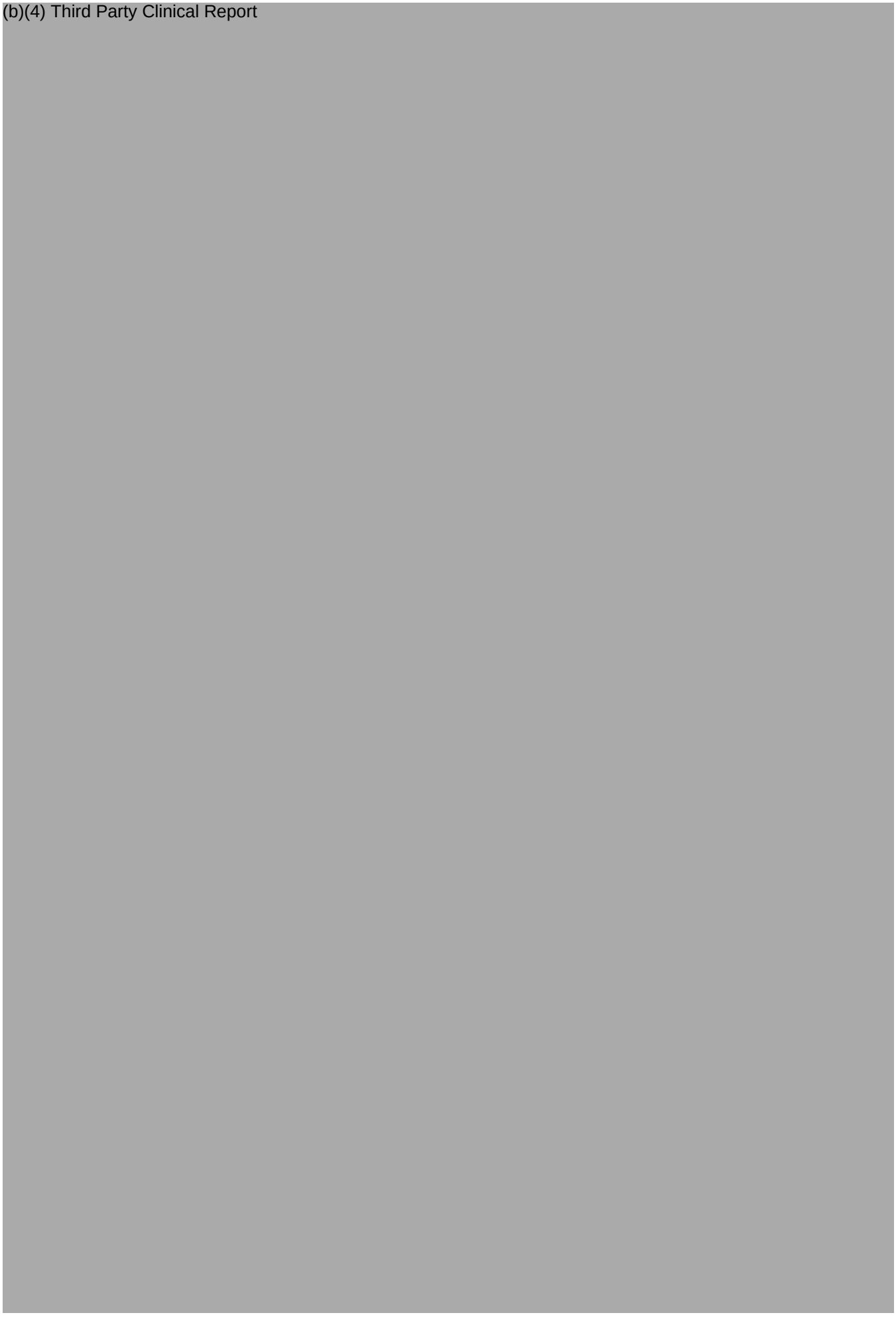
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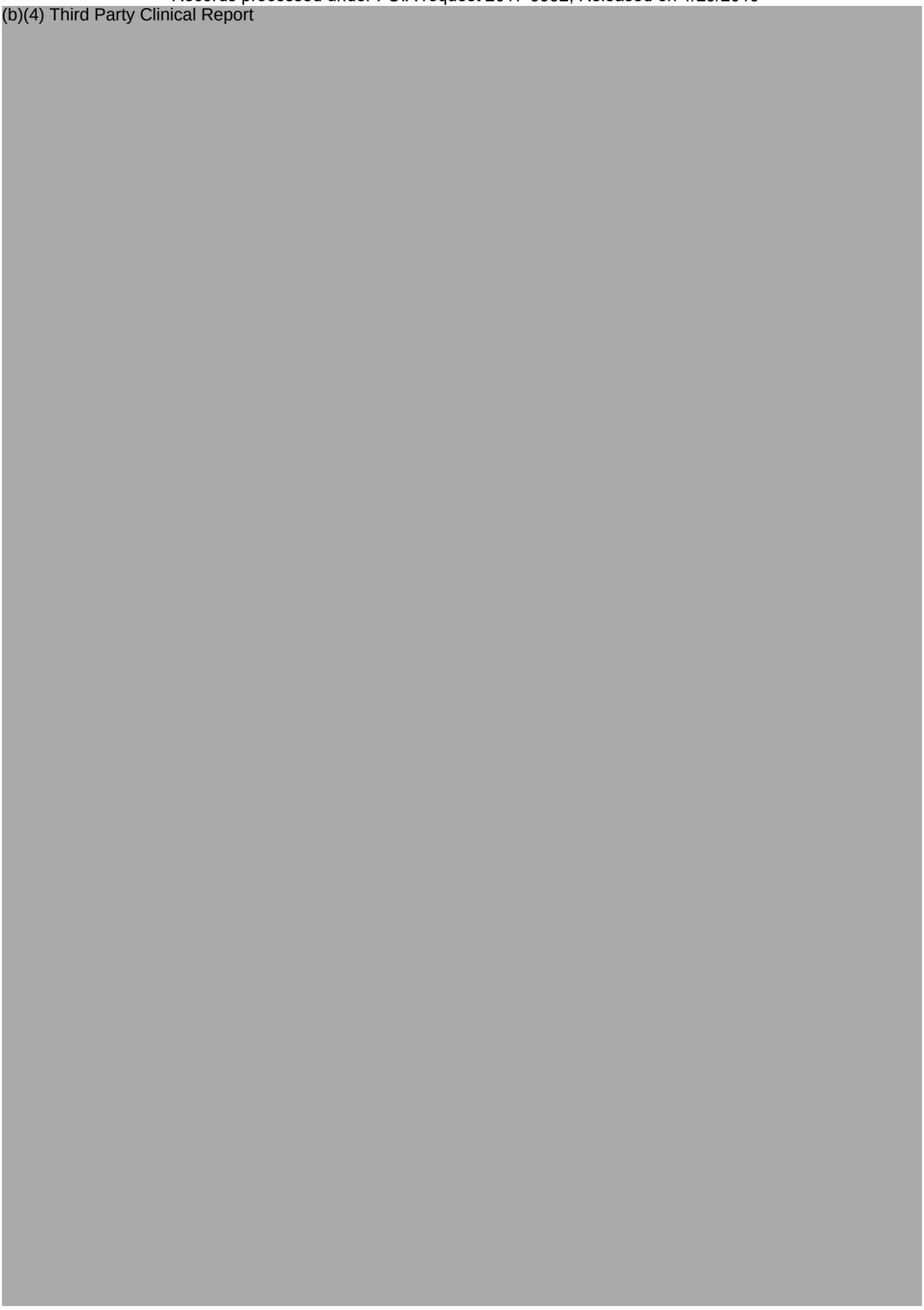
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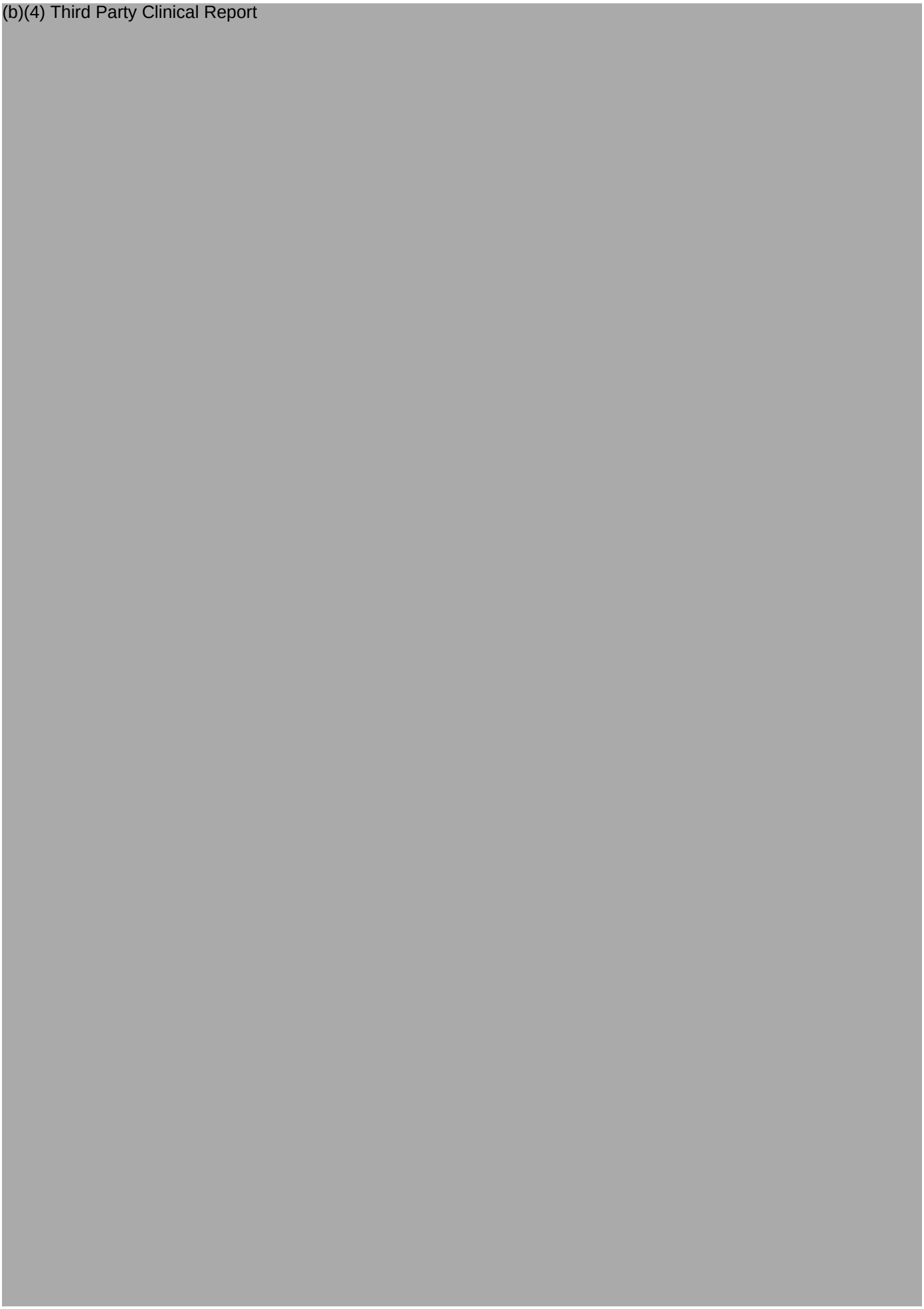
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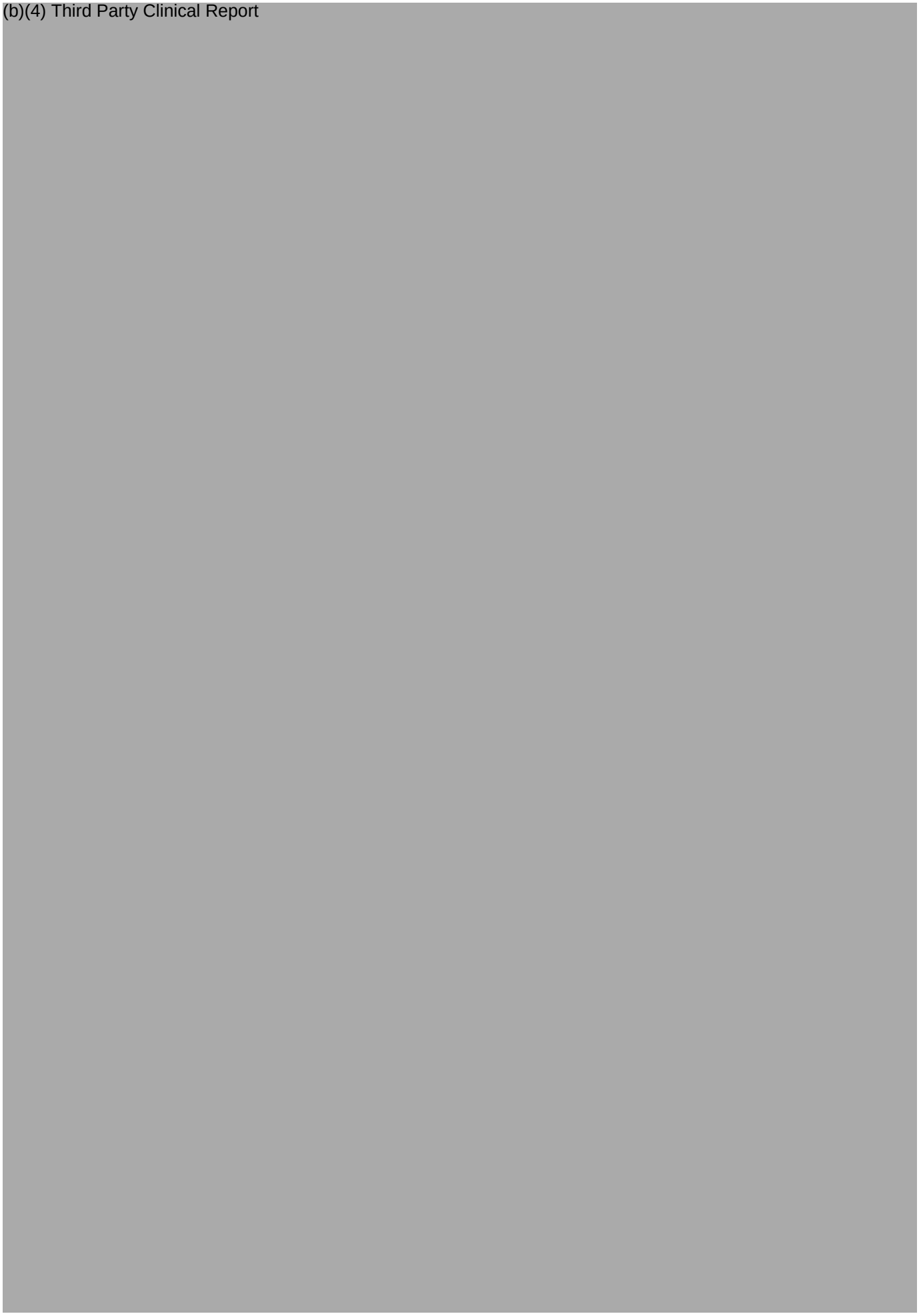
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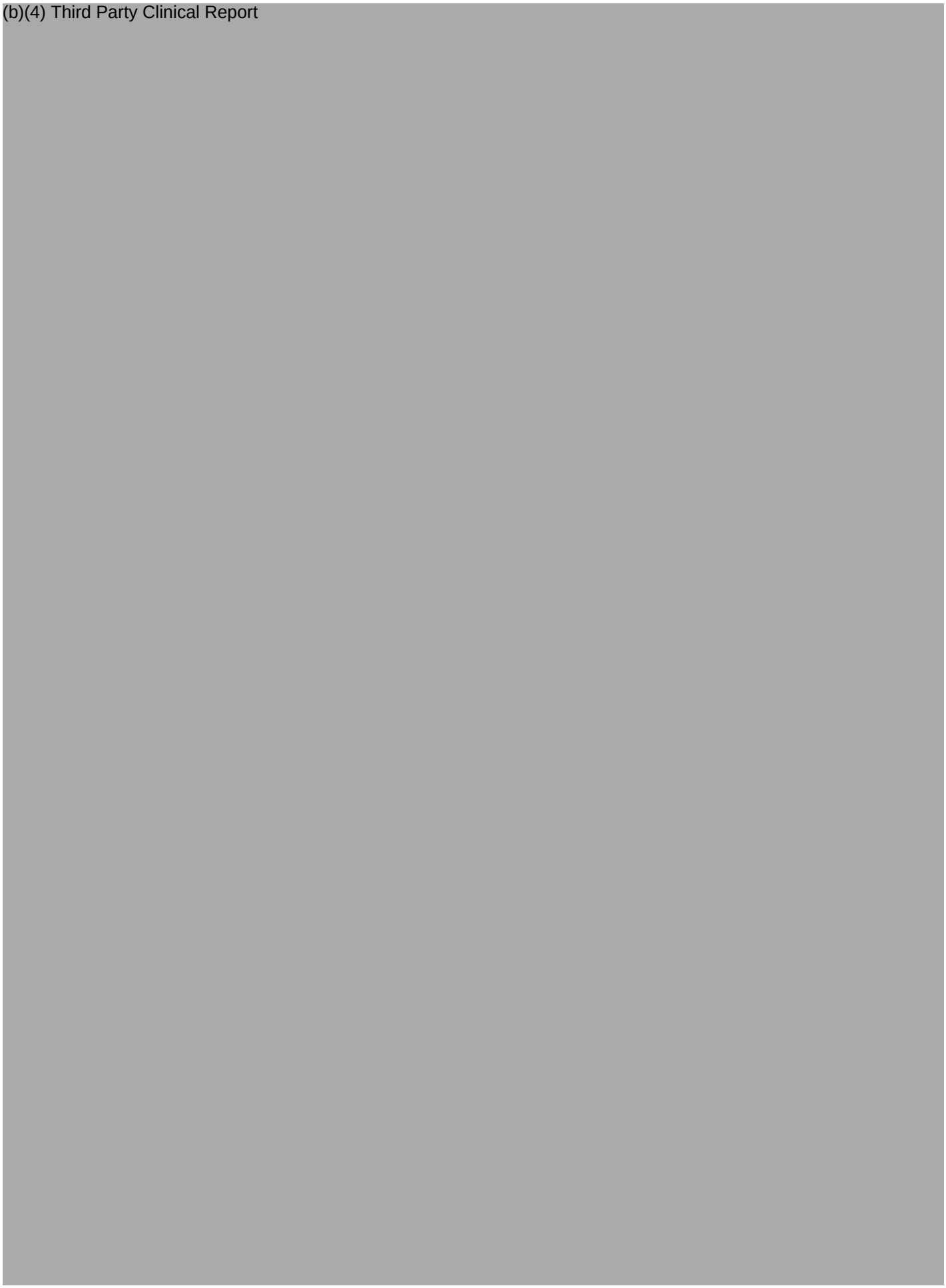
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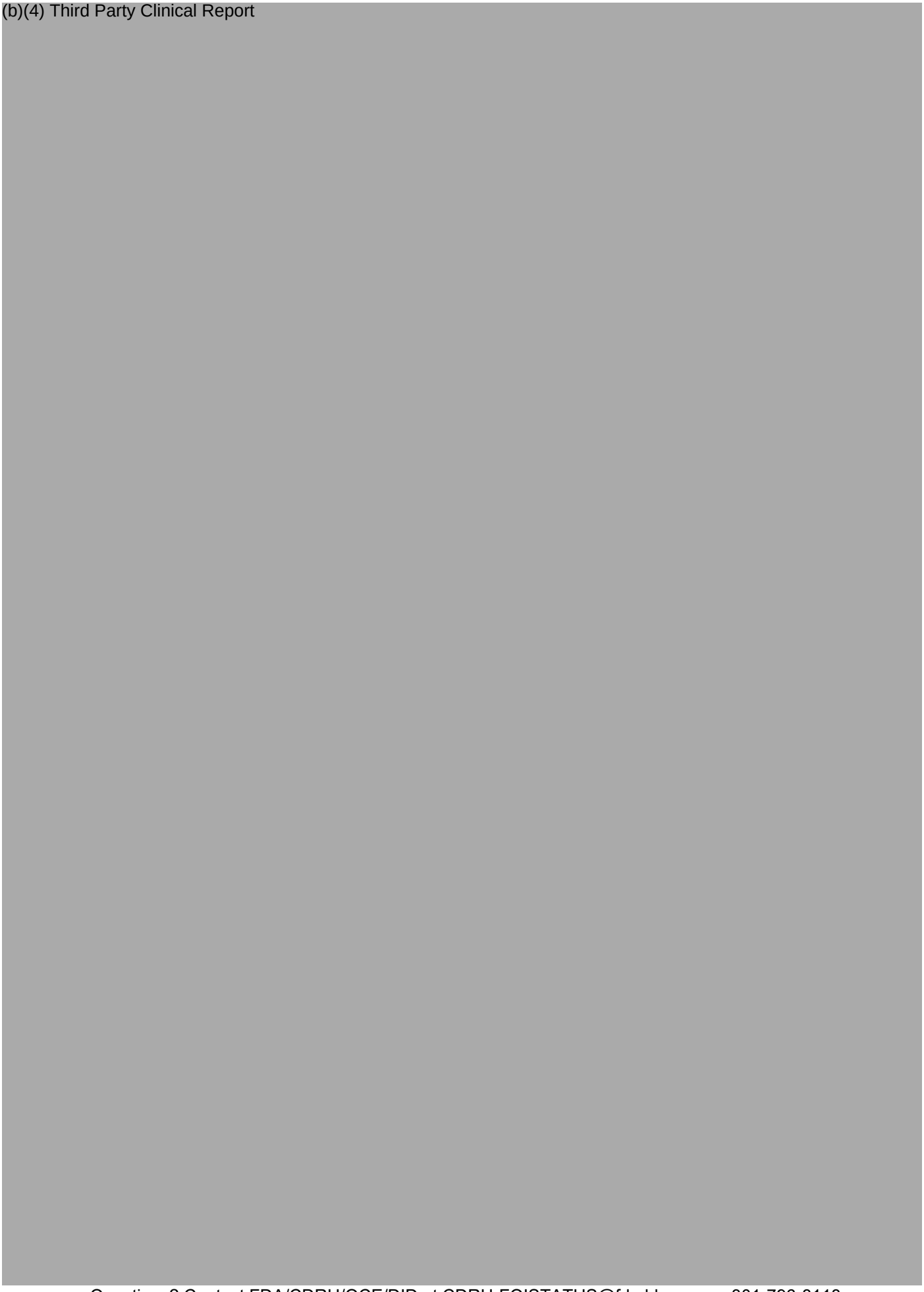
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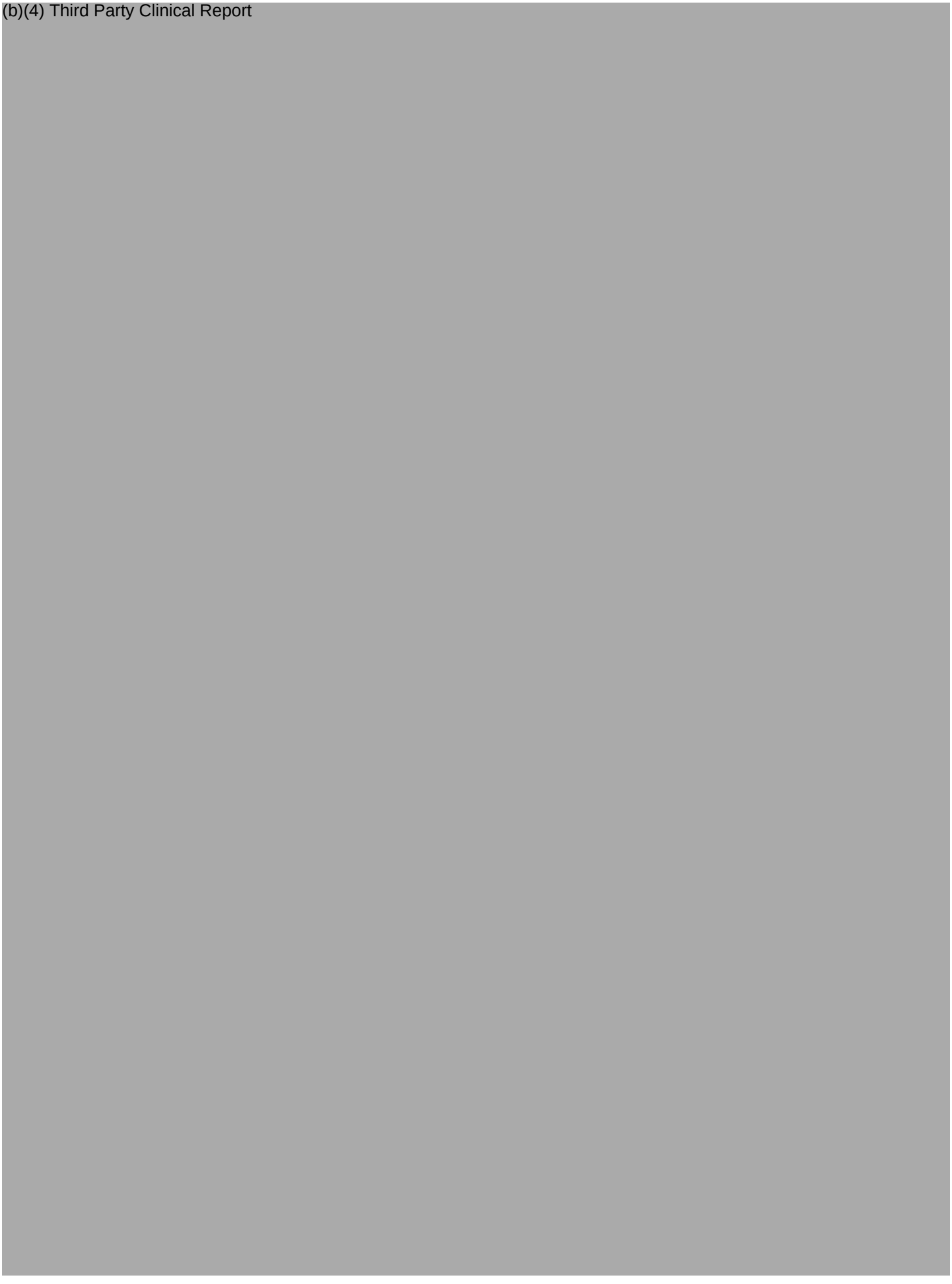
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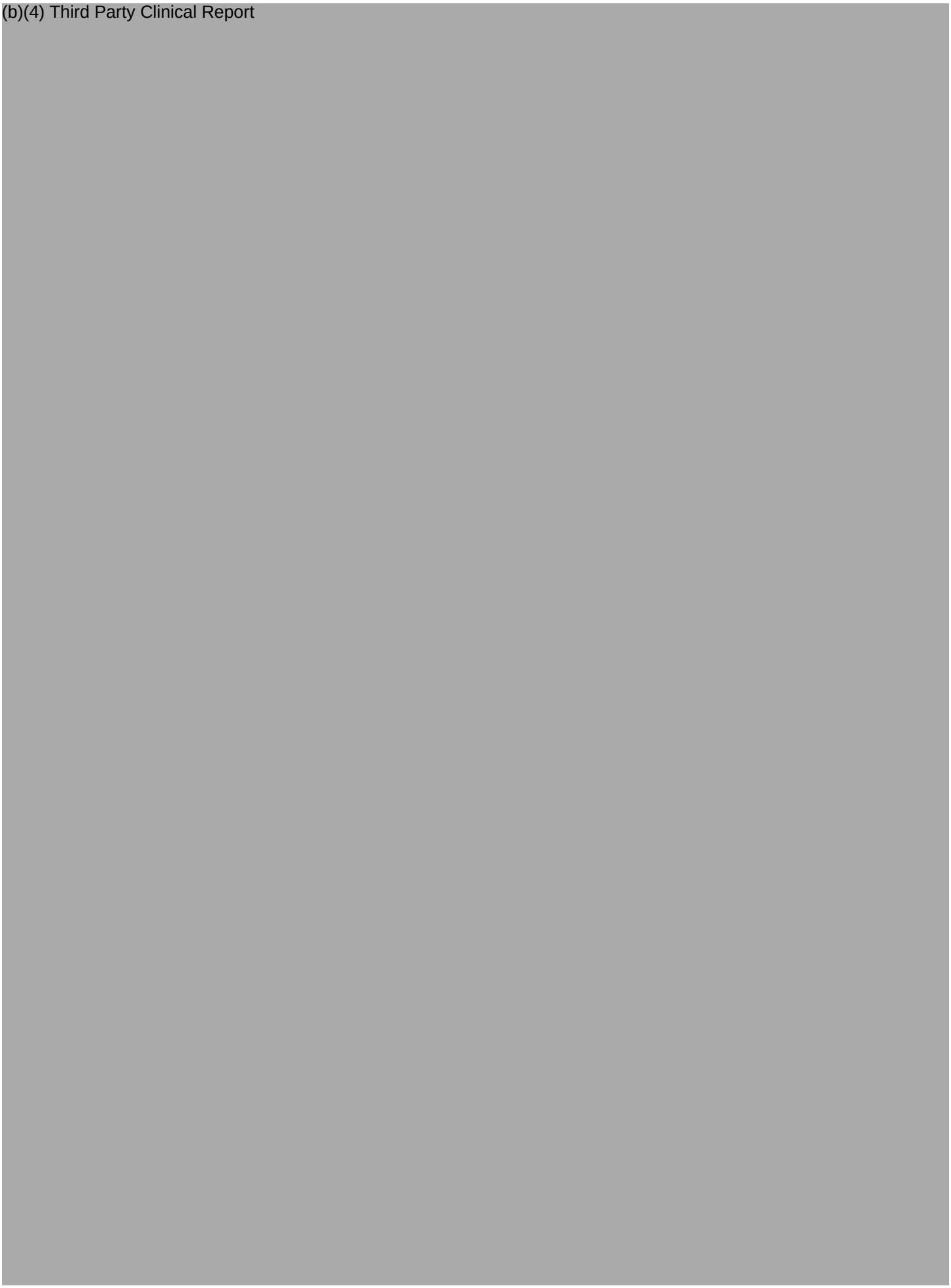
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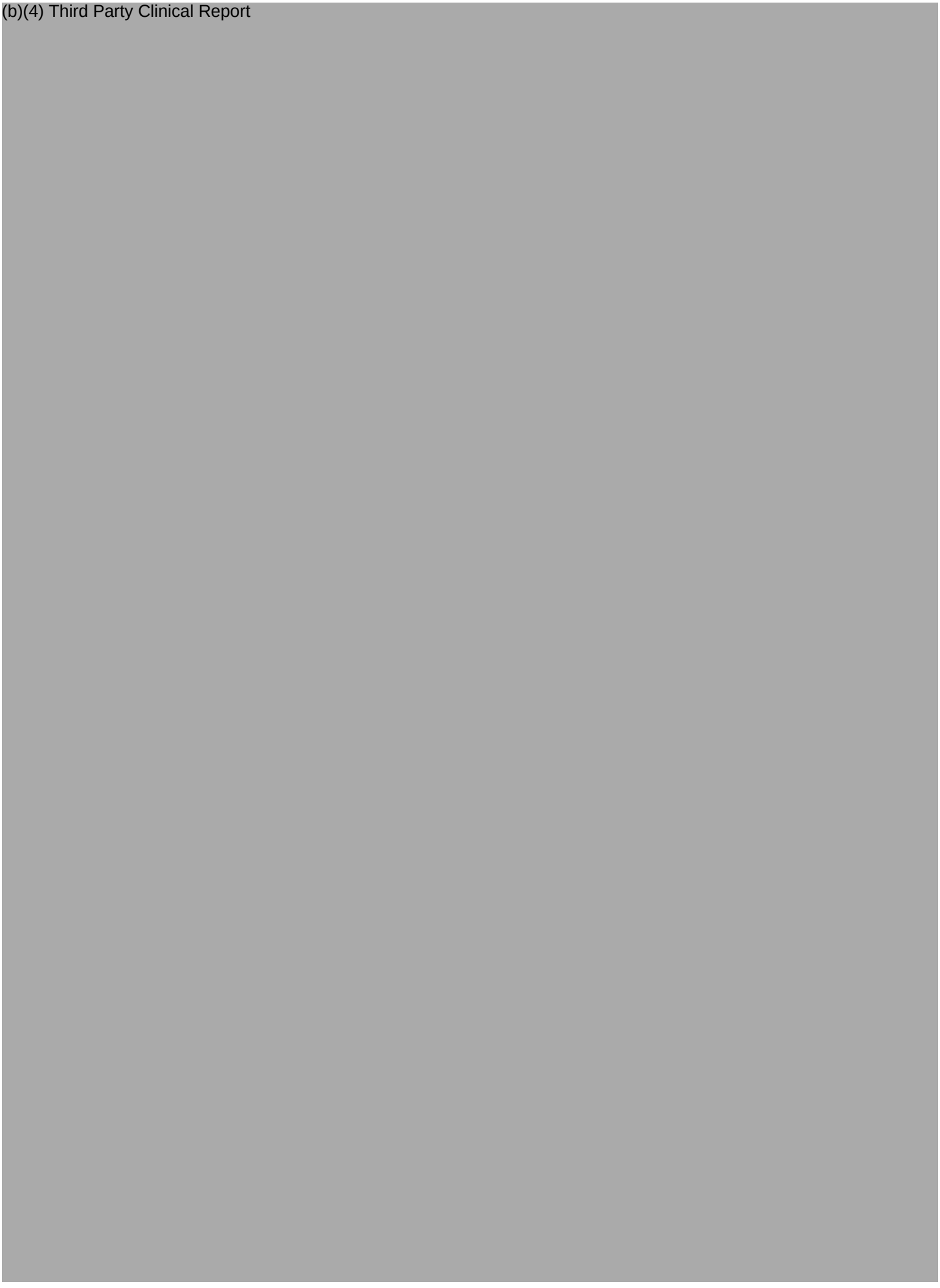
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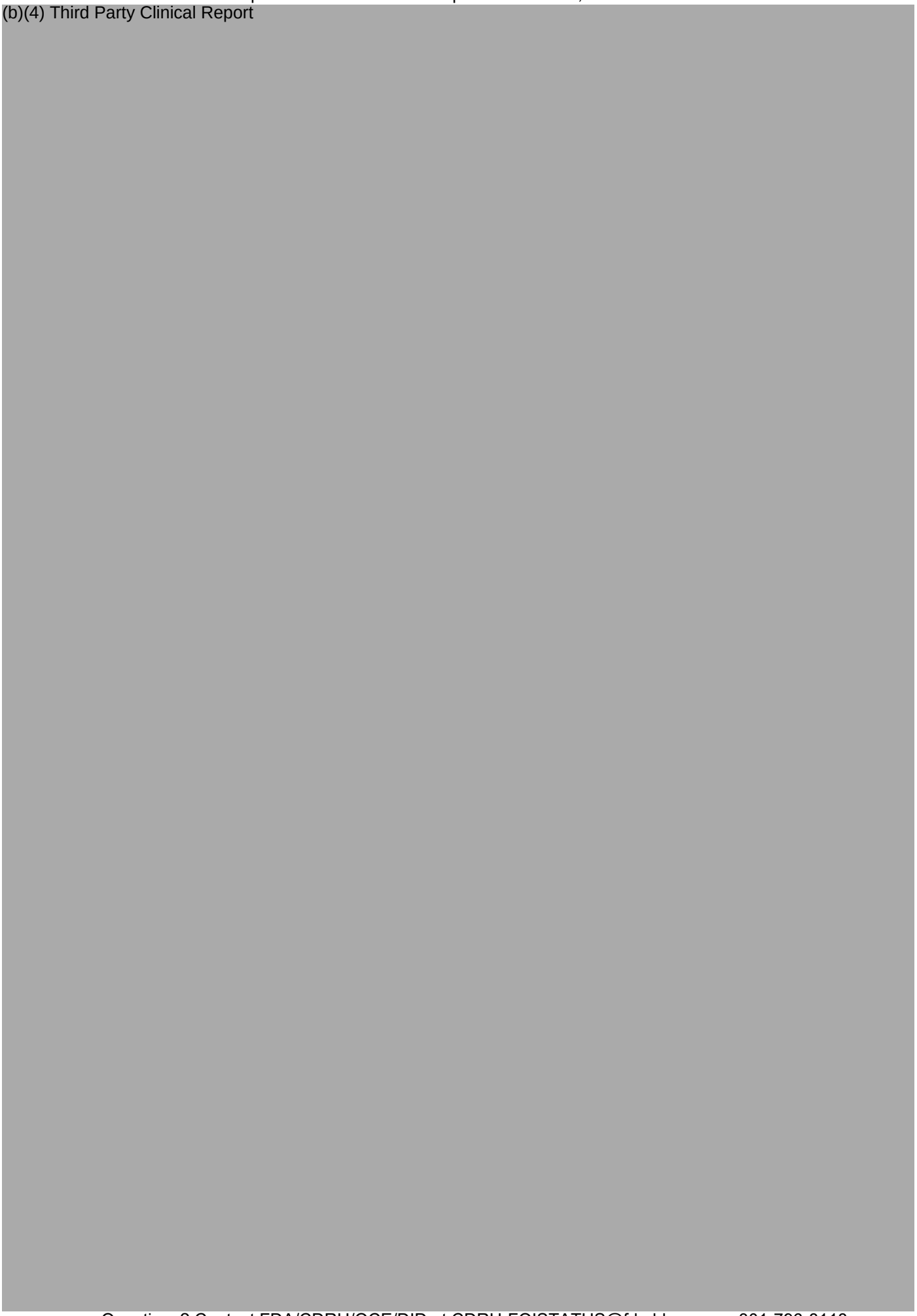
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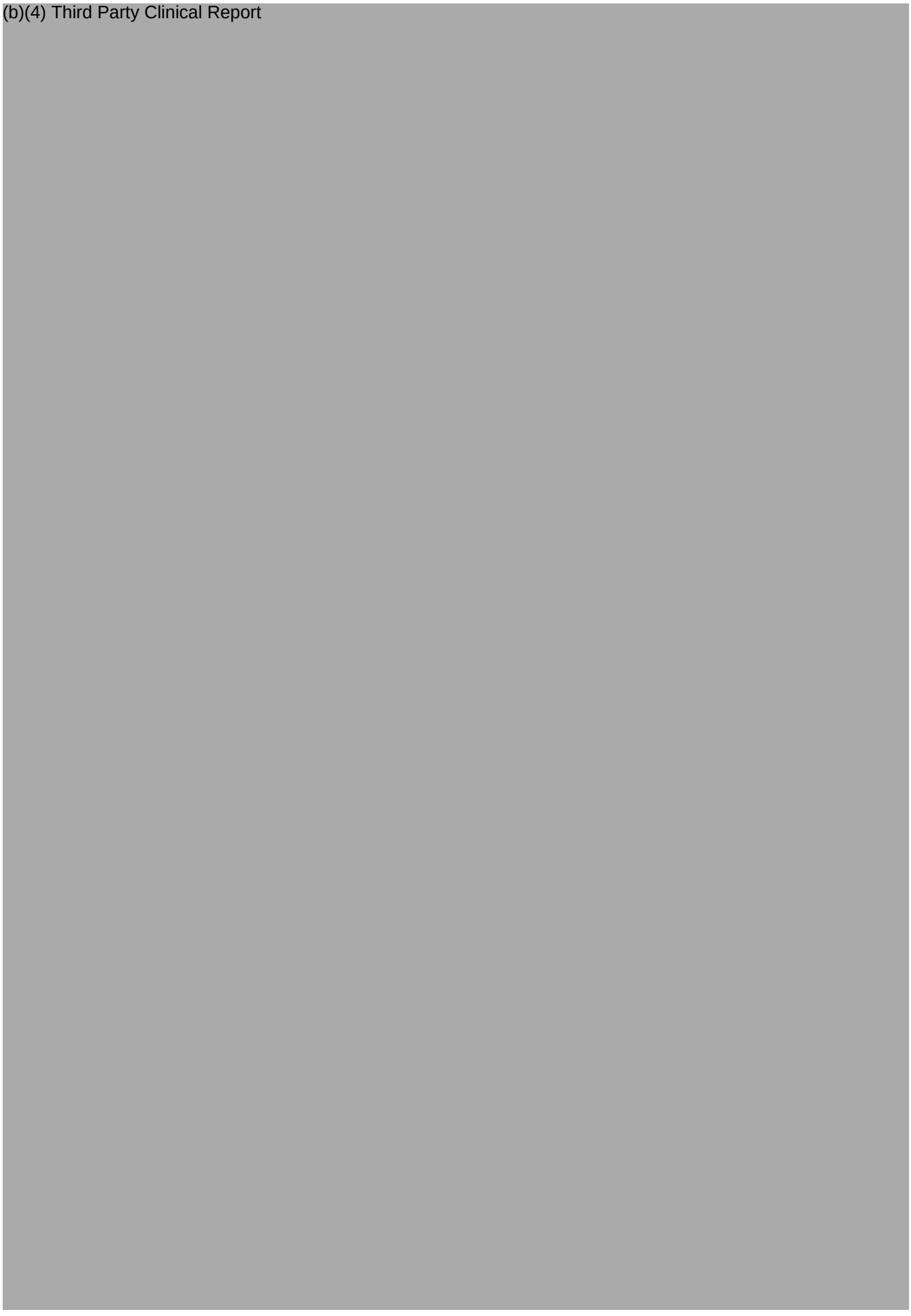
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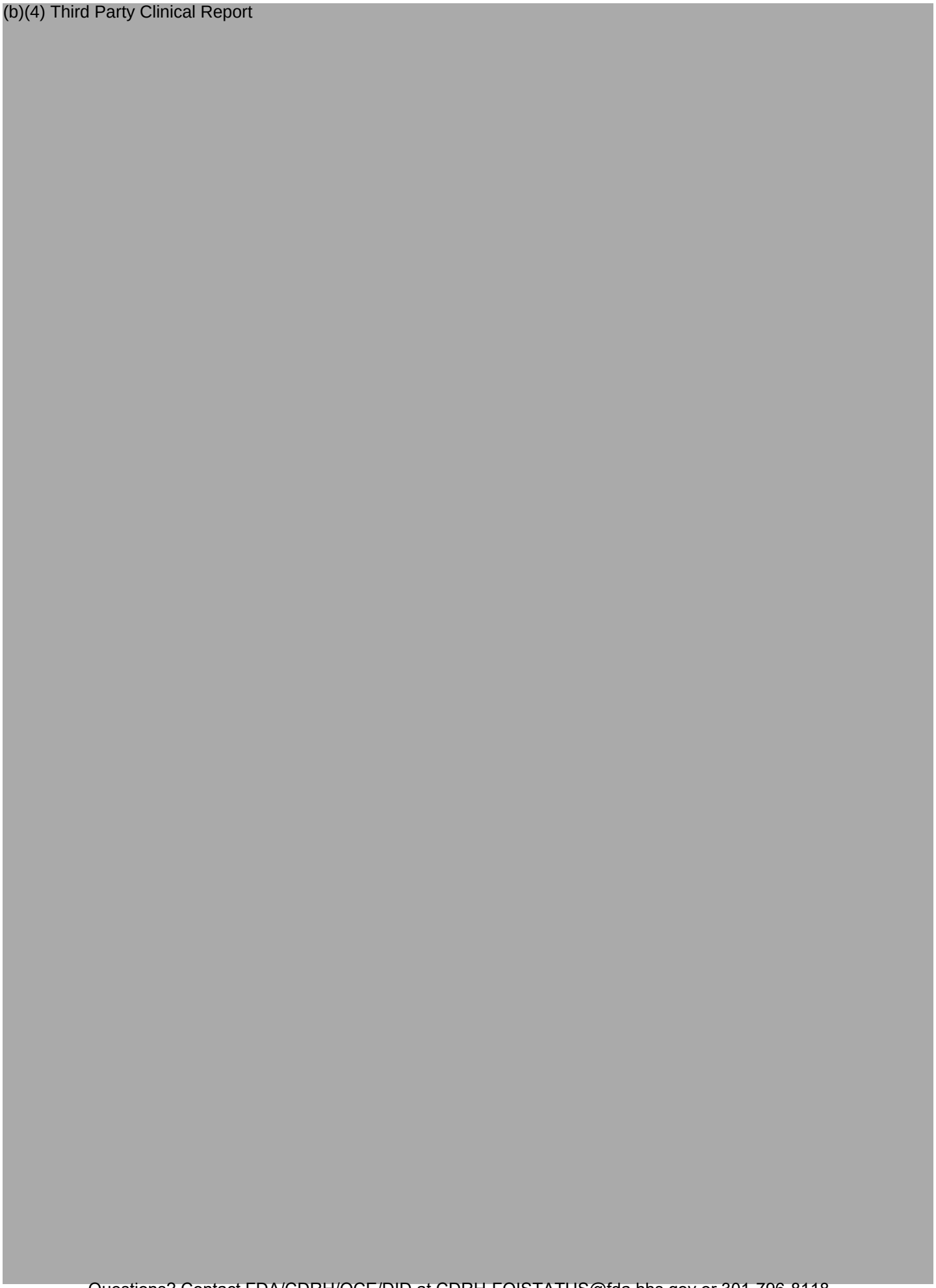
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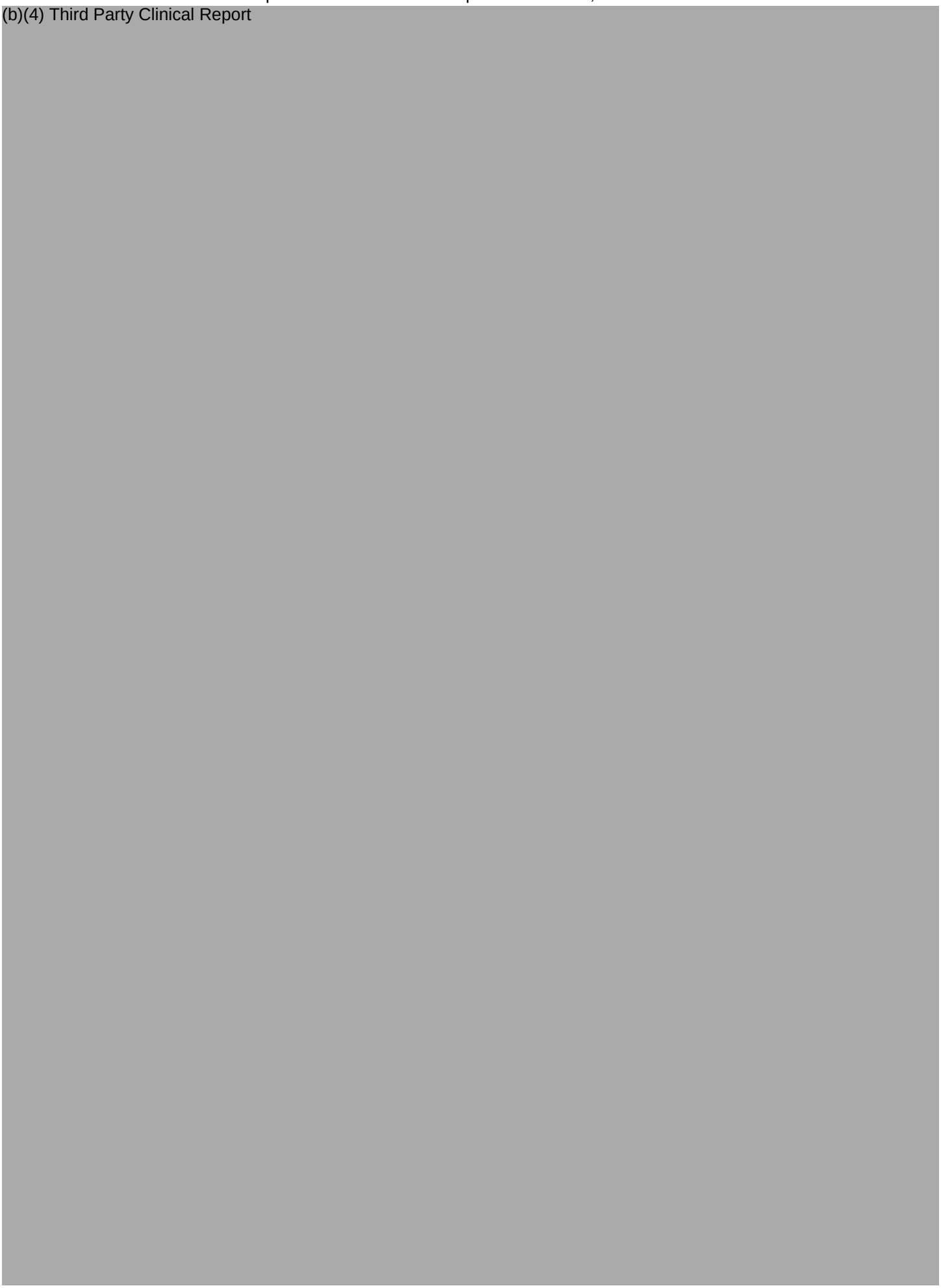
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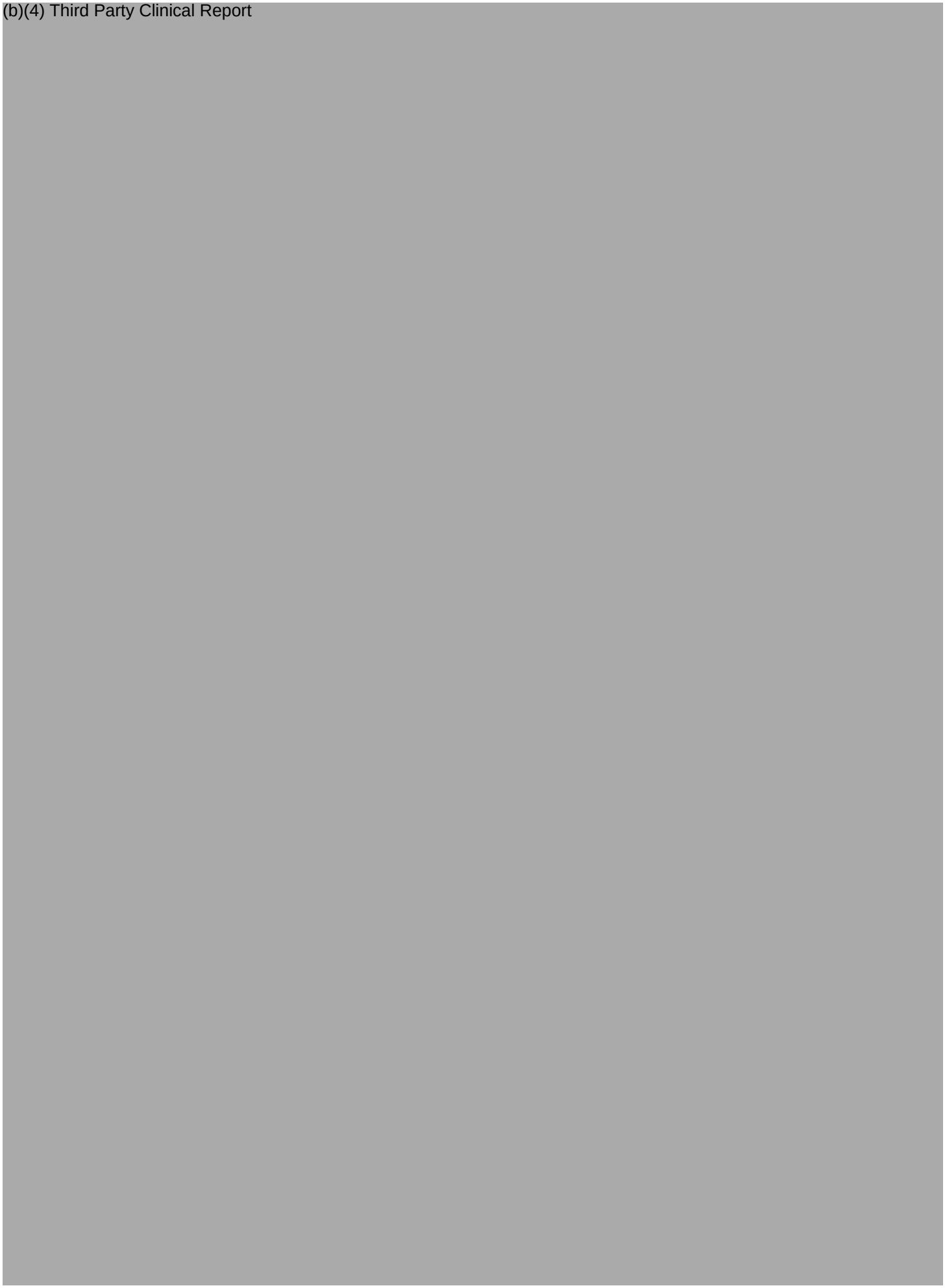
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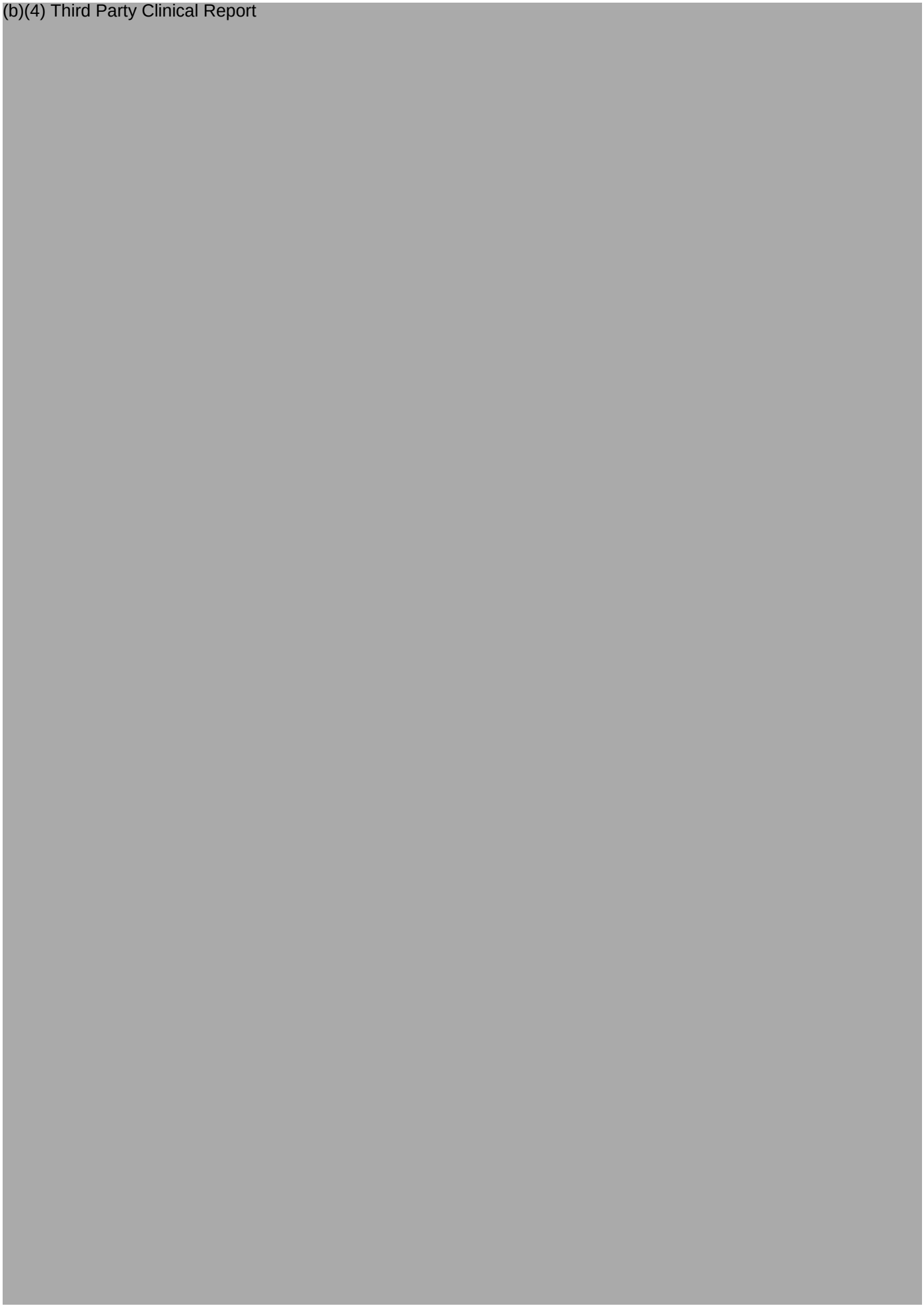
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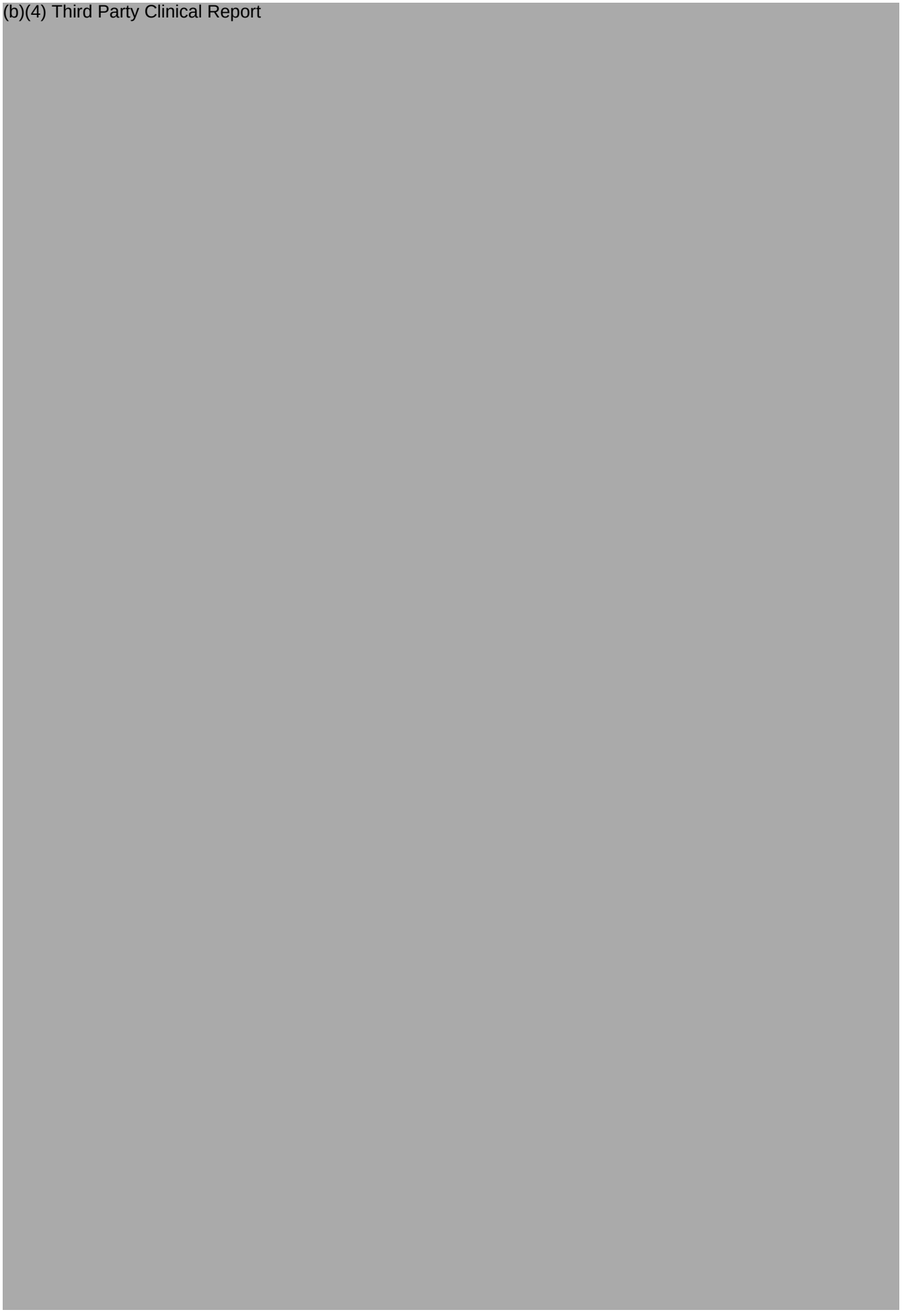
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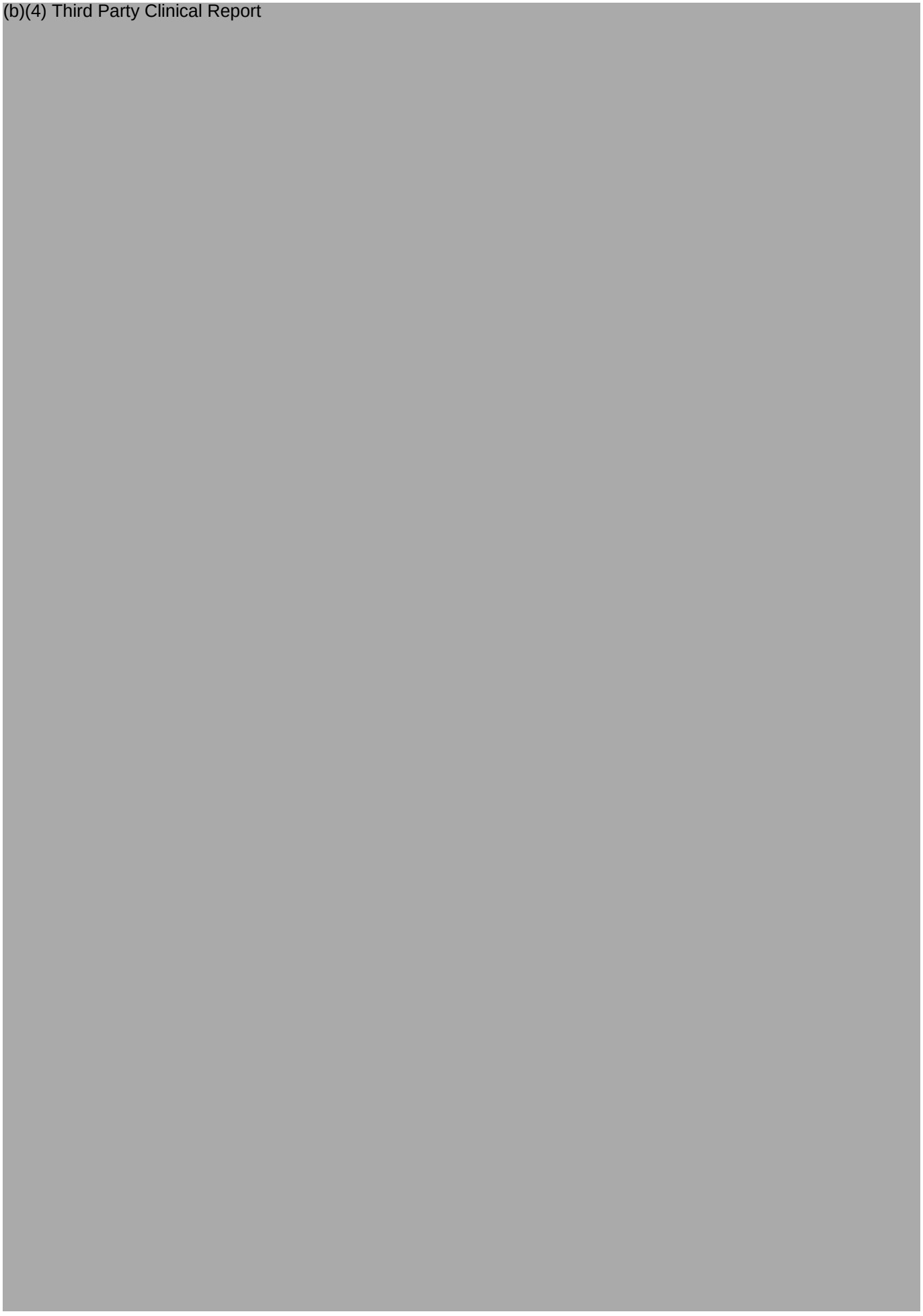
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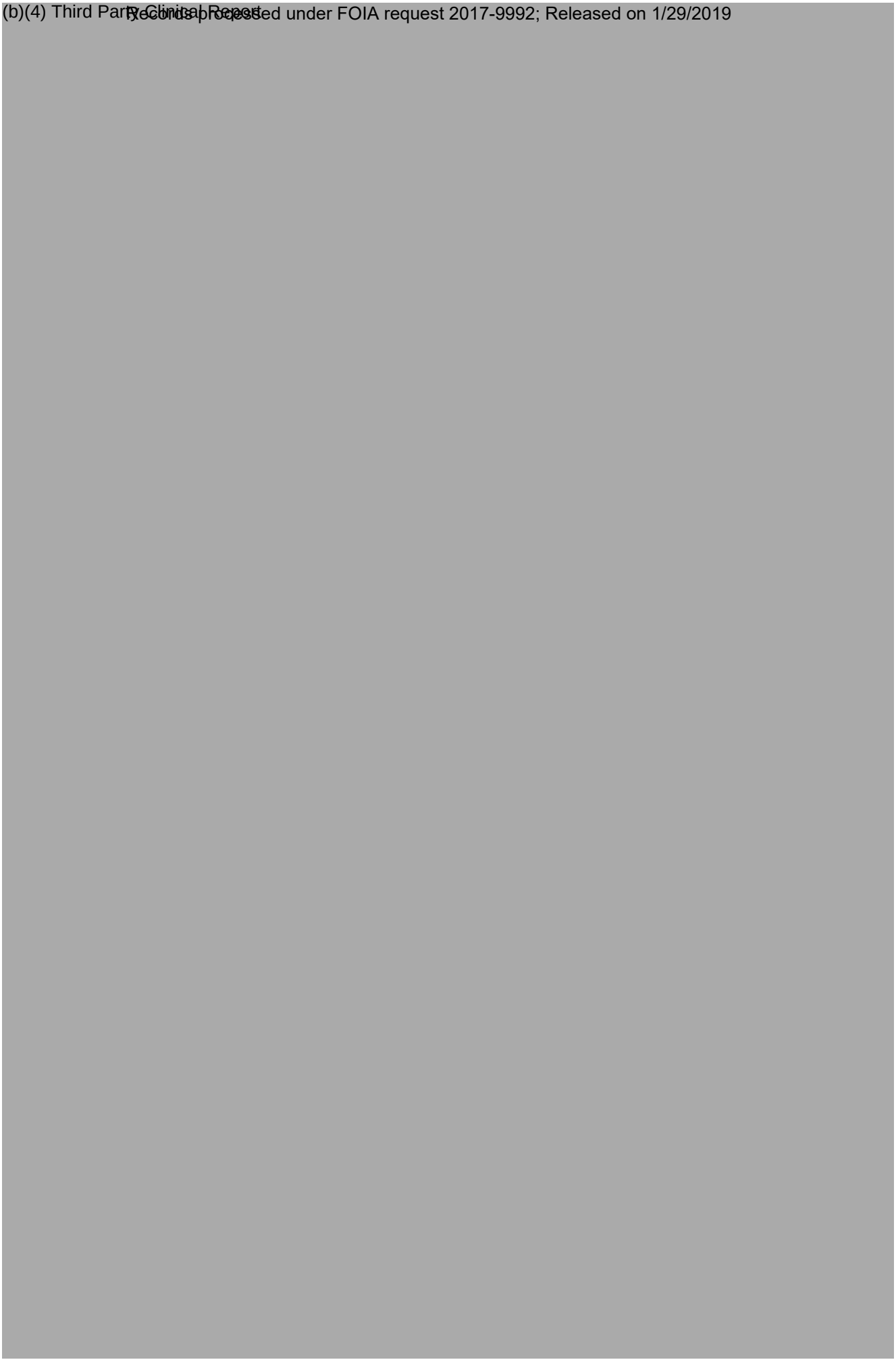
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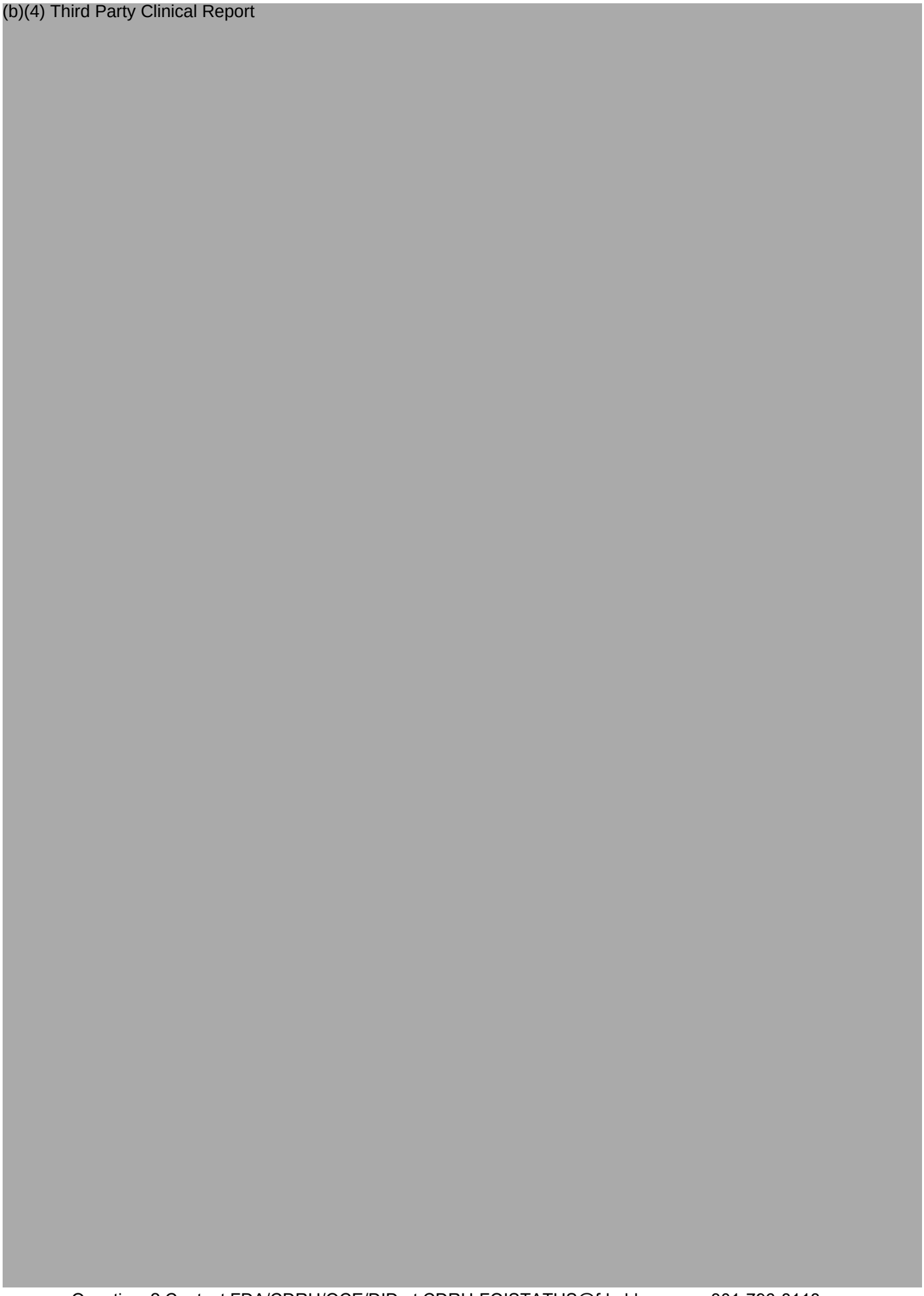
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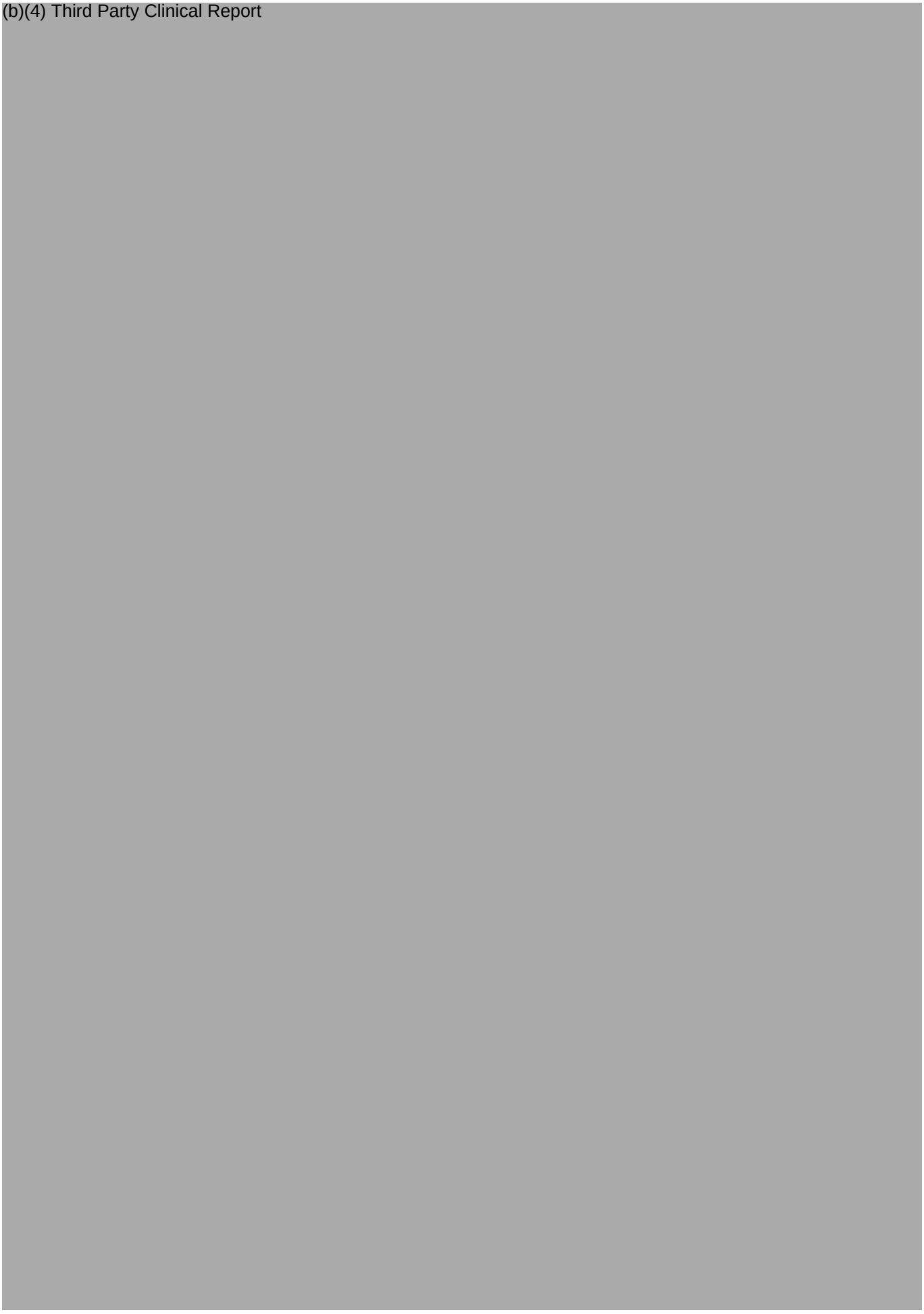
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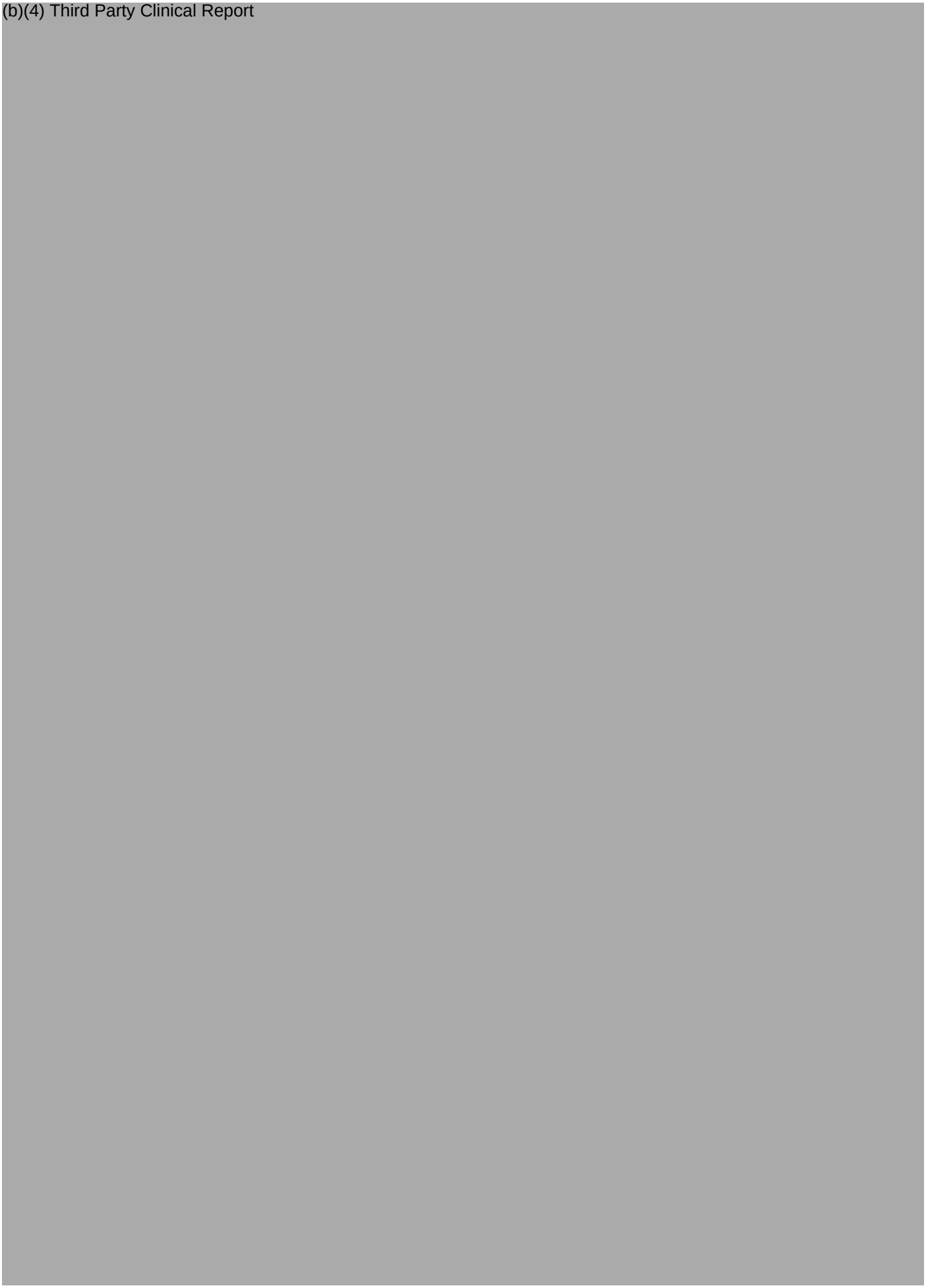
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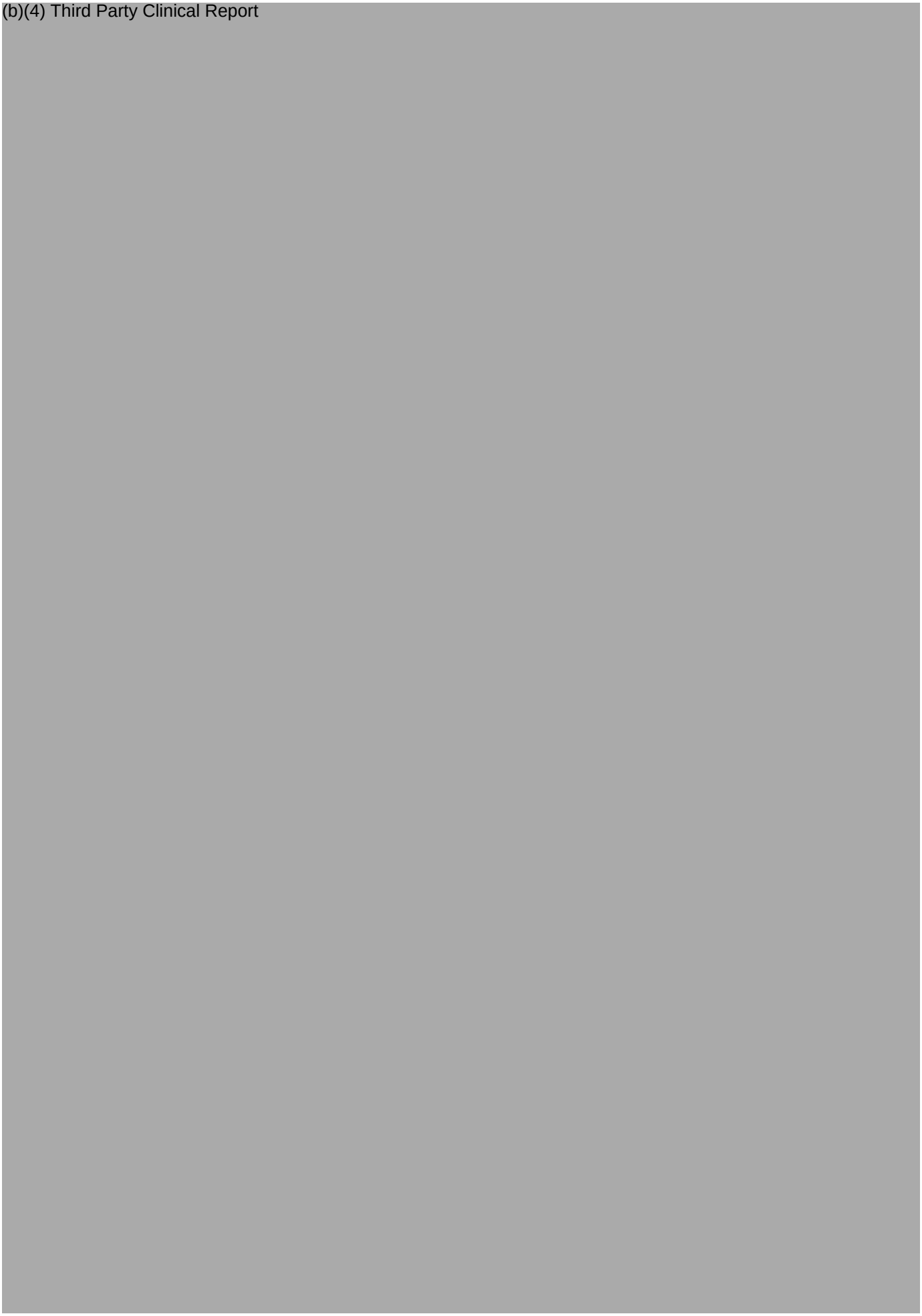
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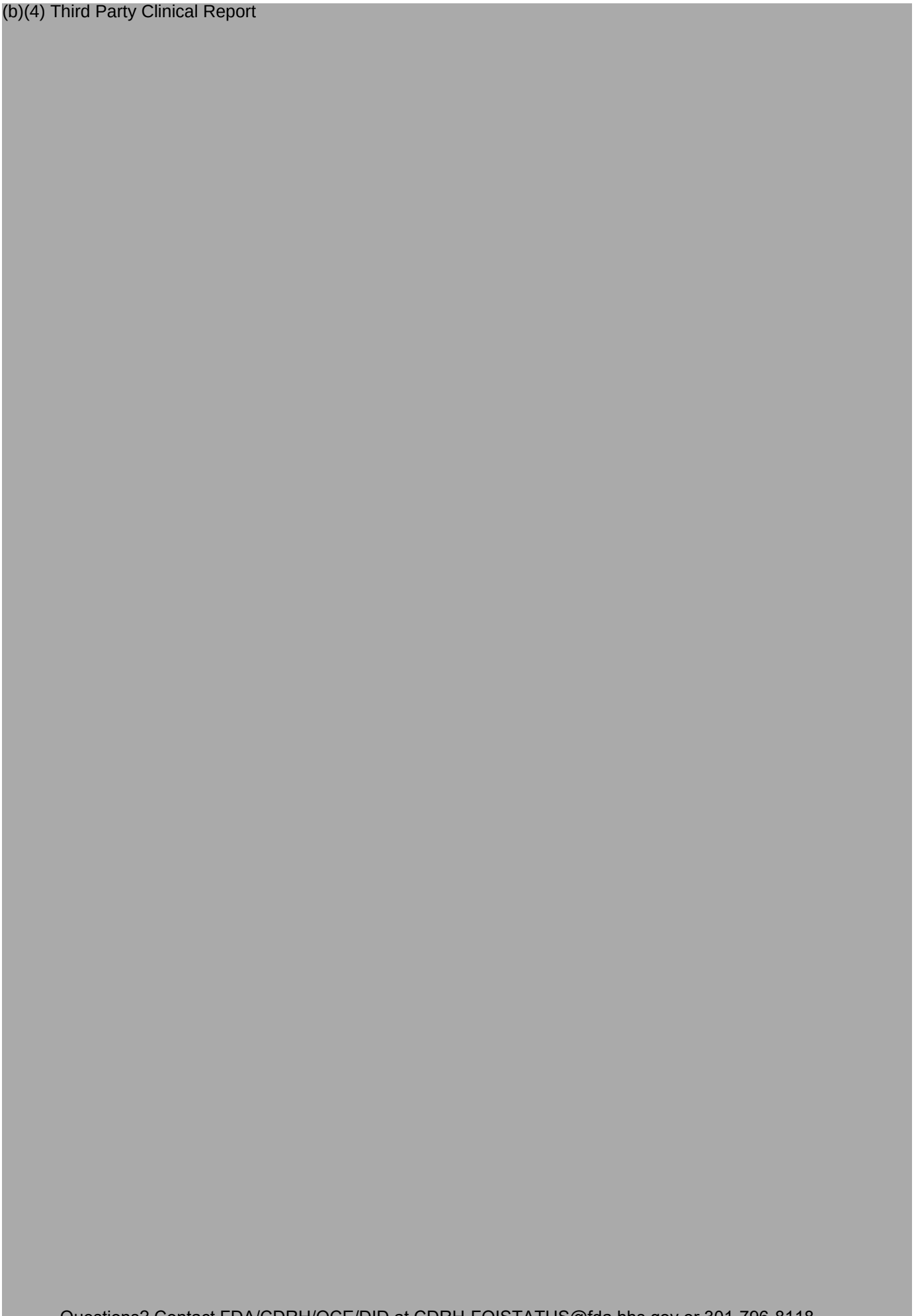
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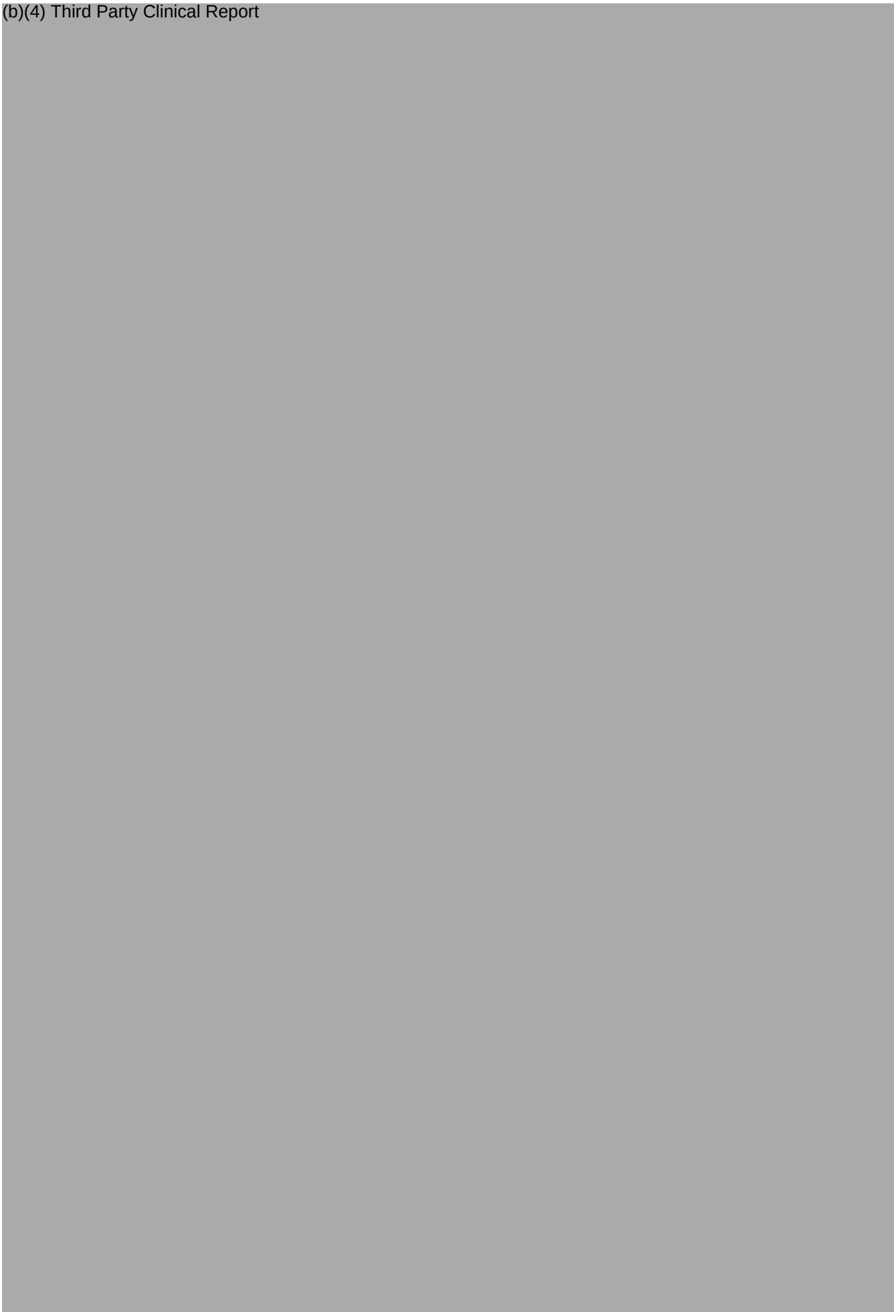
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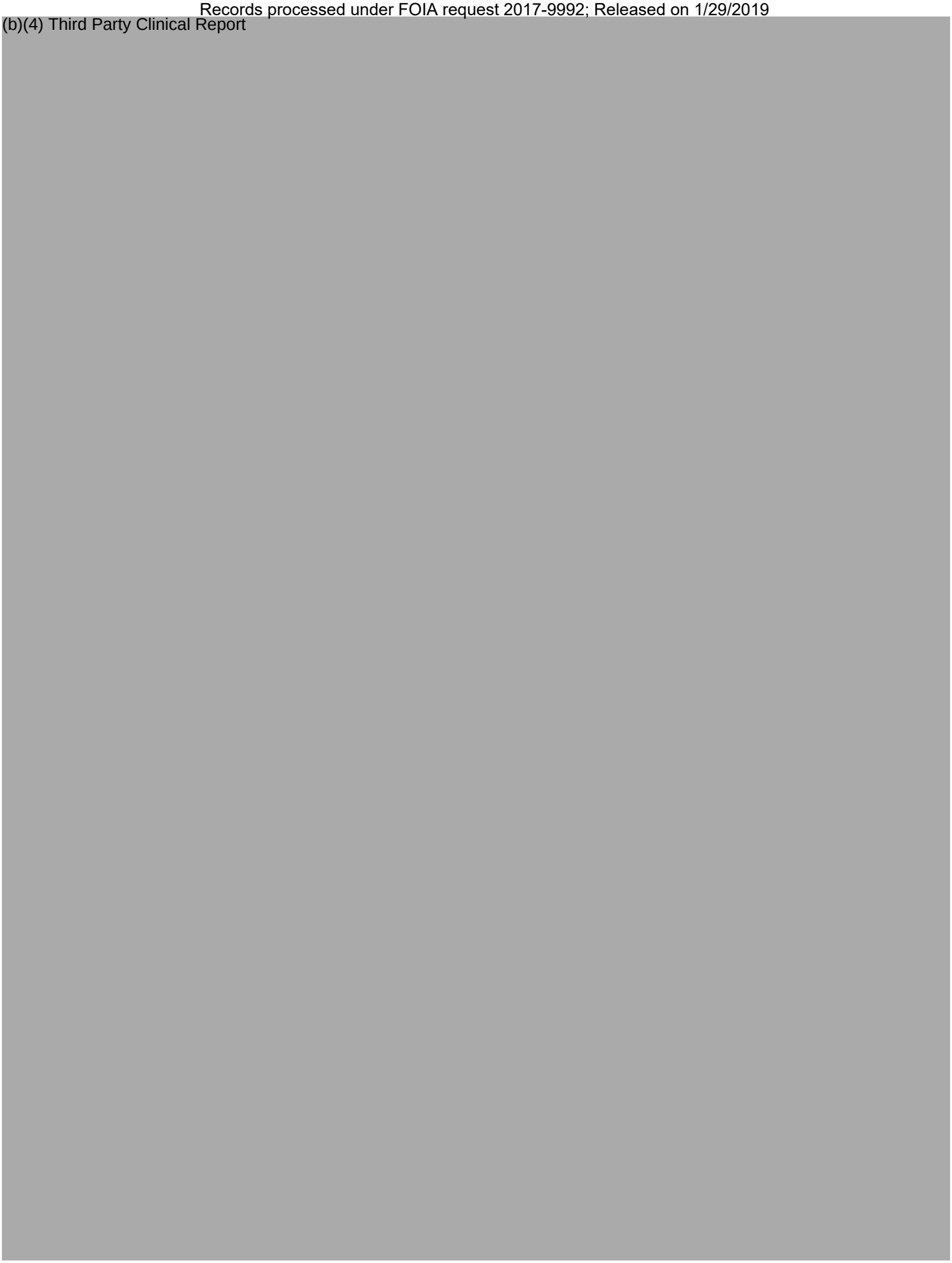
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Appendix C: List of Sites, Investigators and IRB Information

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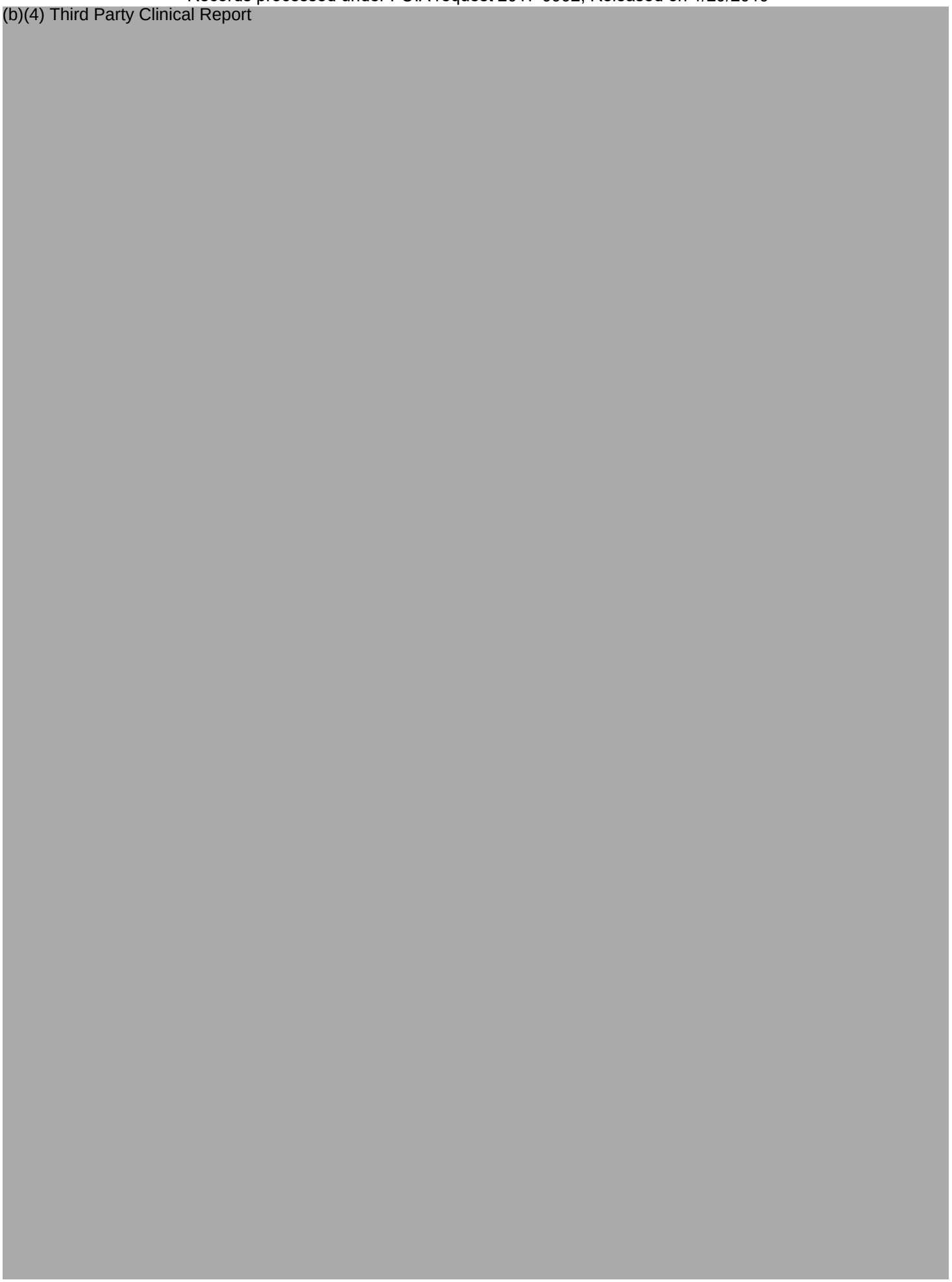
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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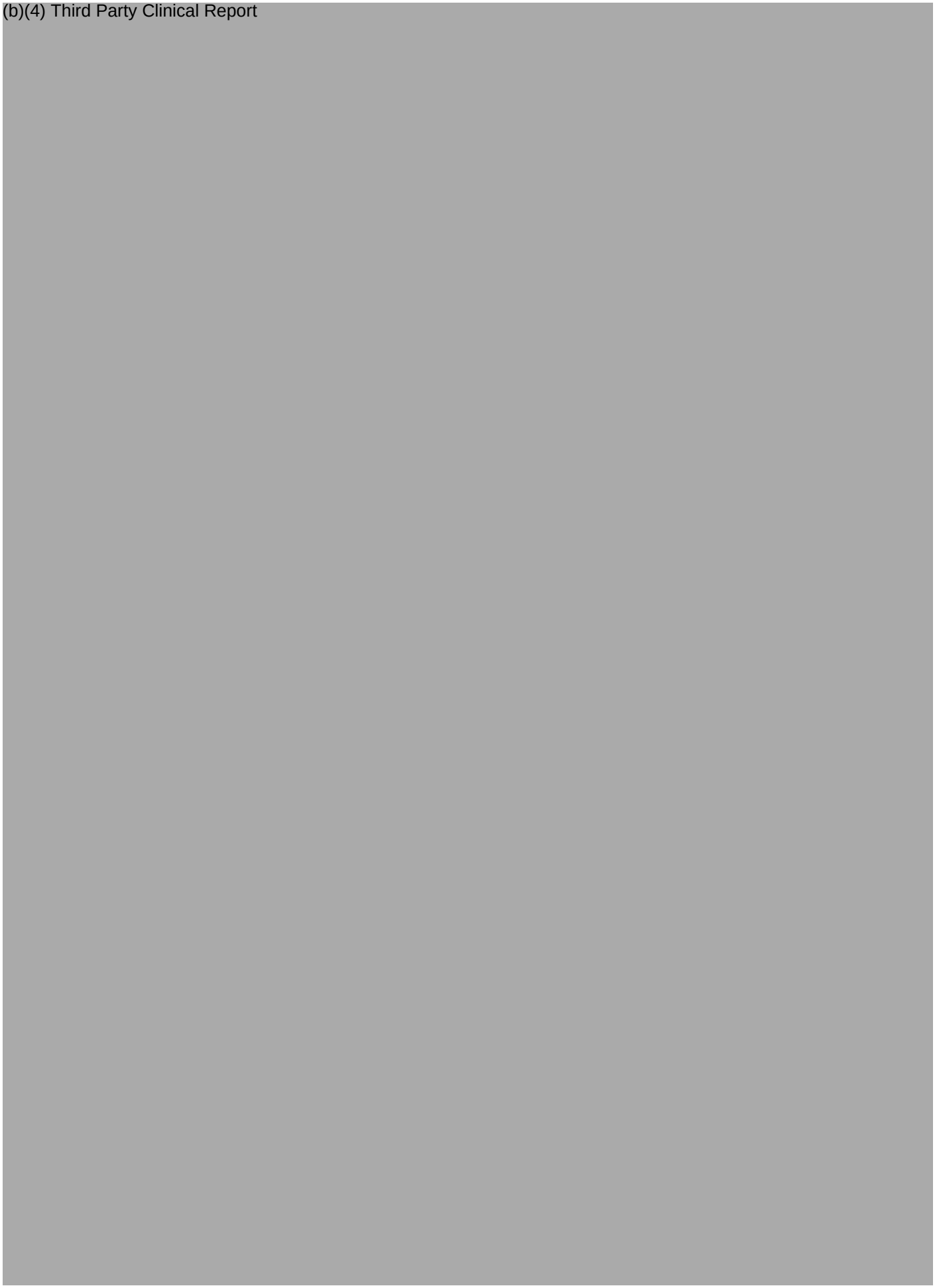
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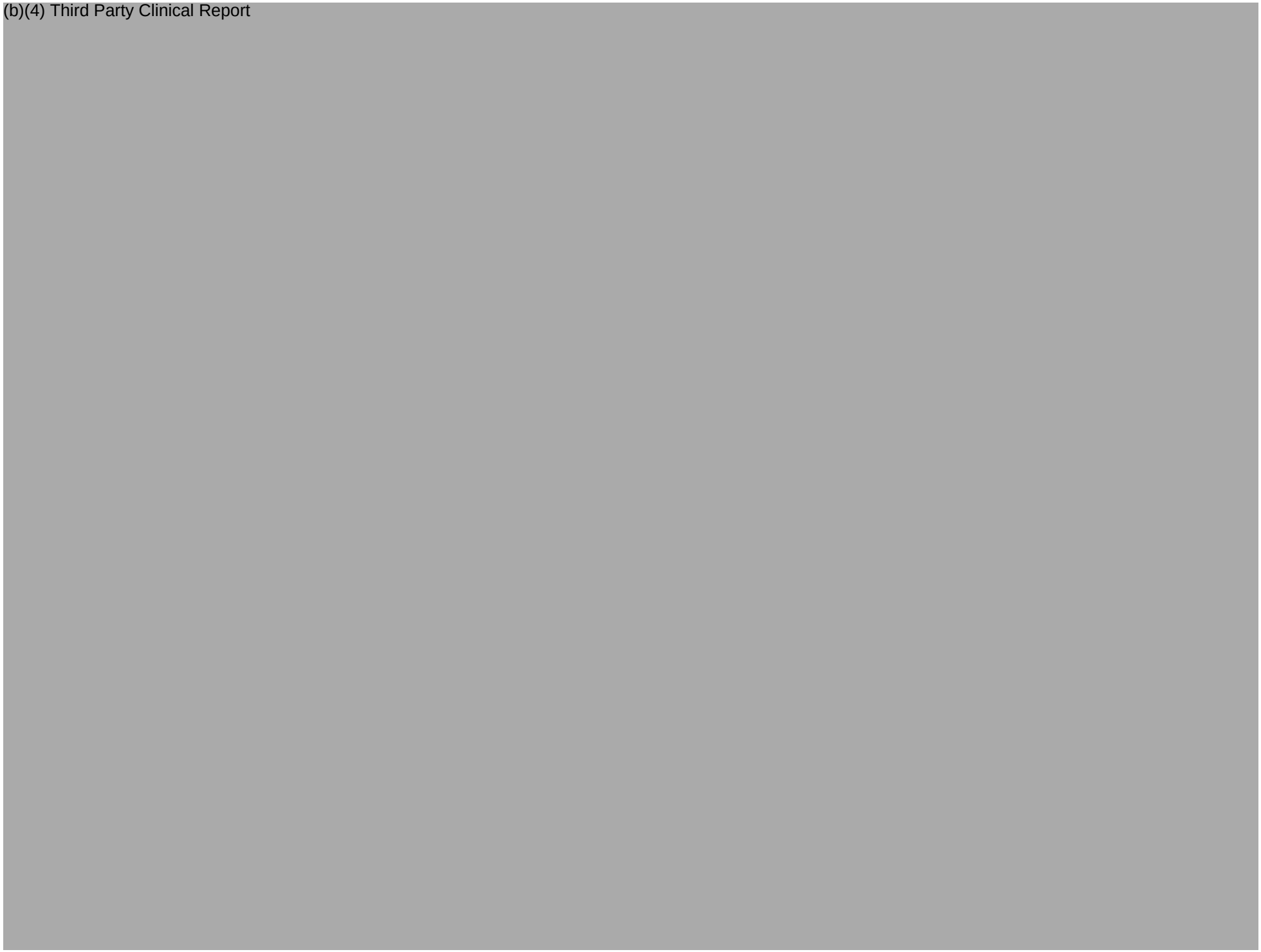
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Appendix D: Subject Listing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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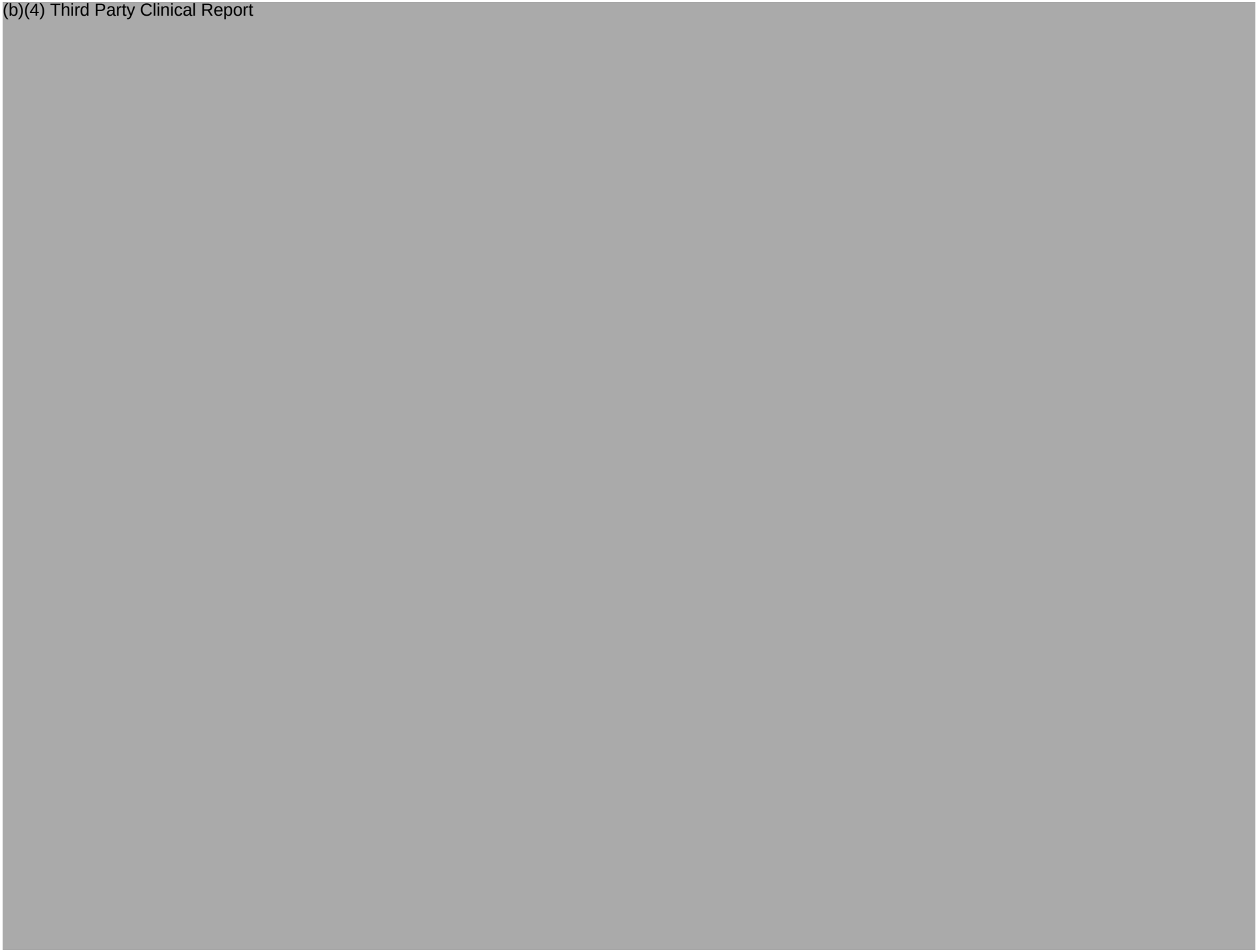
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

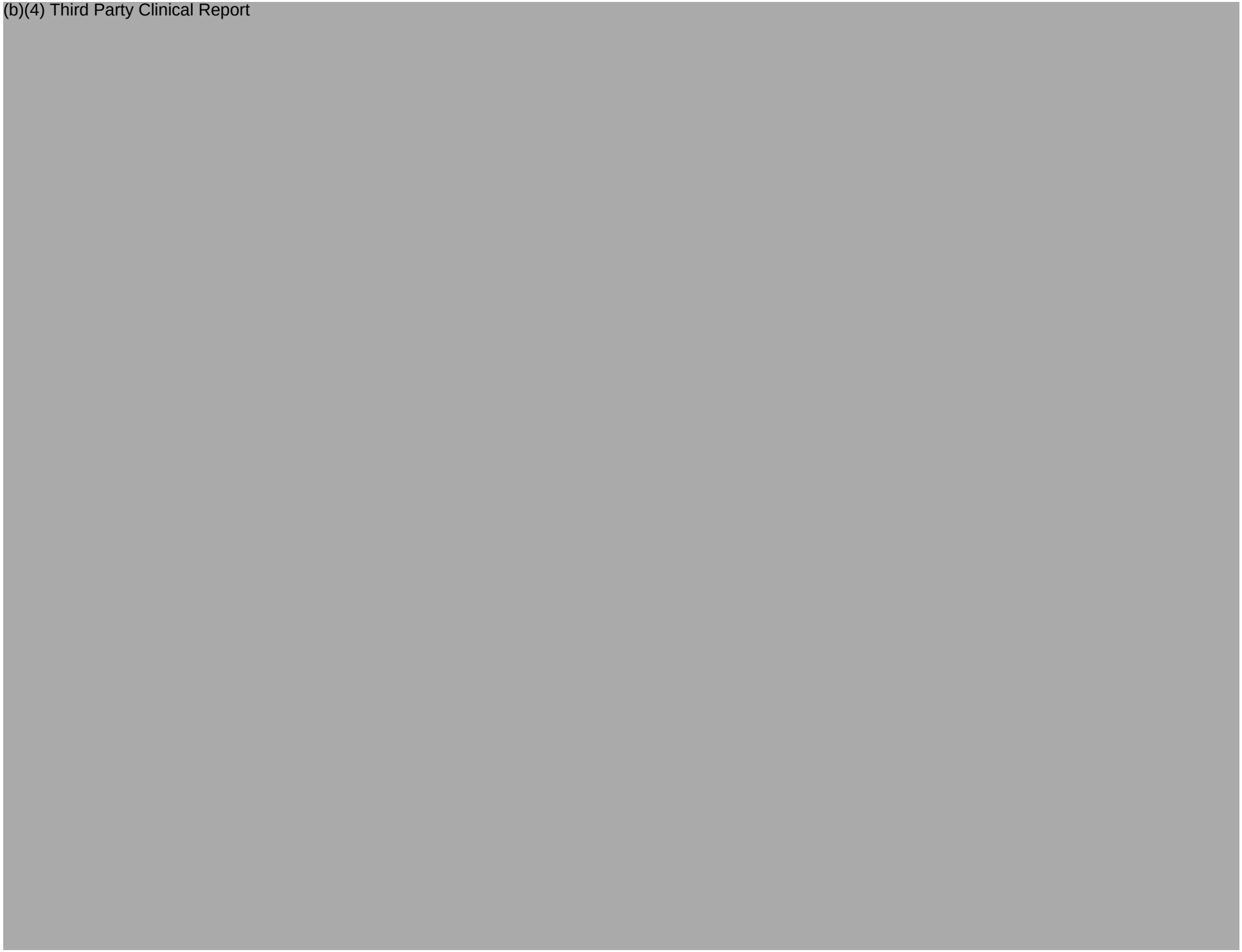
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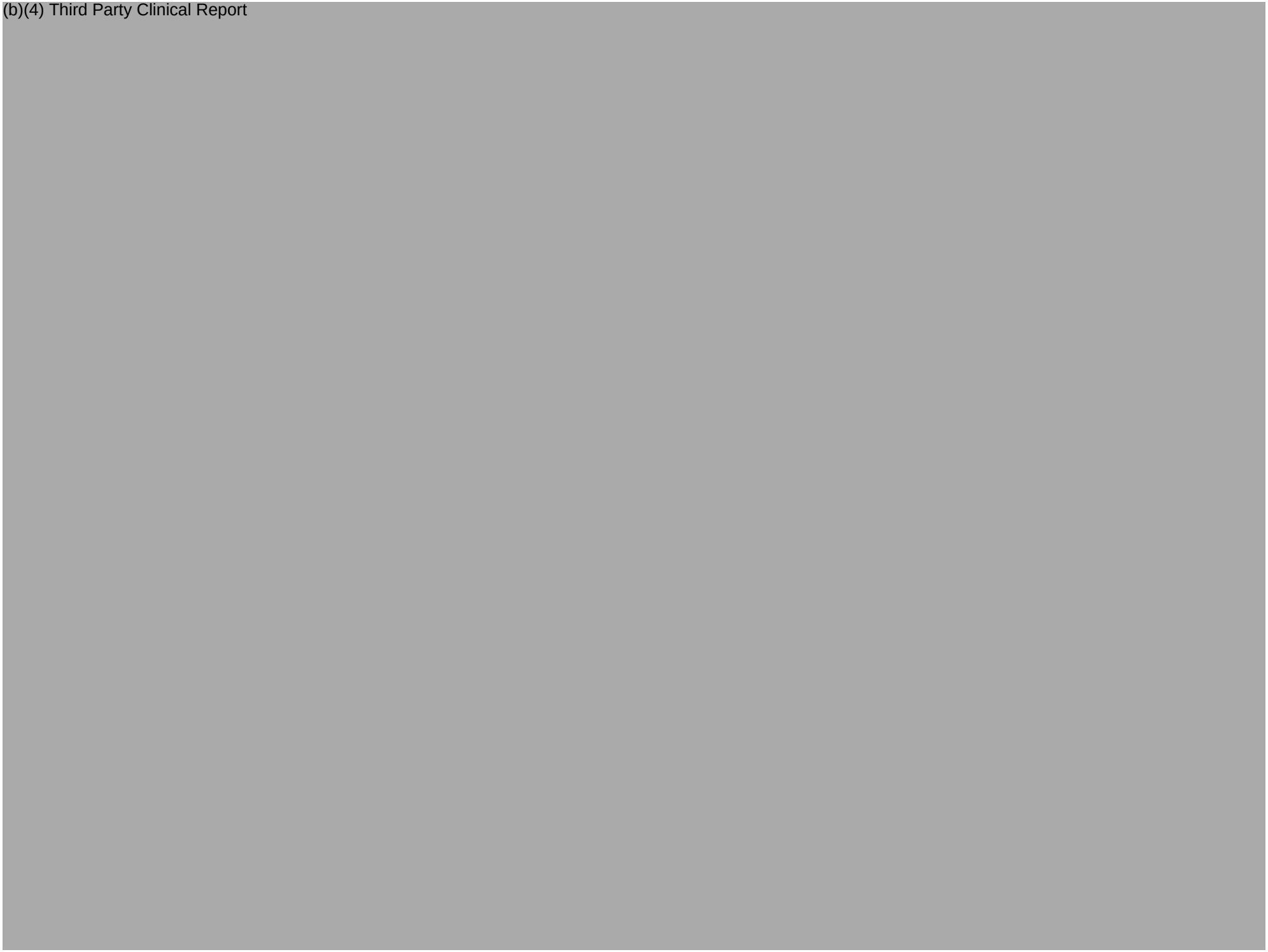
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

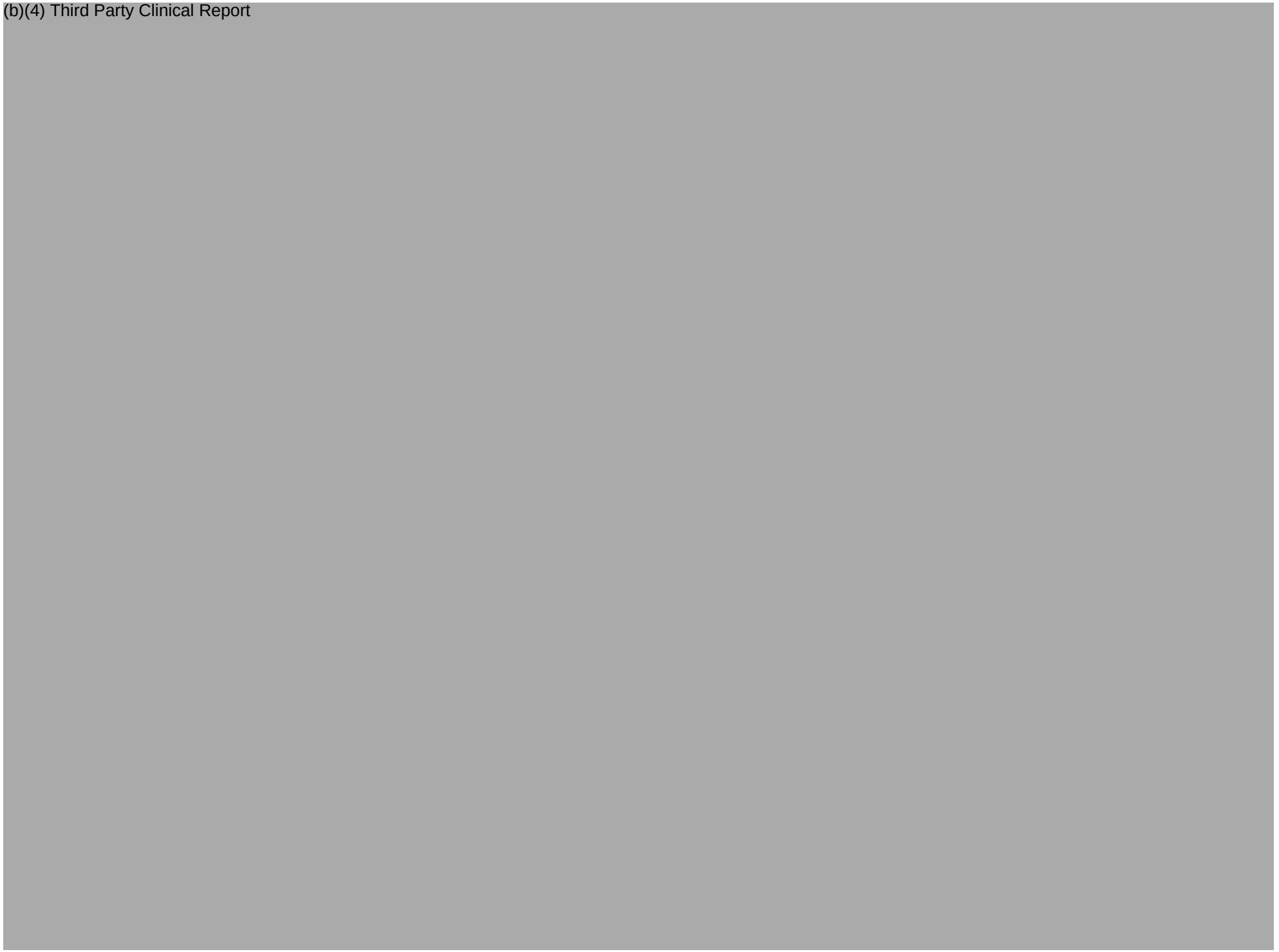
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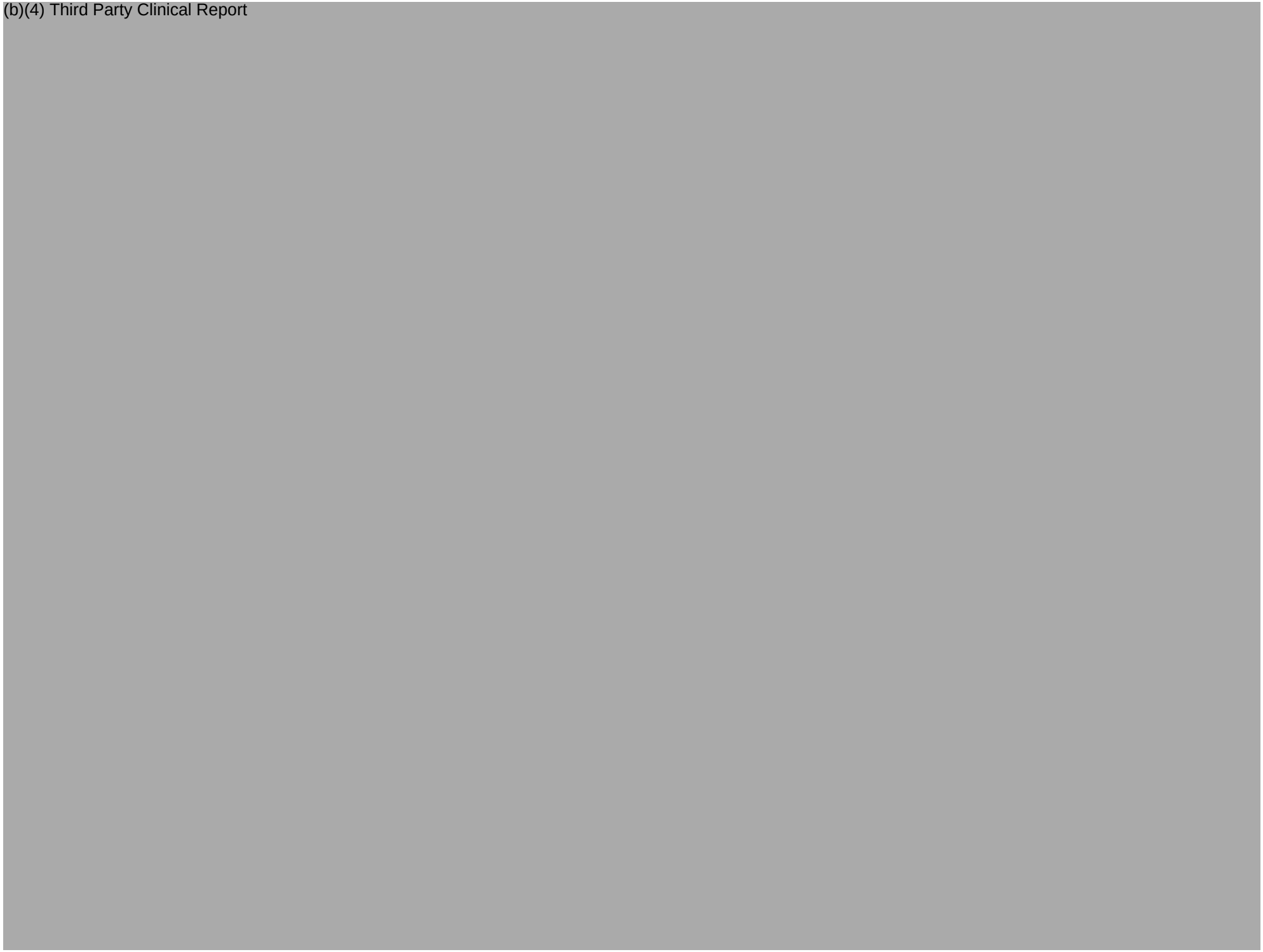
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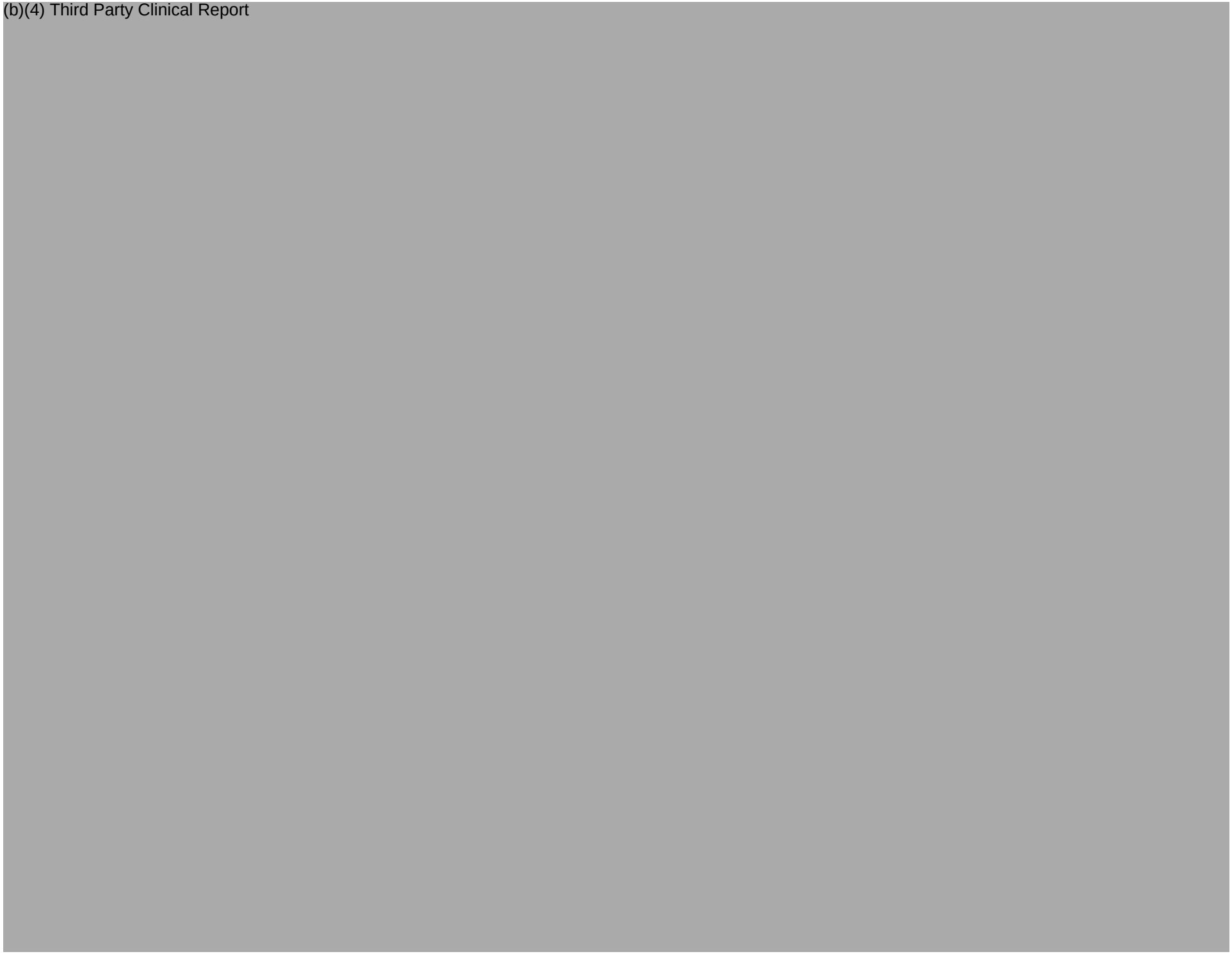
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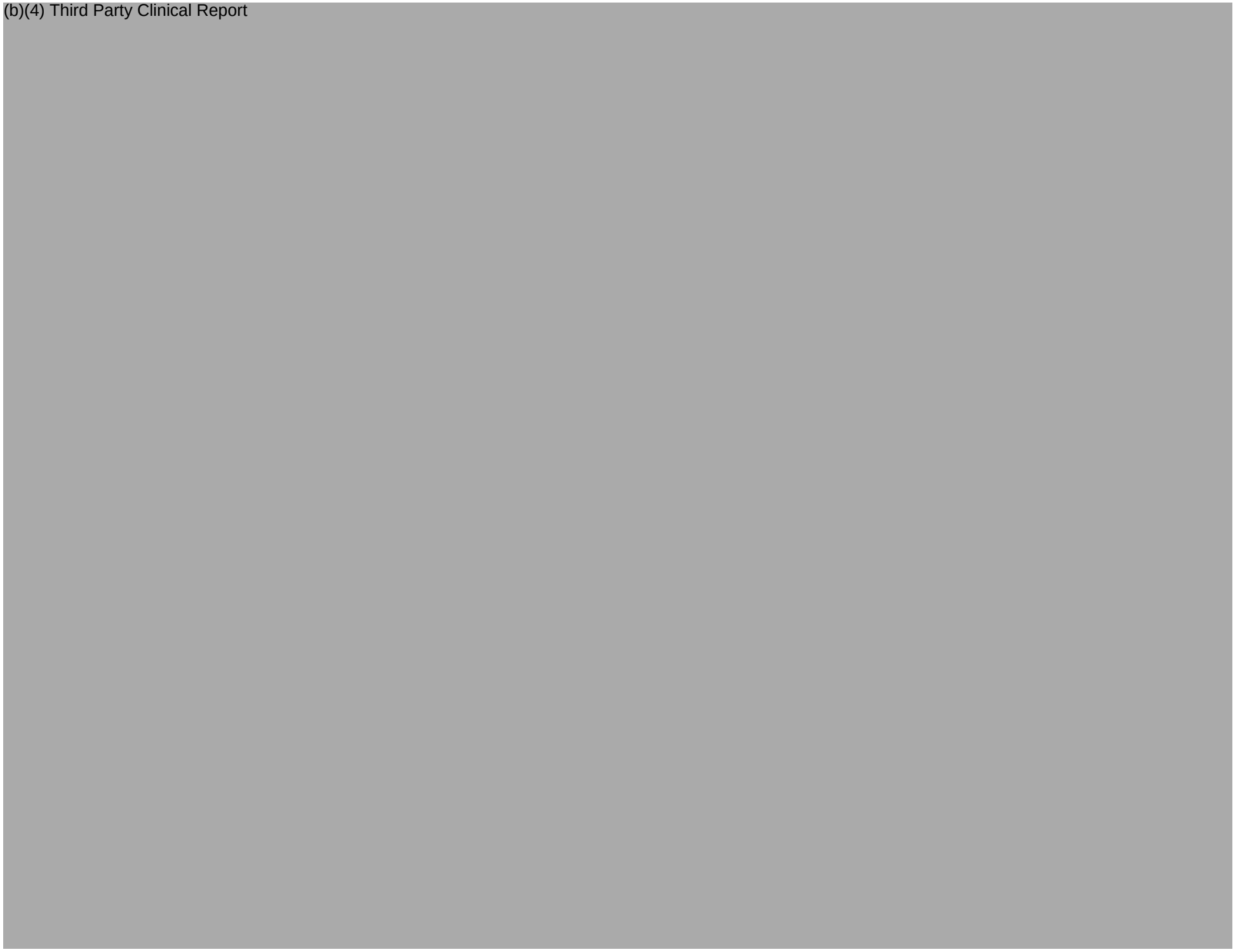
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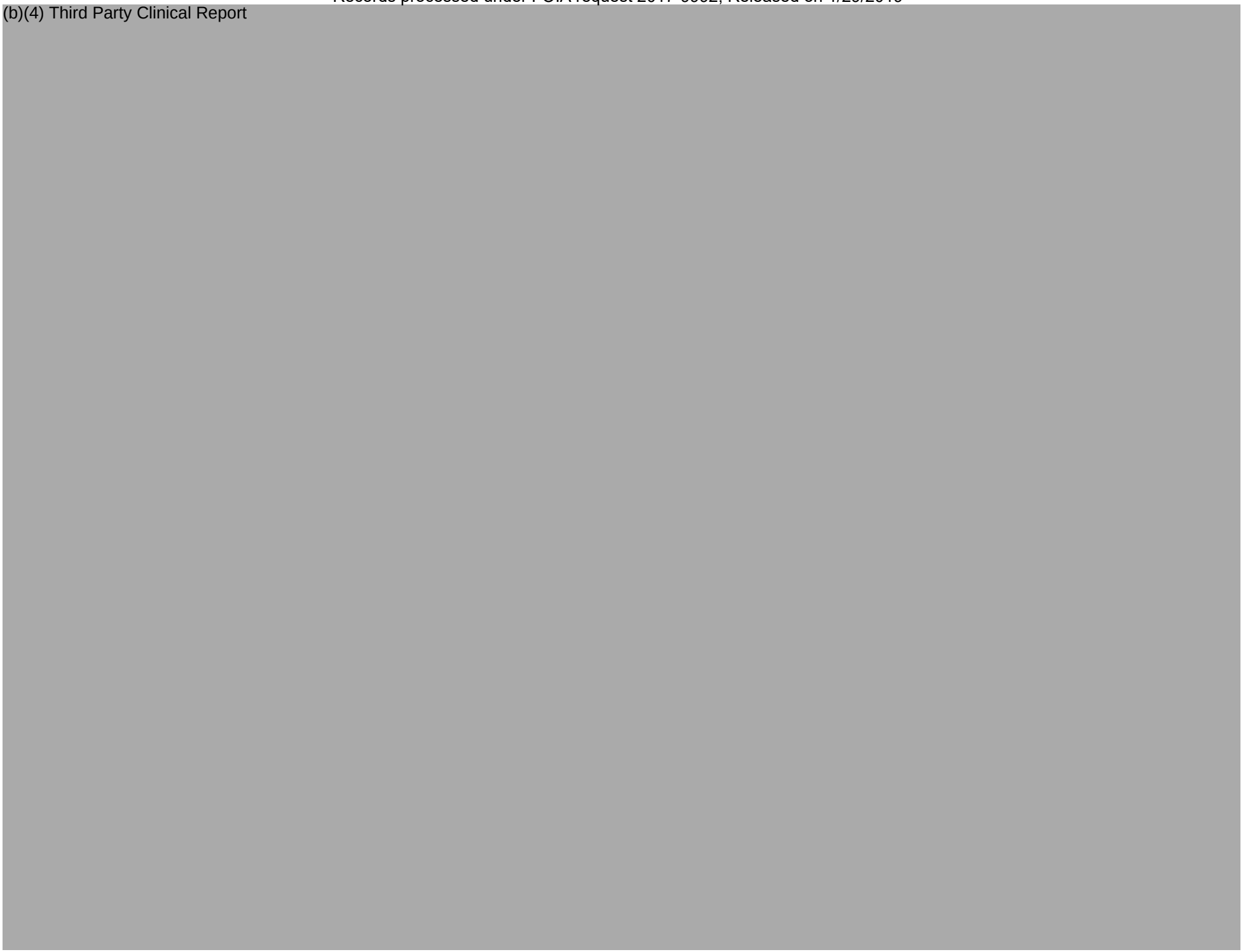
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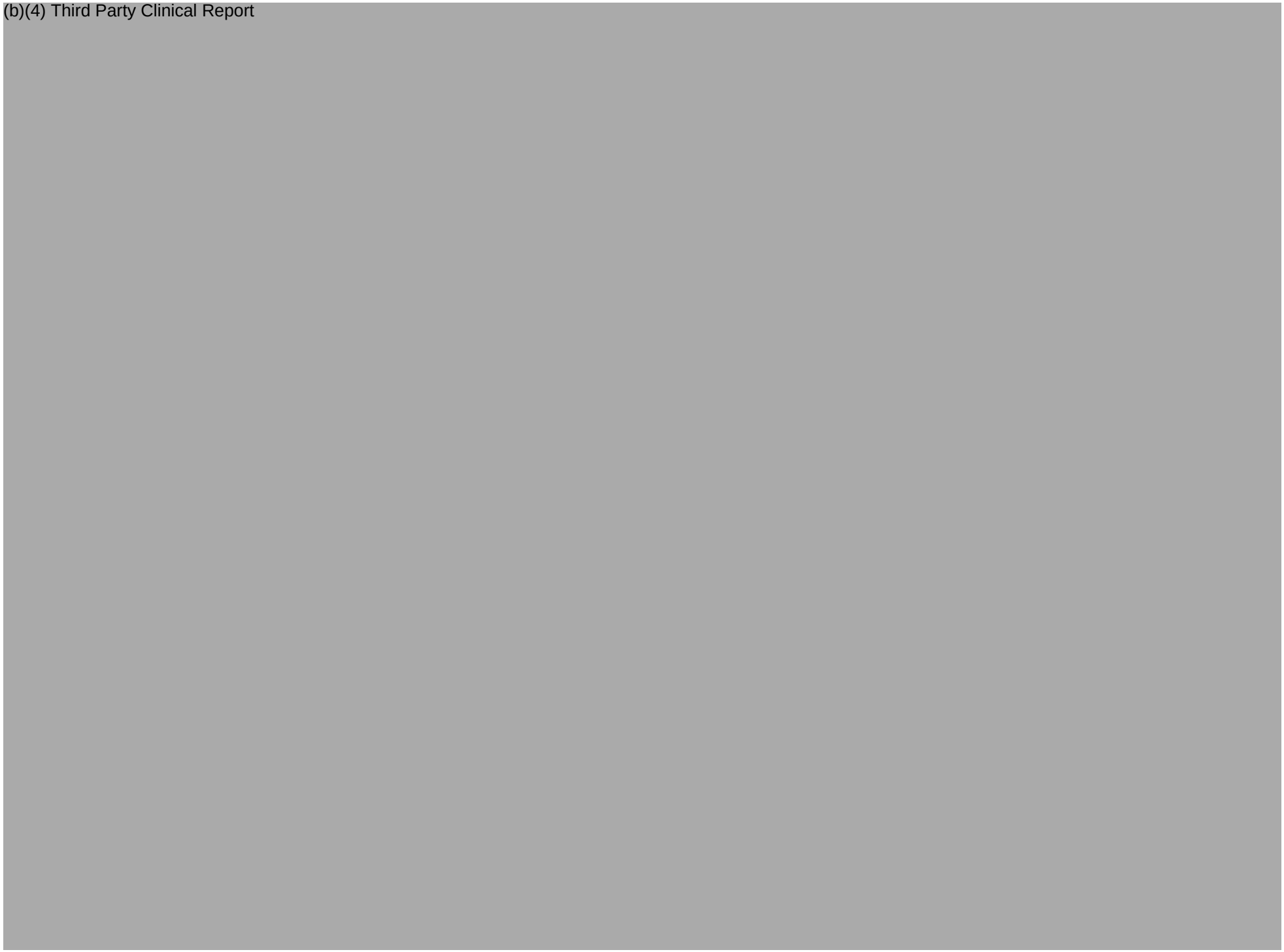
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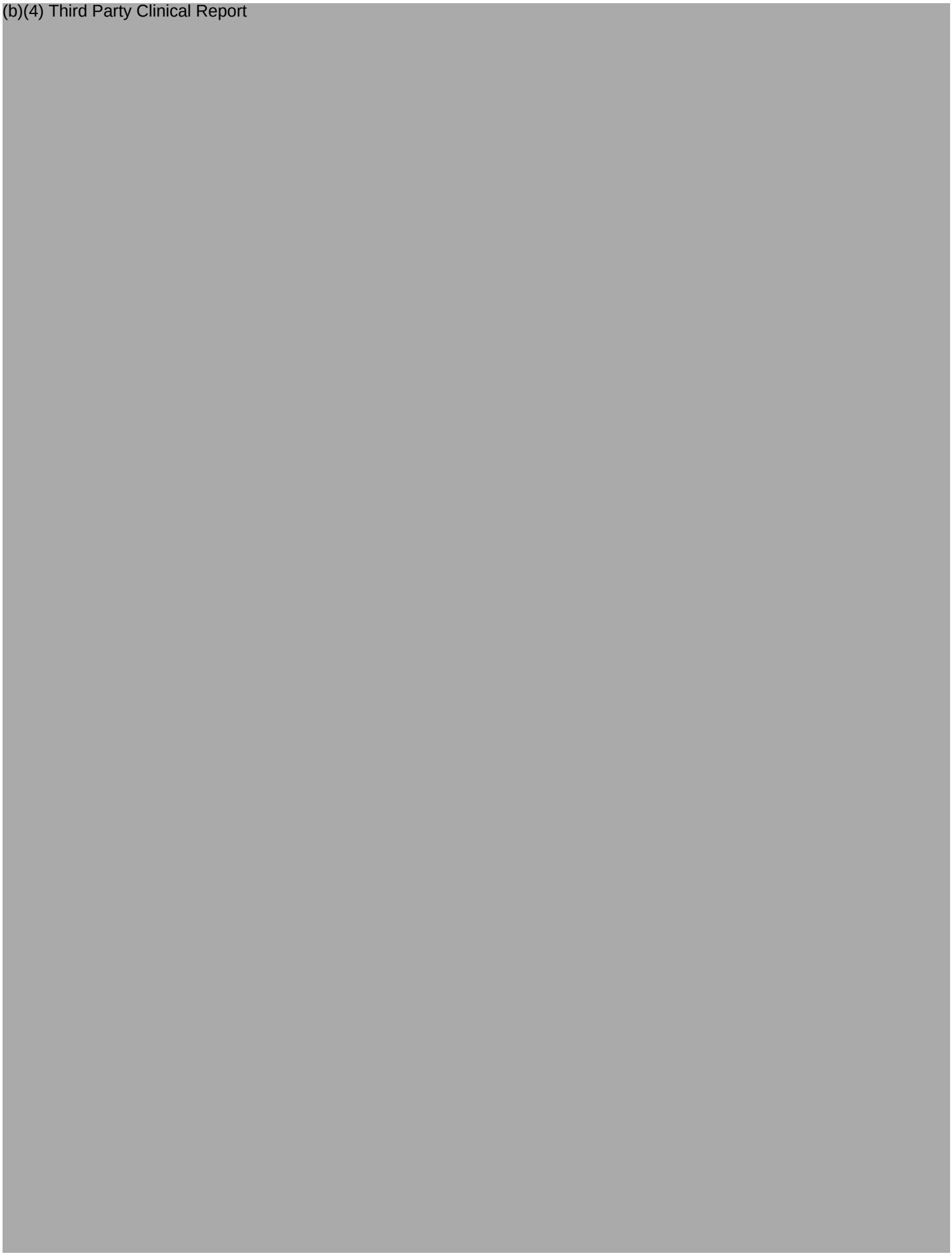
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Appendix E: Supplemental Statistical Analyses

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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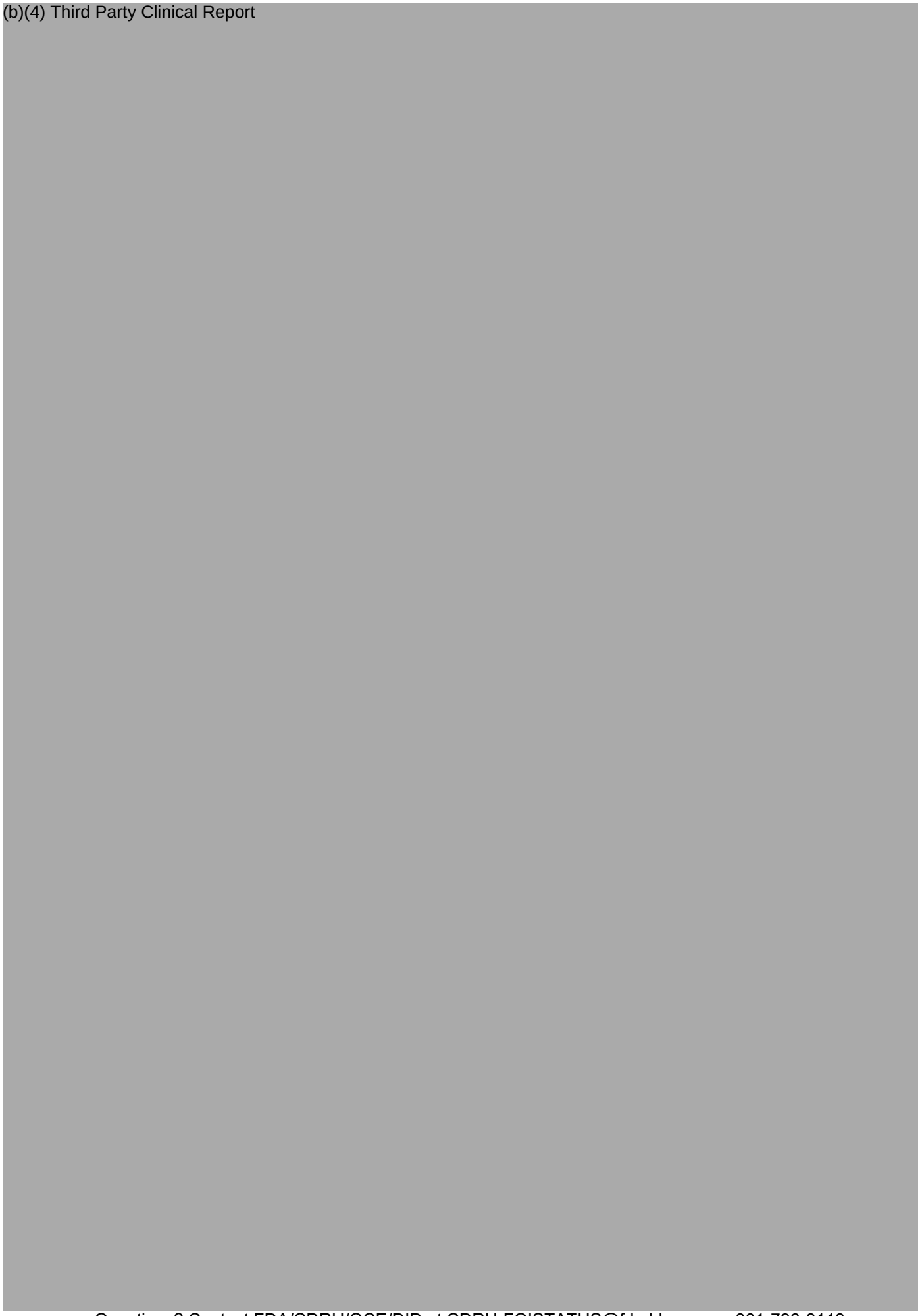
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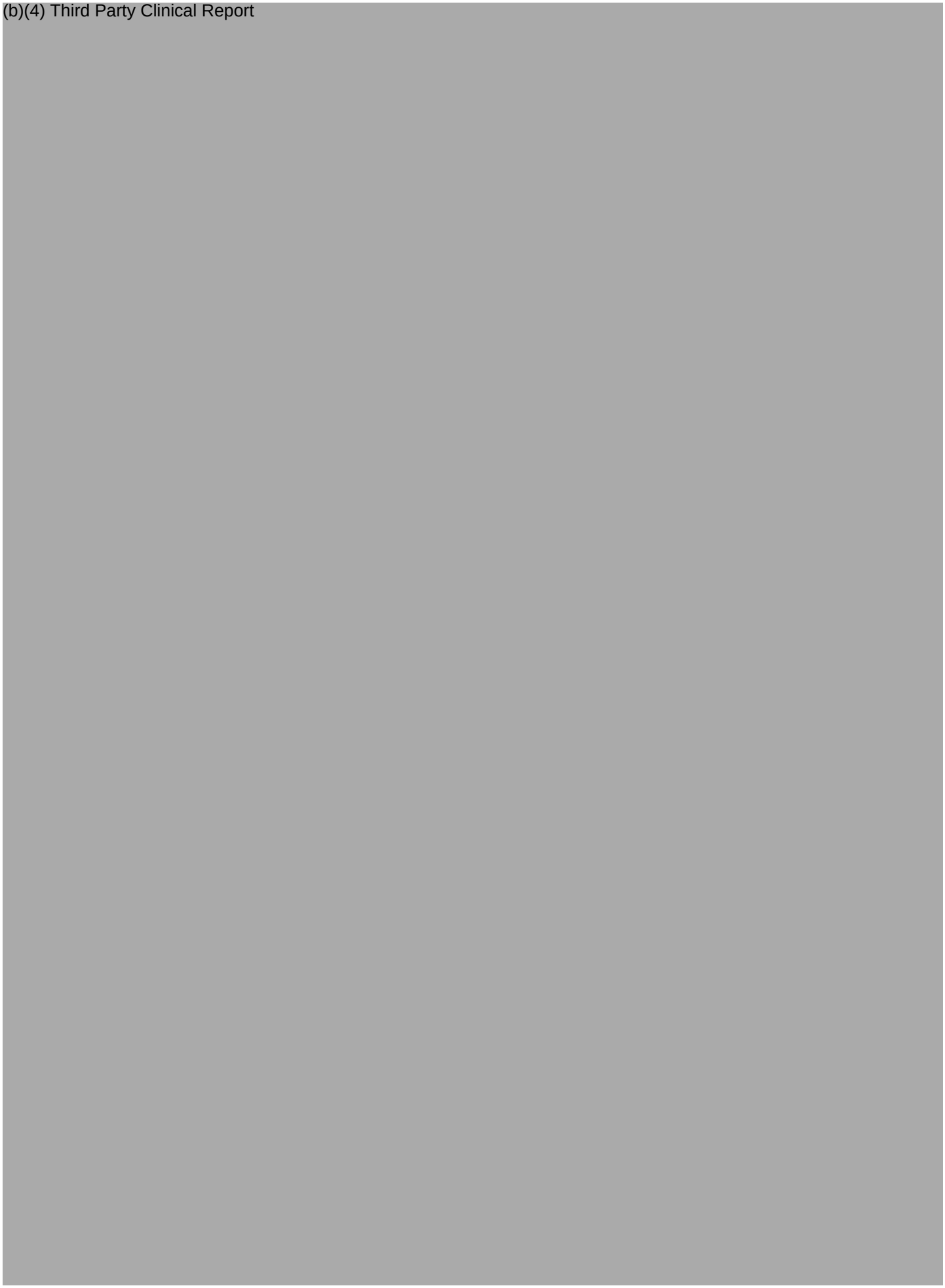
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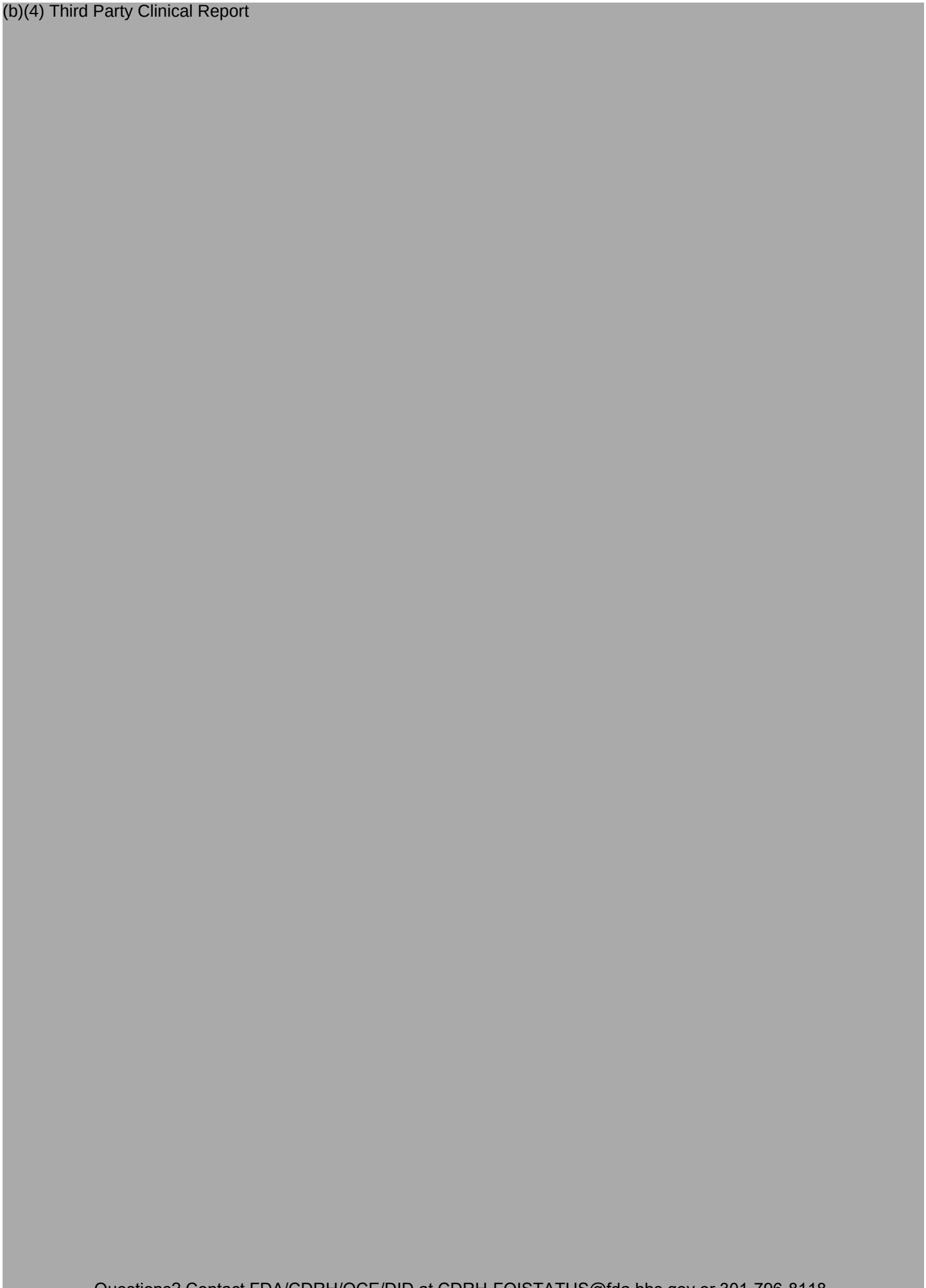
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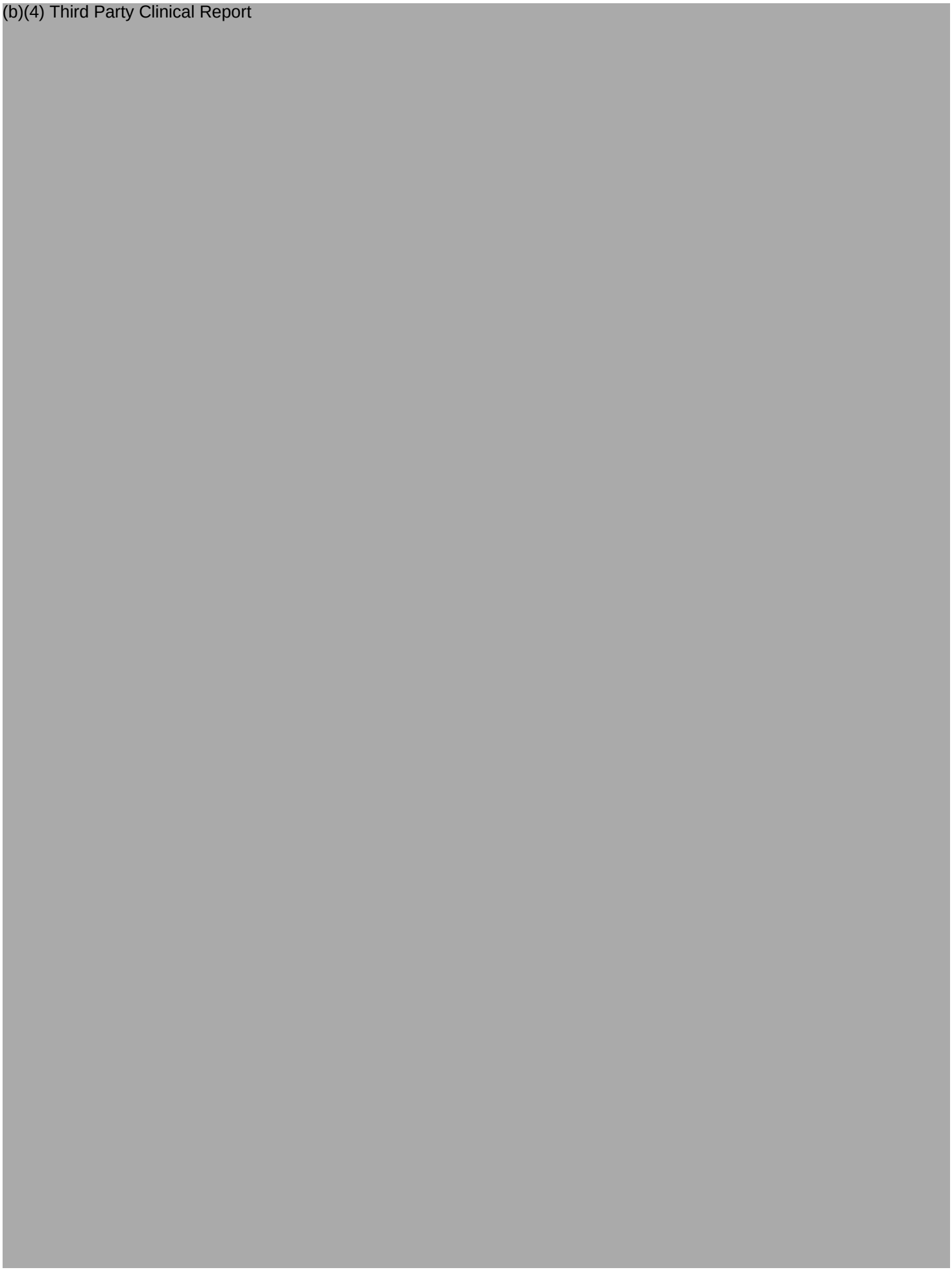
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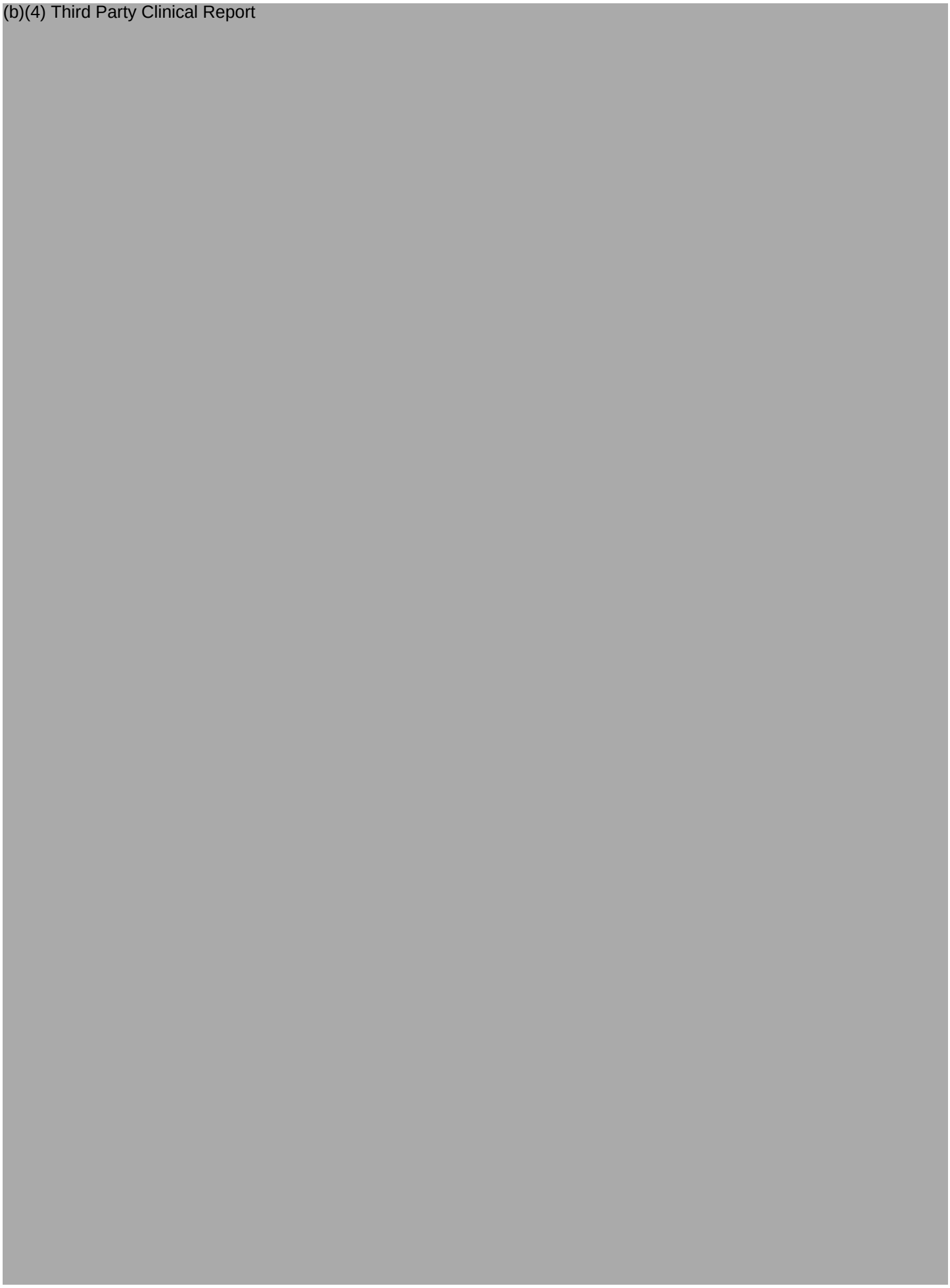
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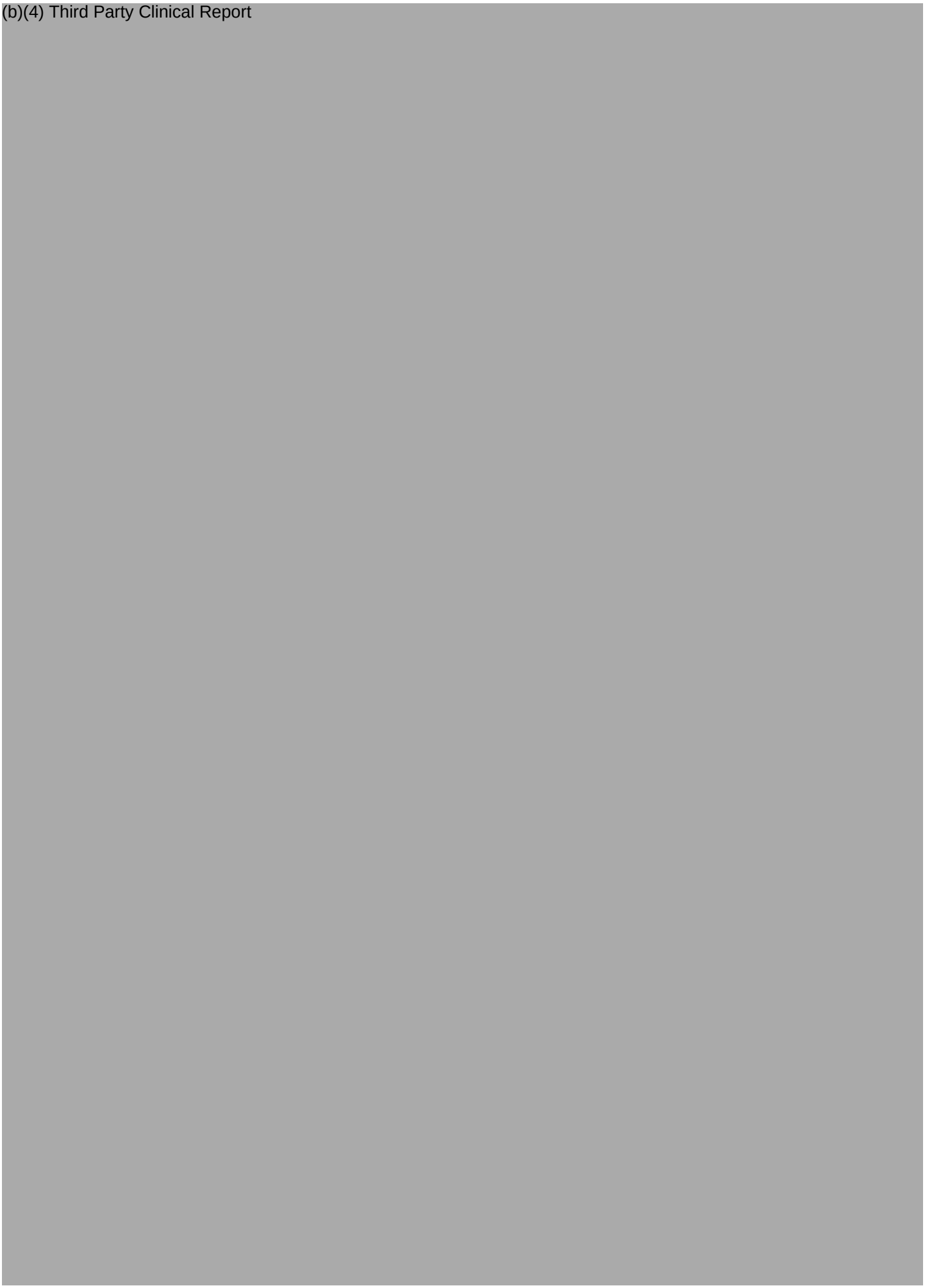
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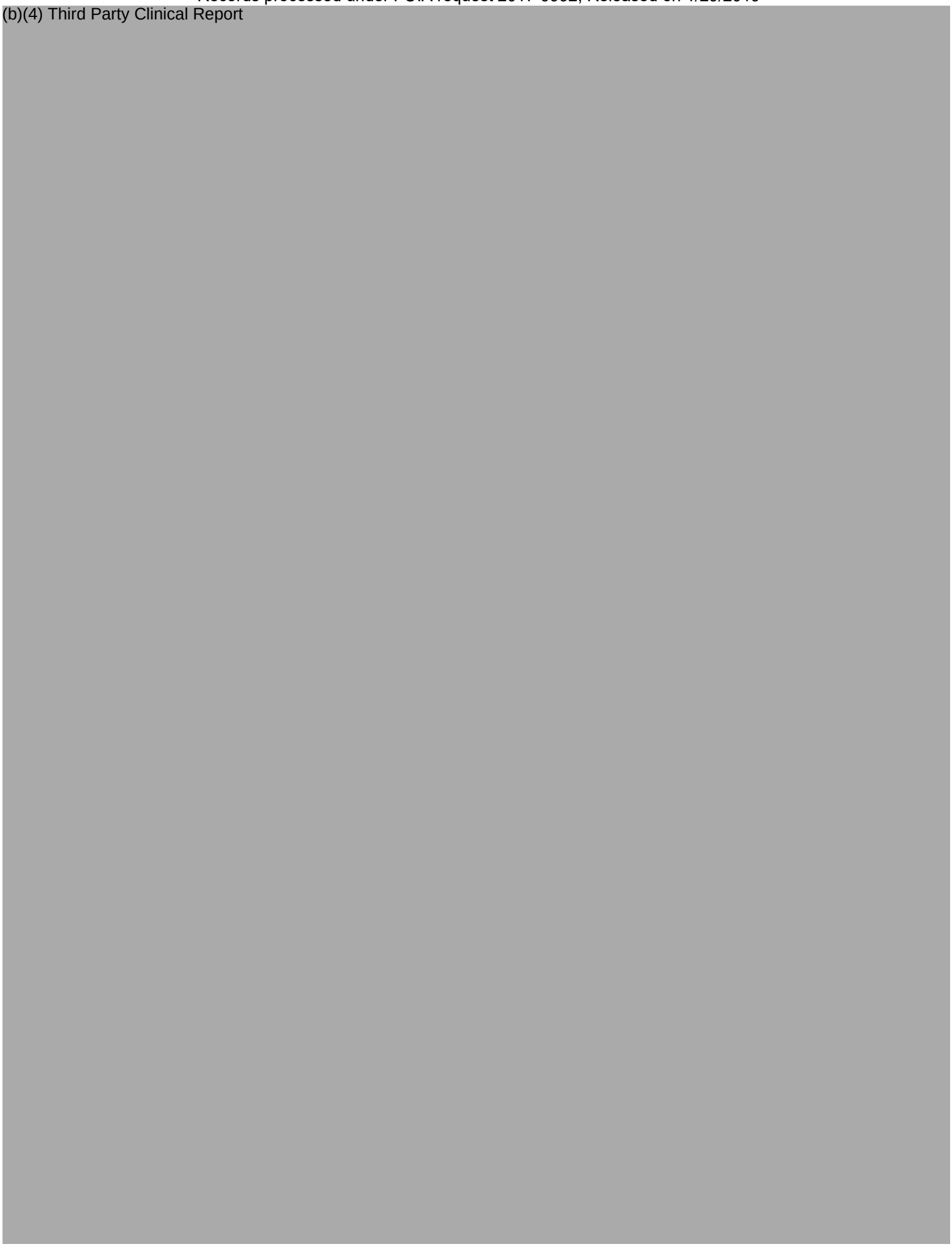
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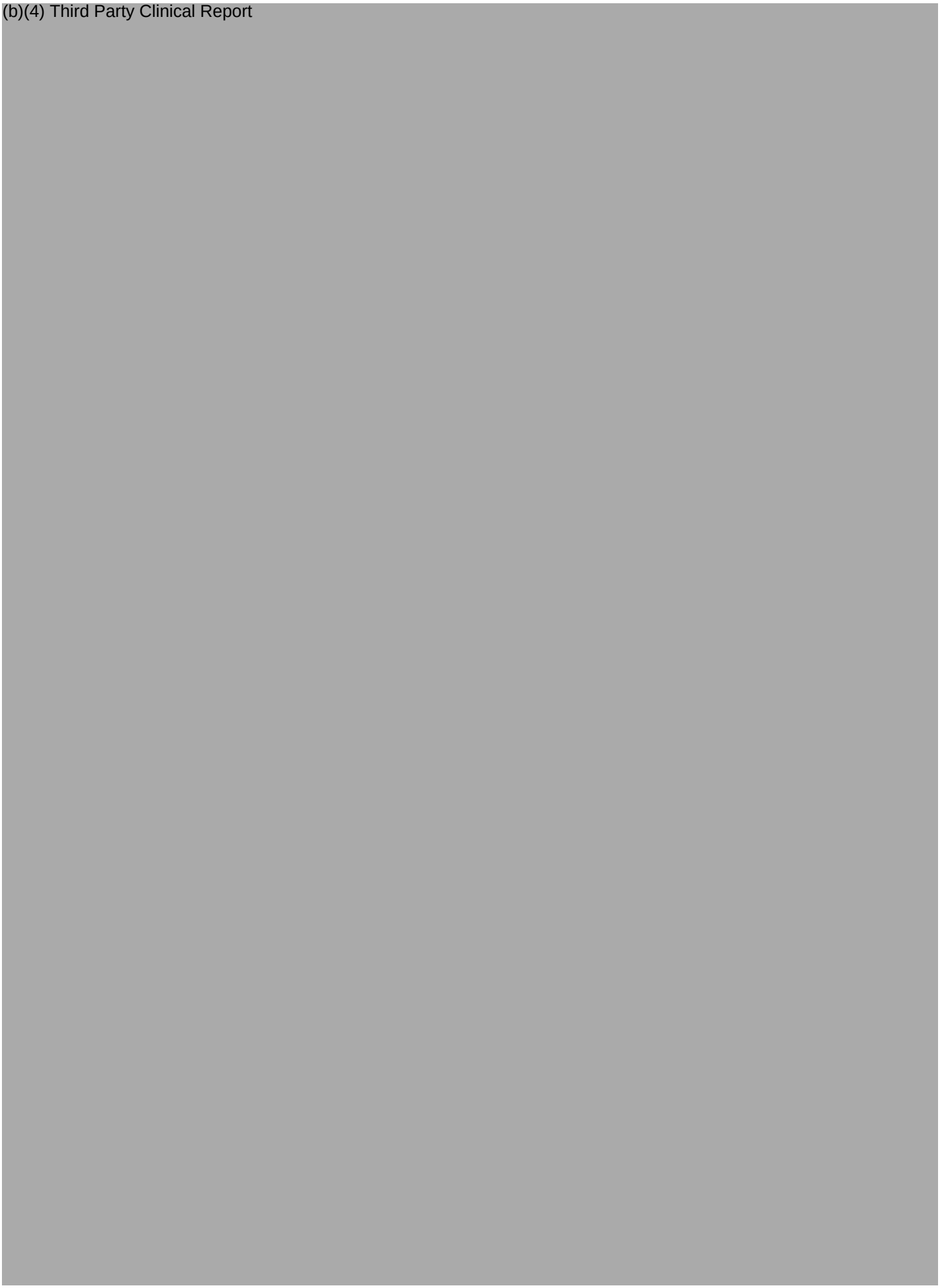
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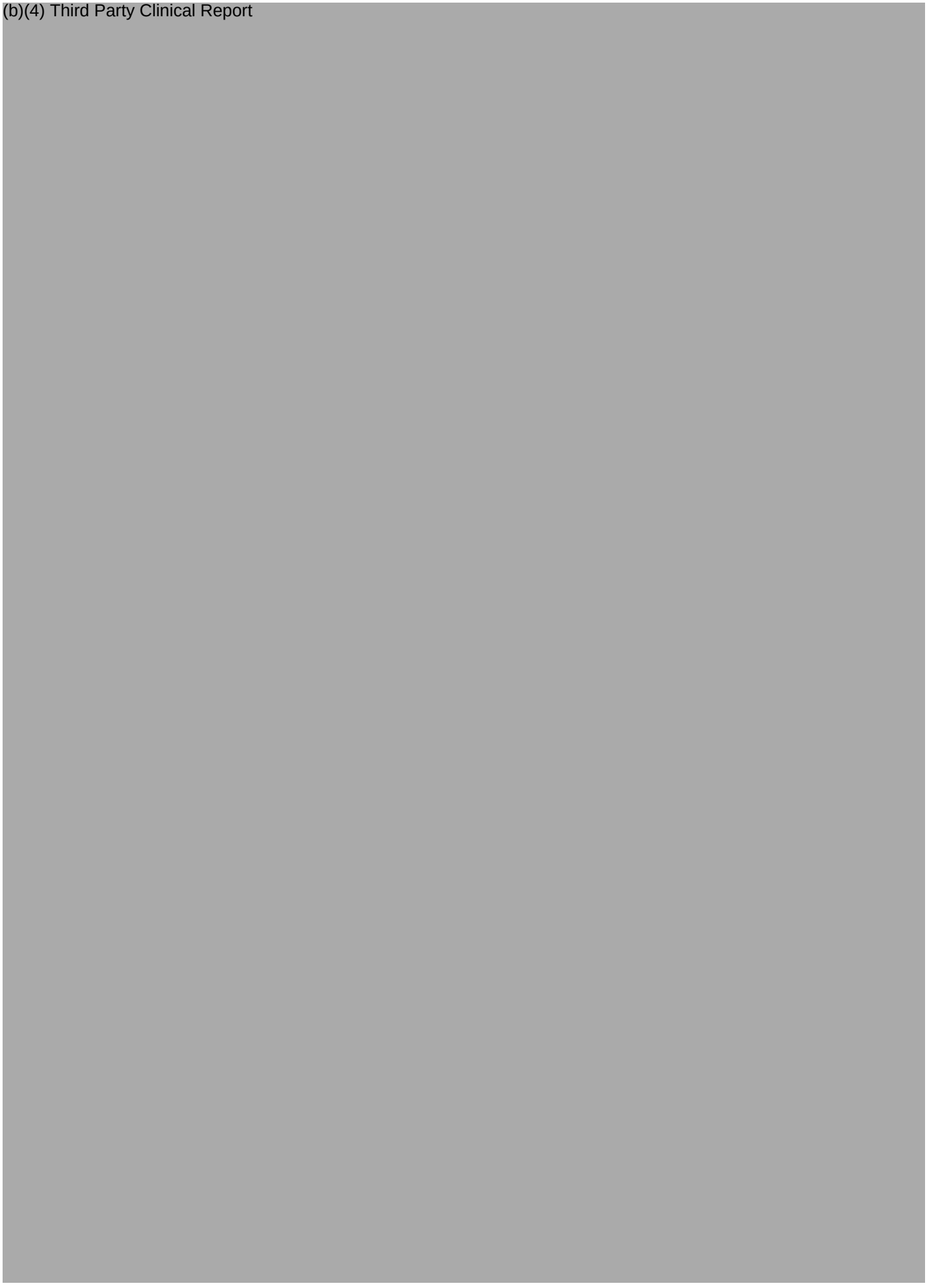
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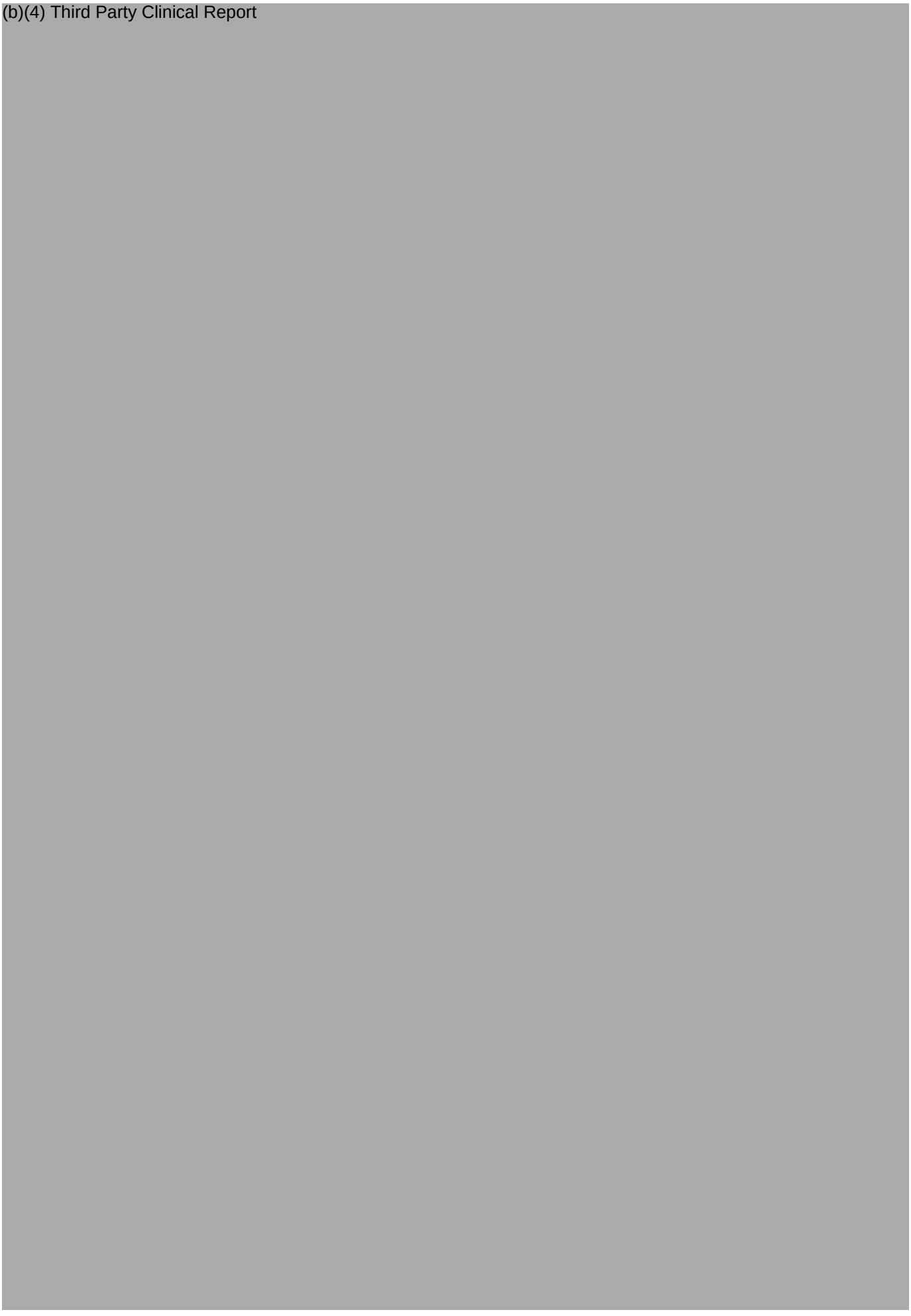
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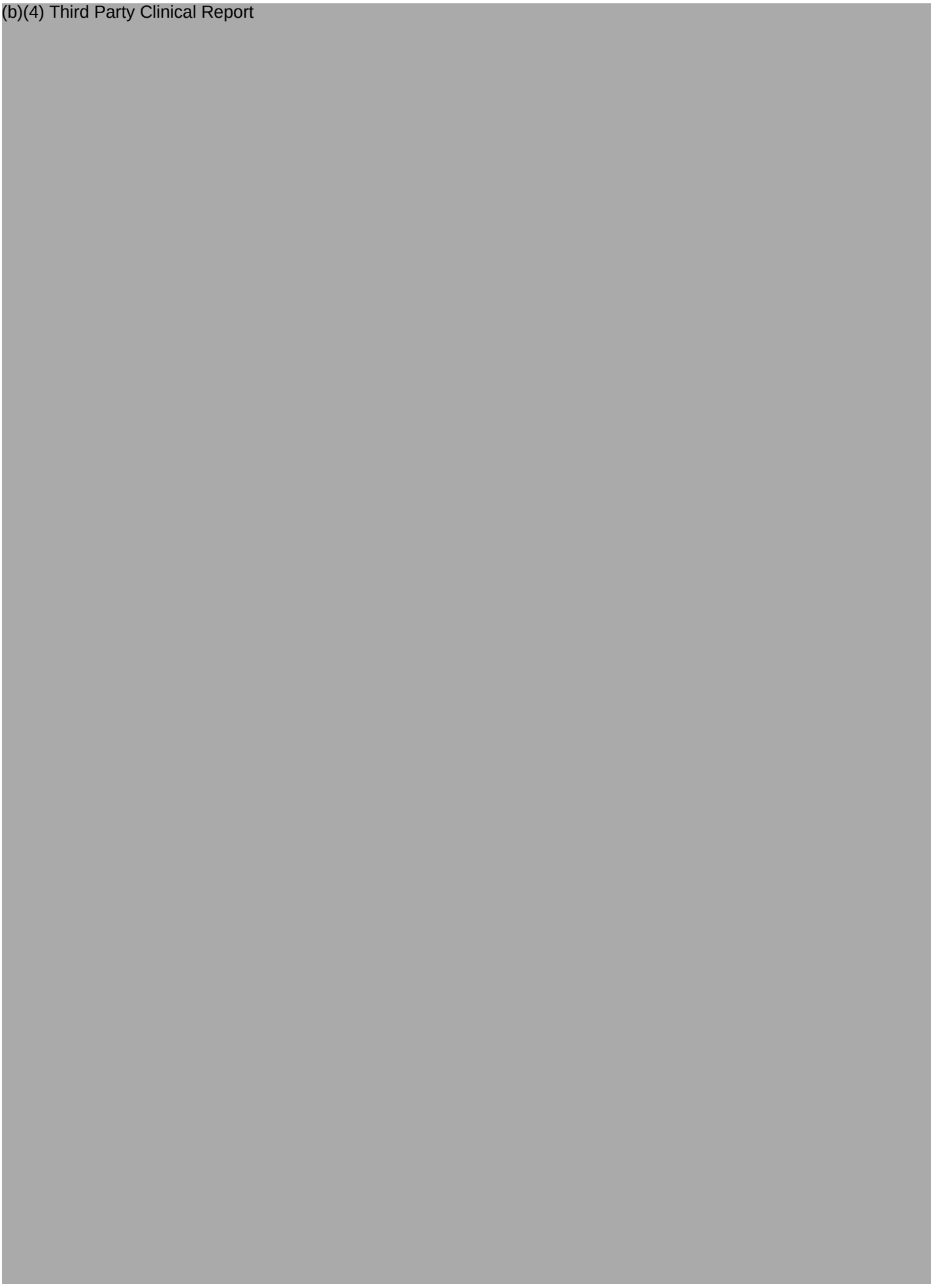
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Appendix F: Major Adverse Event Narratives

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

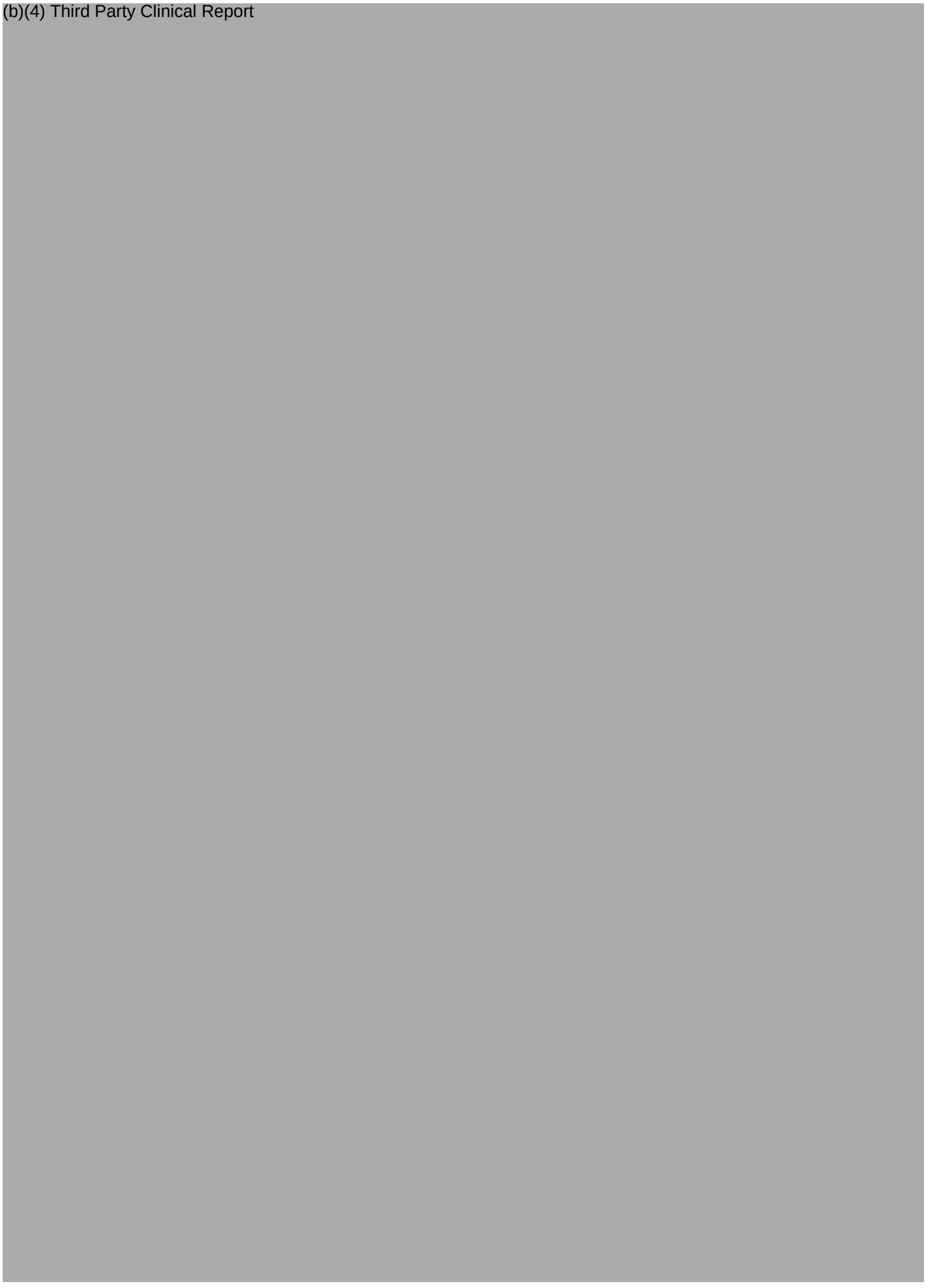
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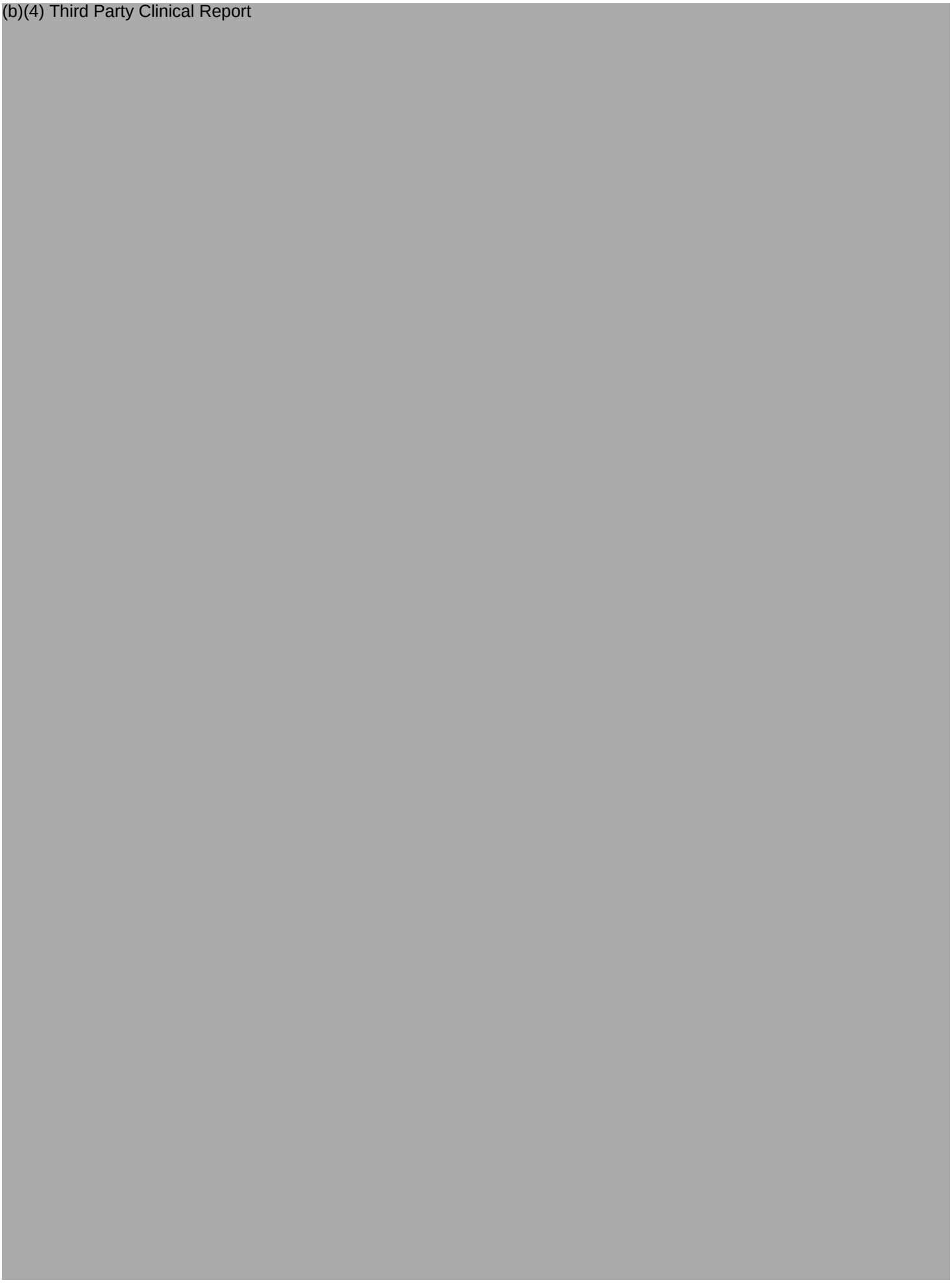
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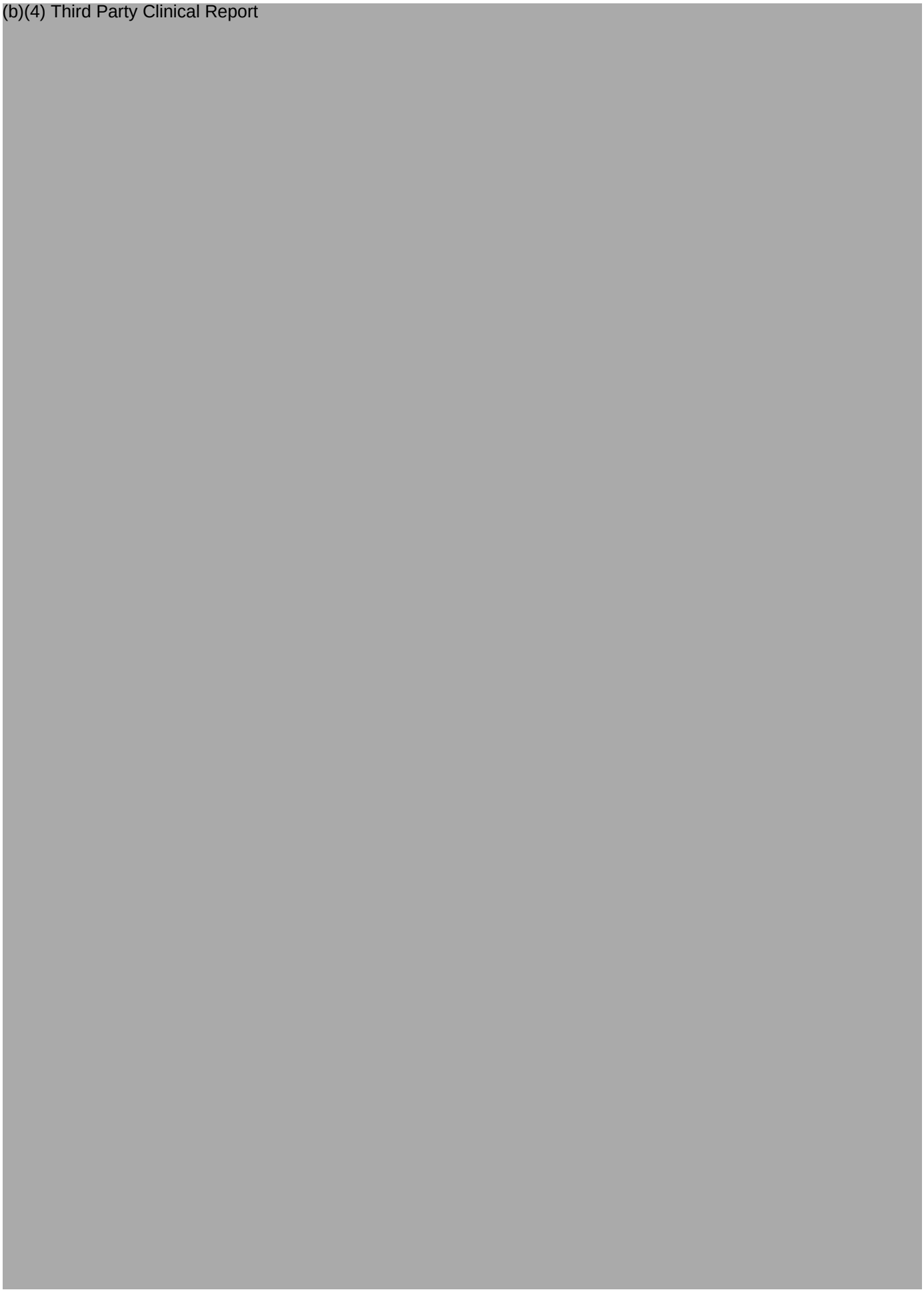
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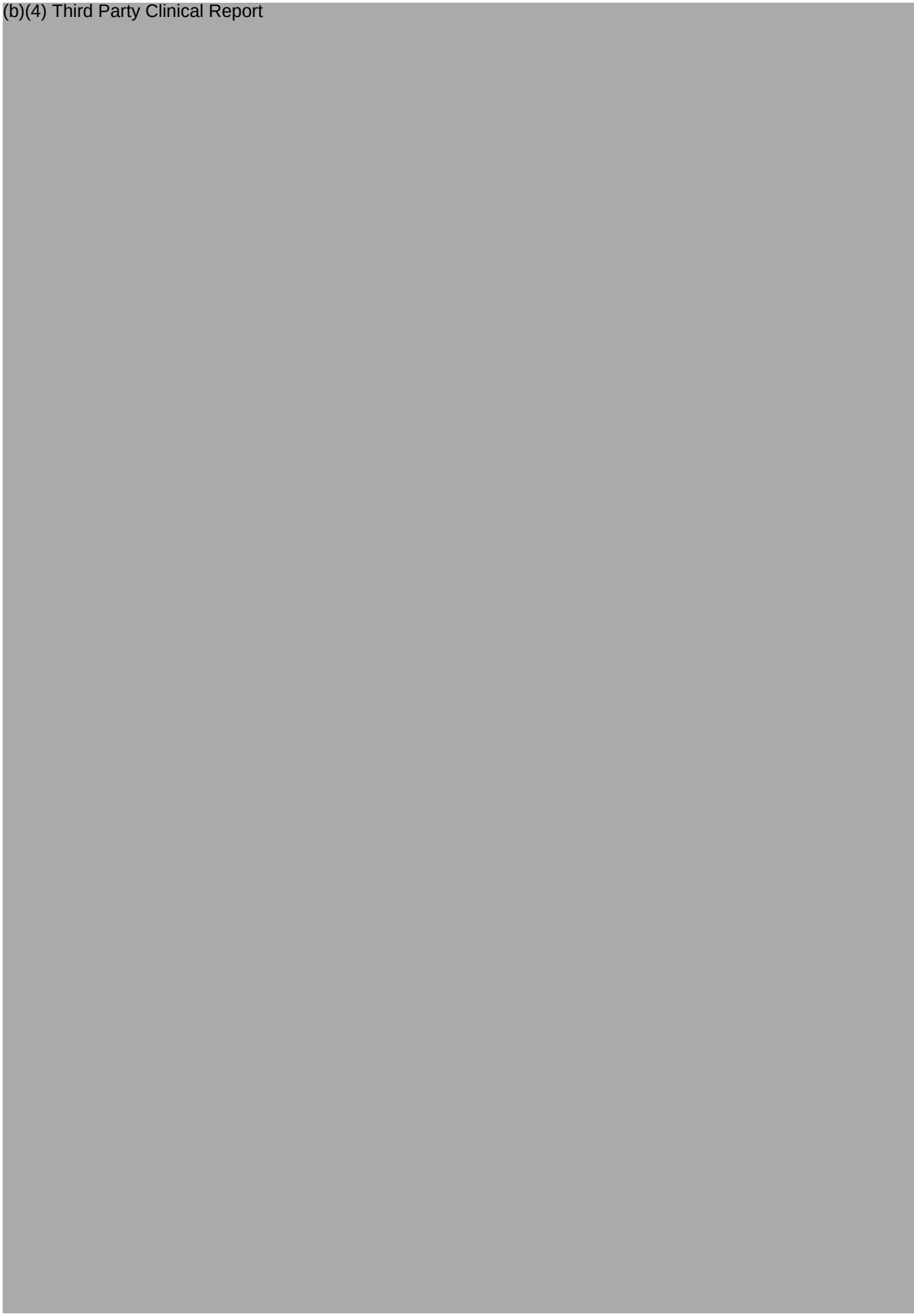
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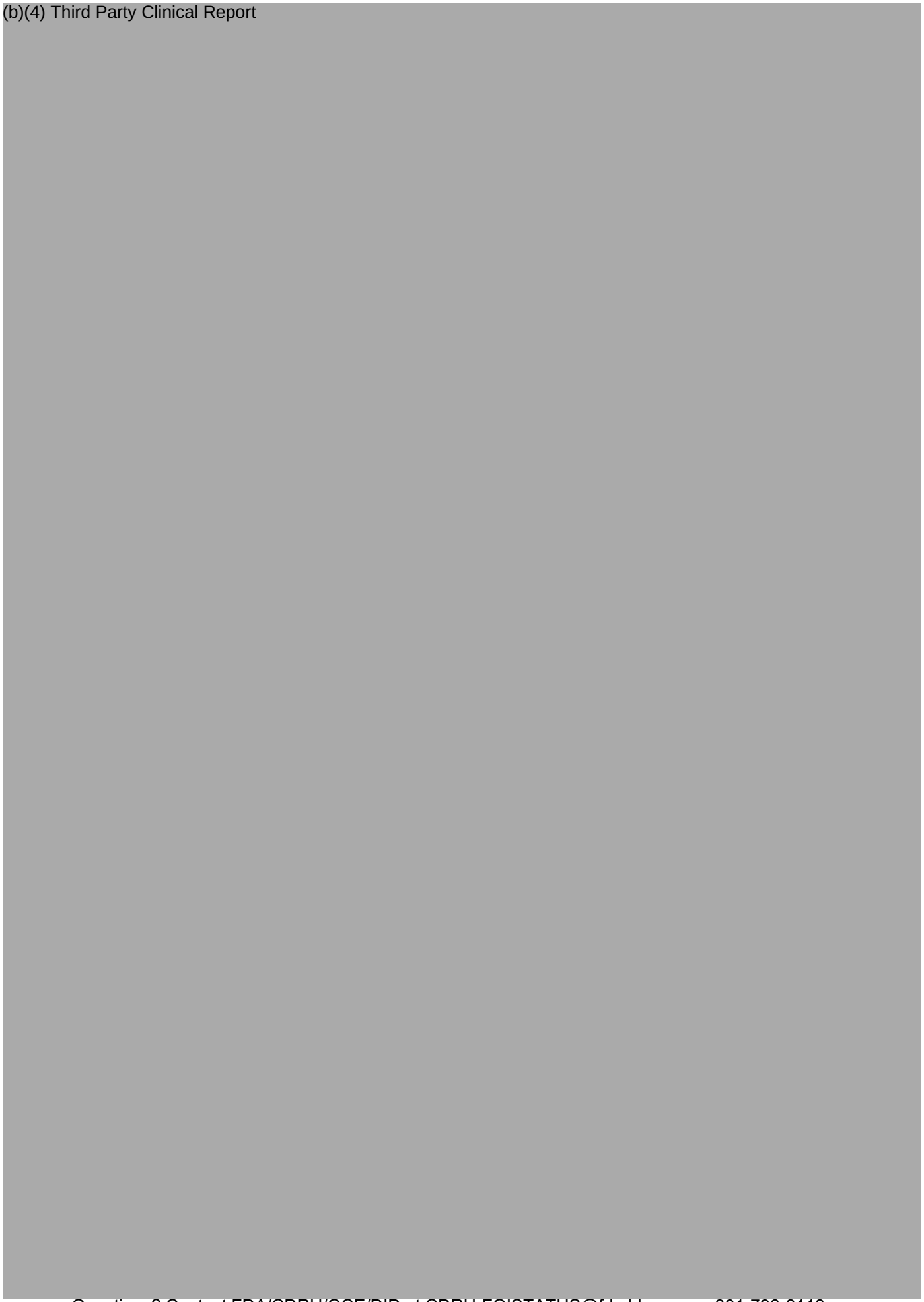
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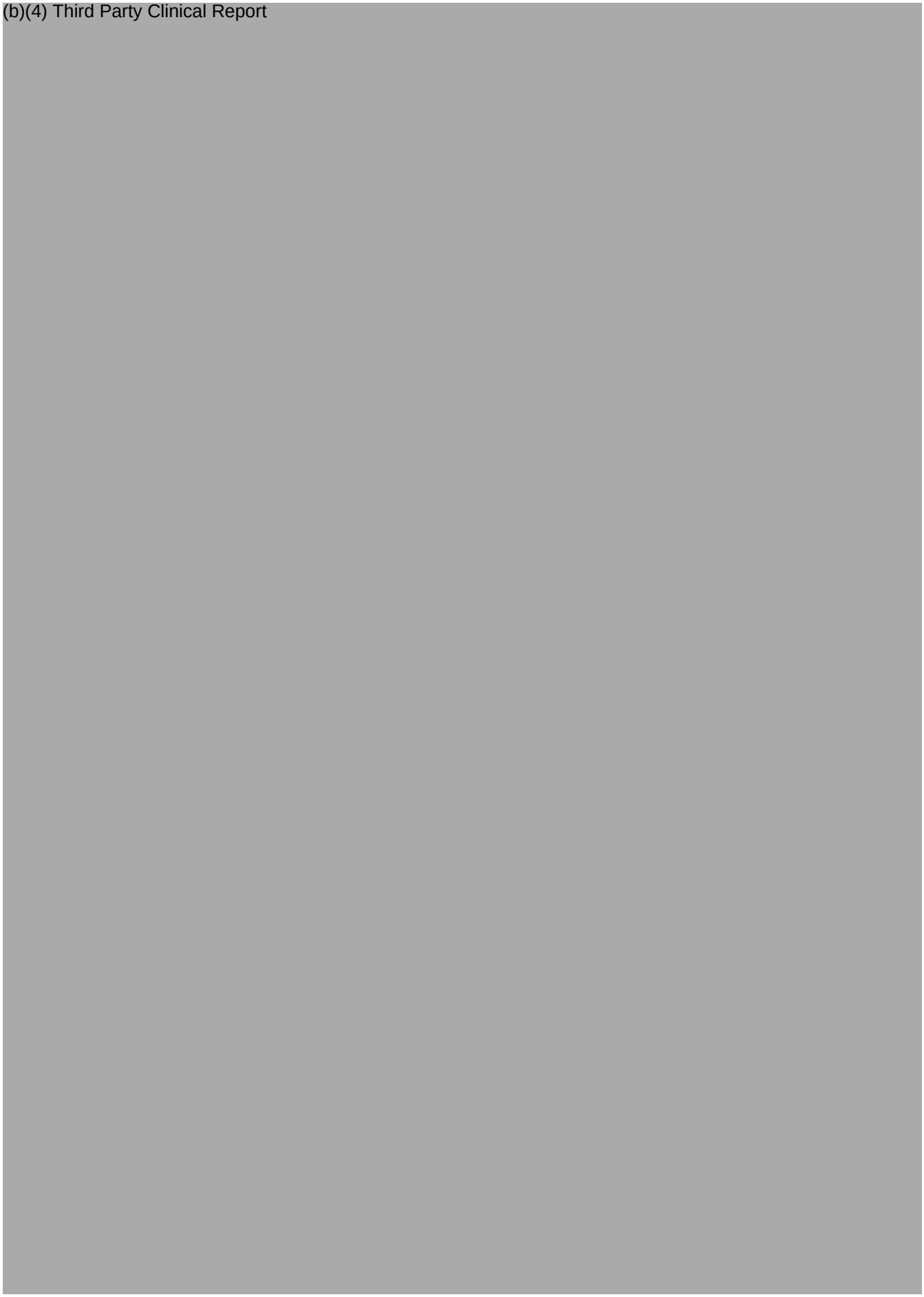
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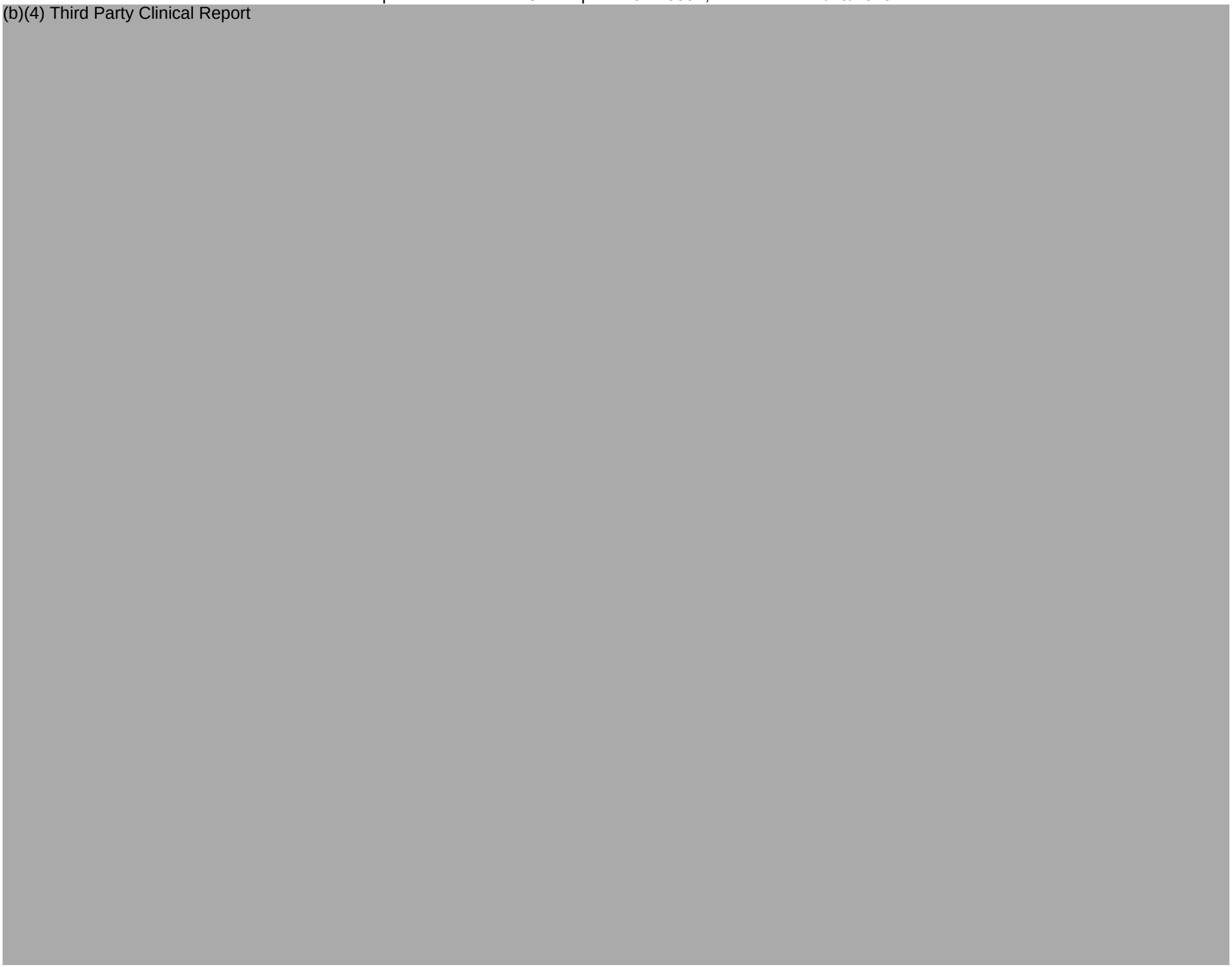
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Appendix G: Protocol Deviation Listing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

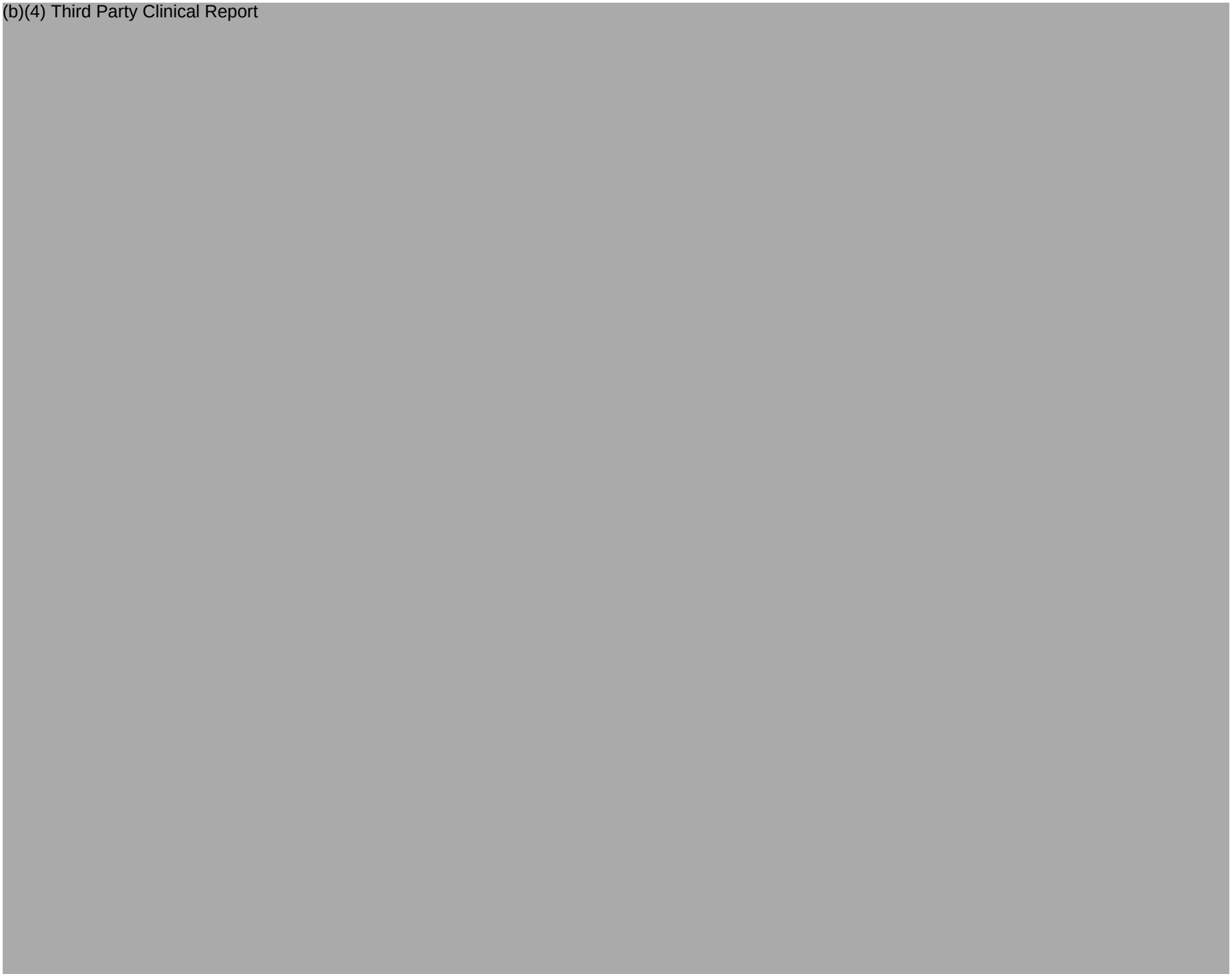
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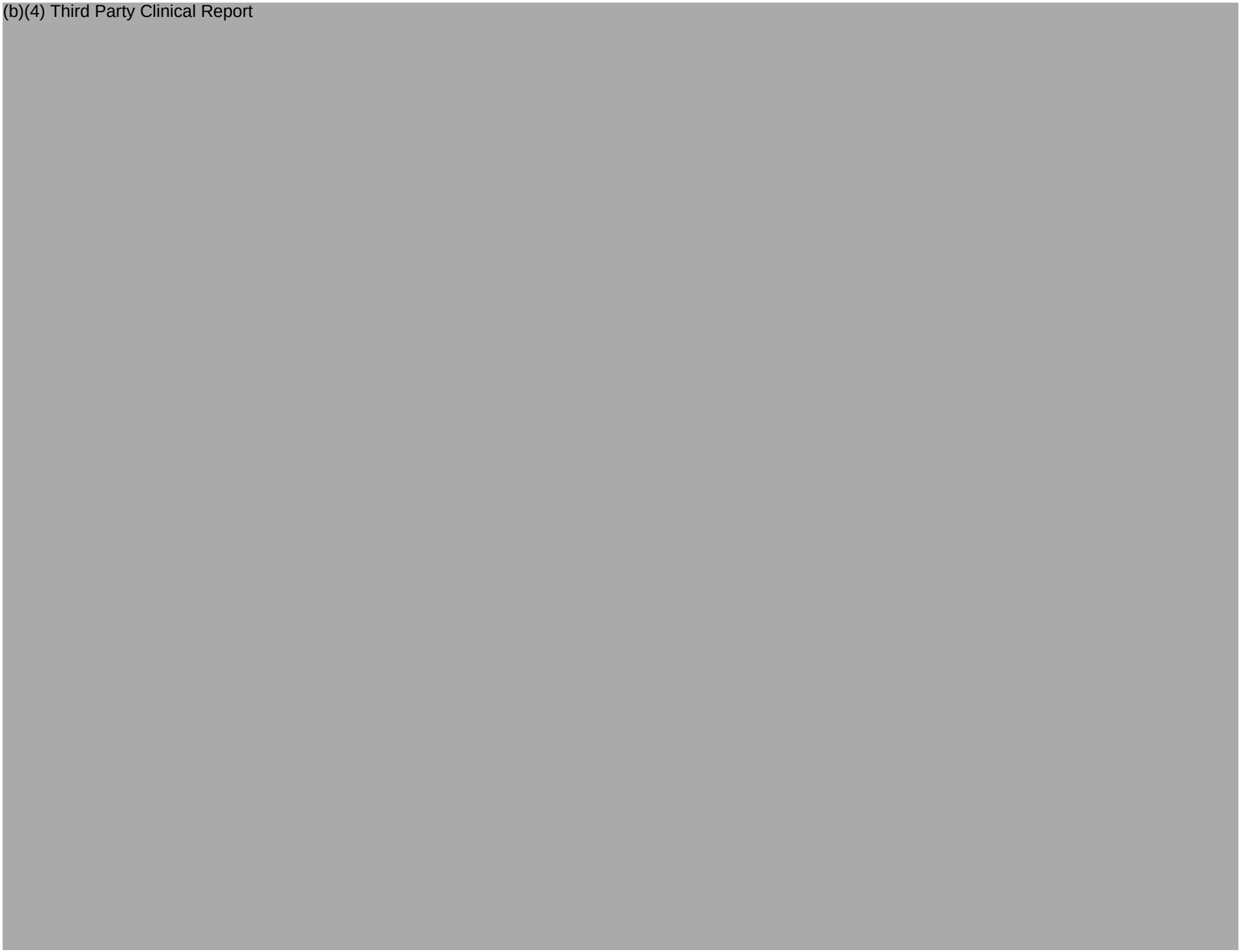
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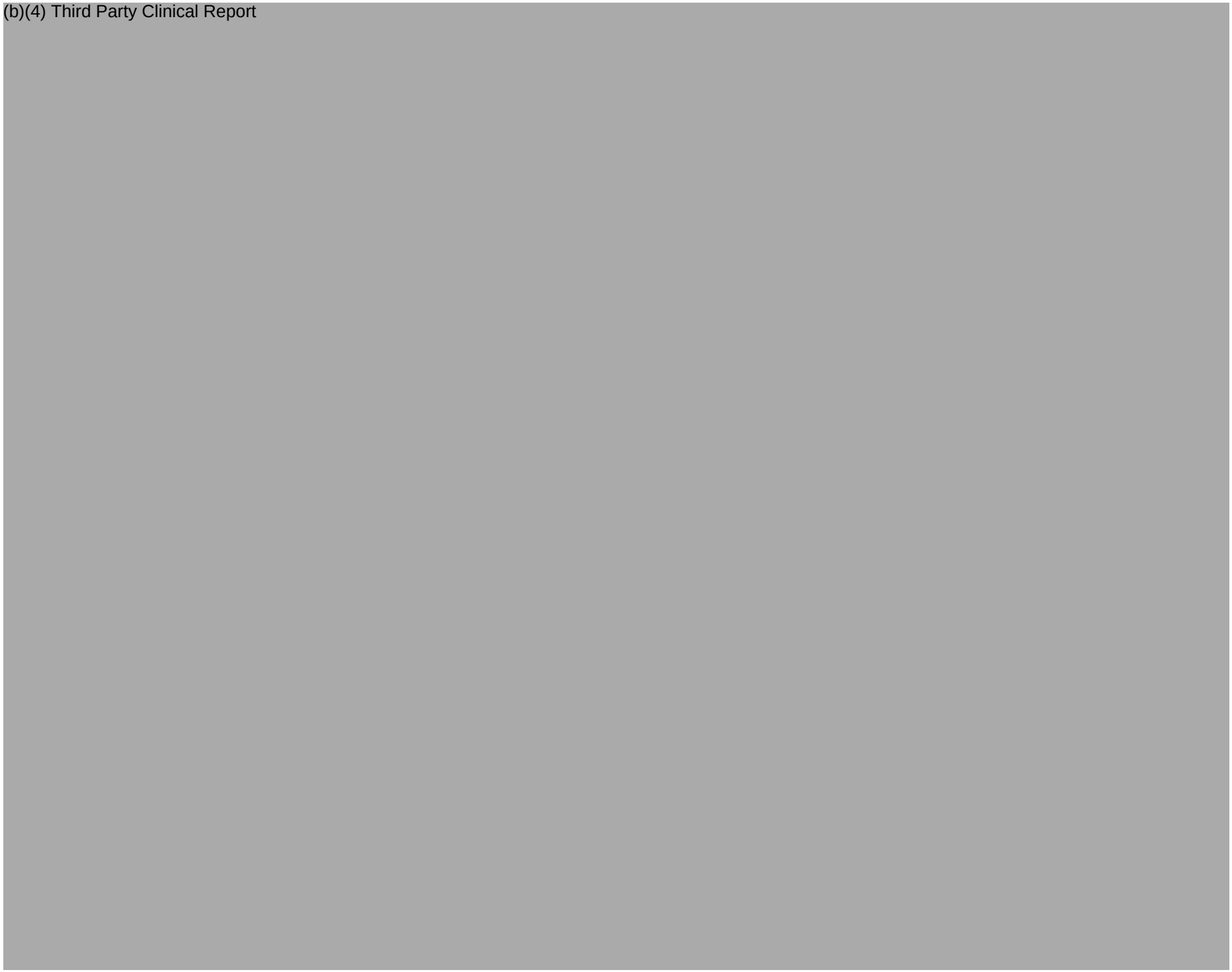
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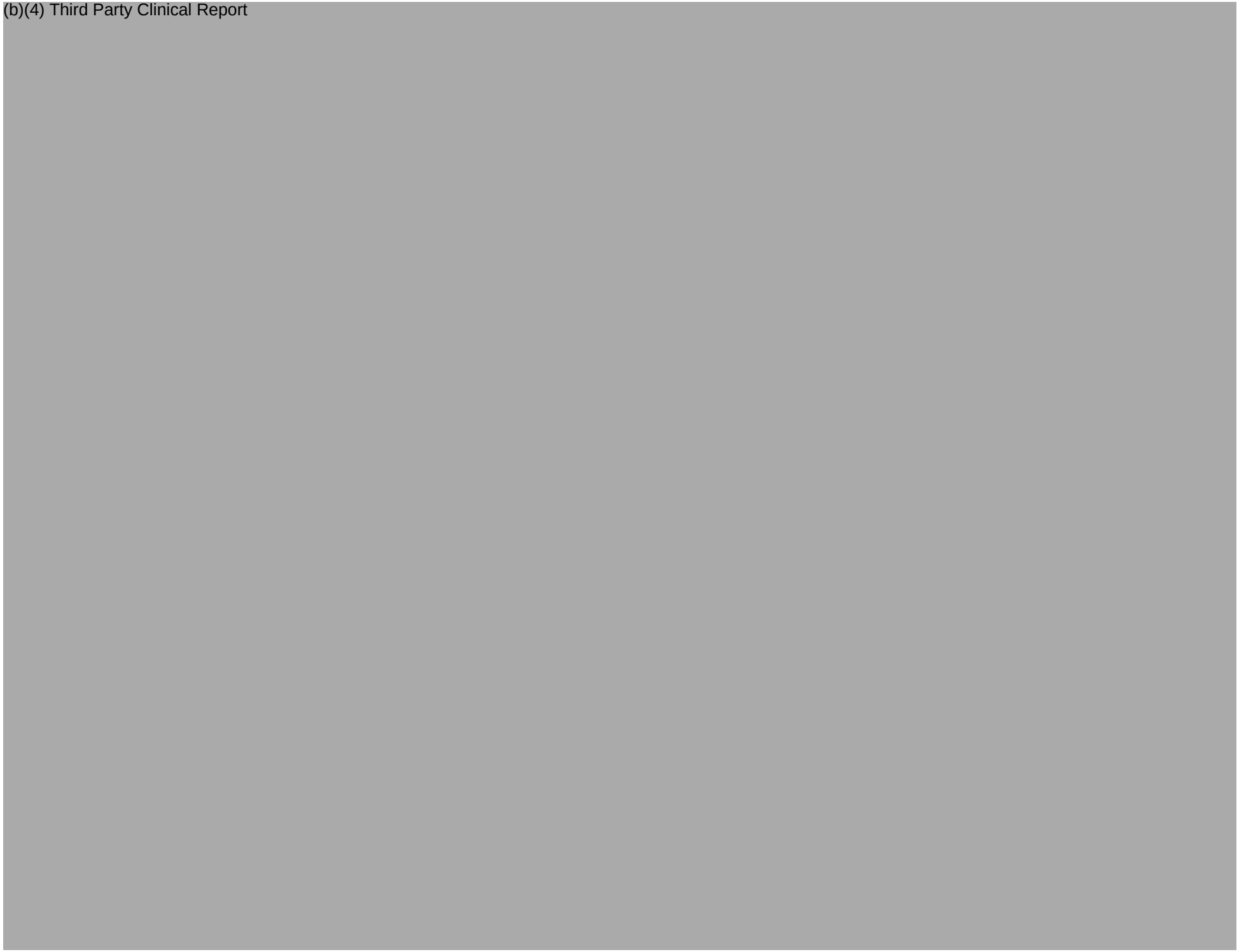
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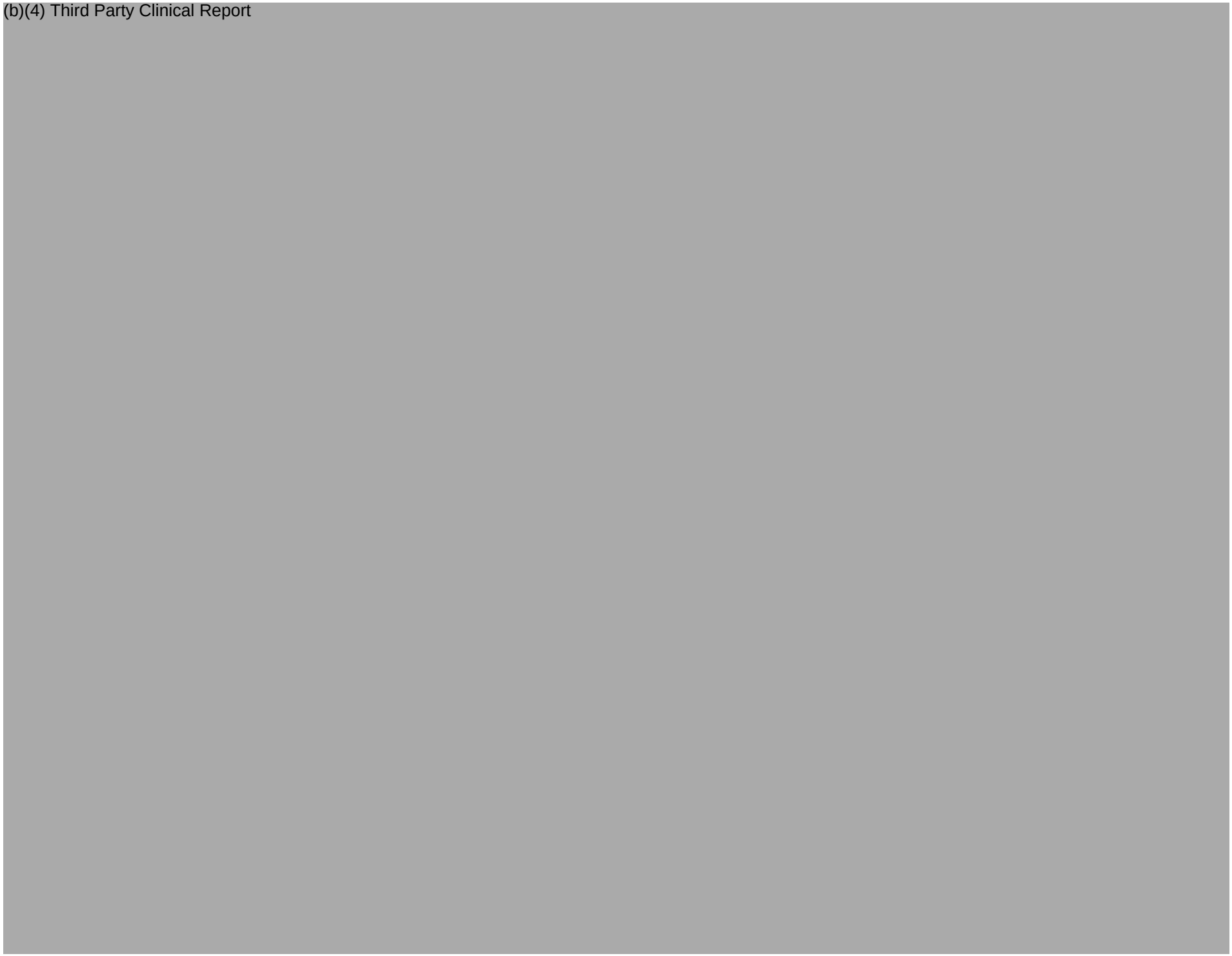
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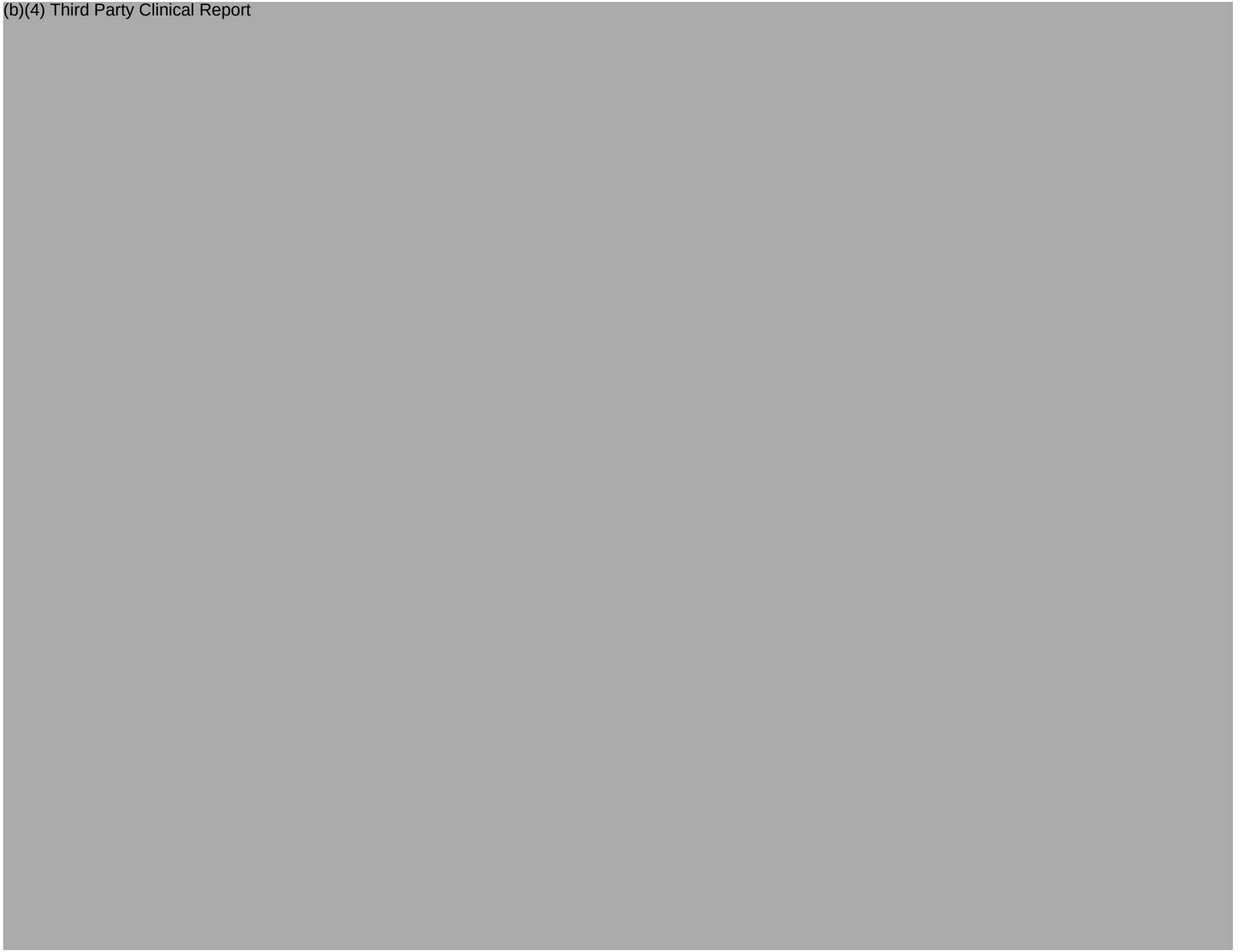
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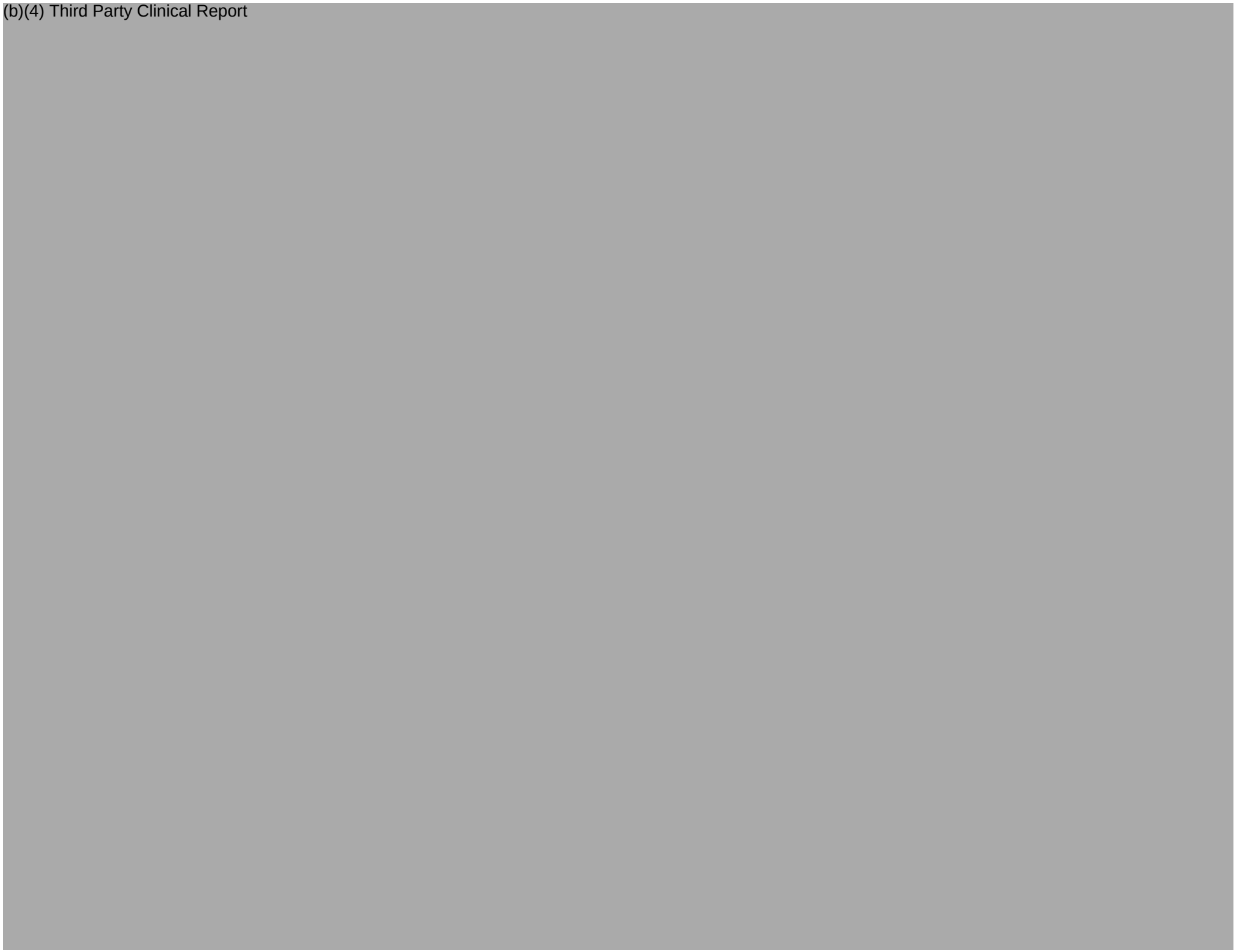
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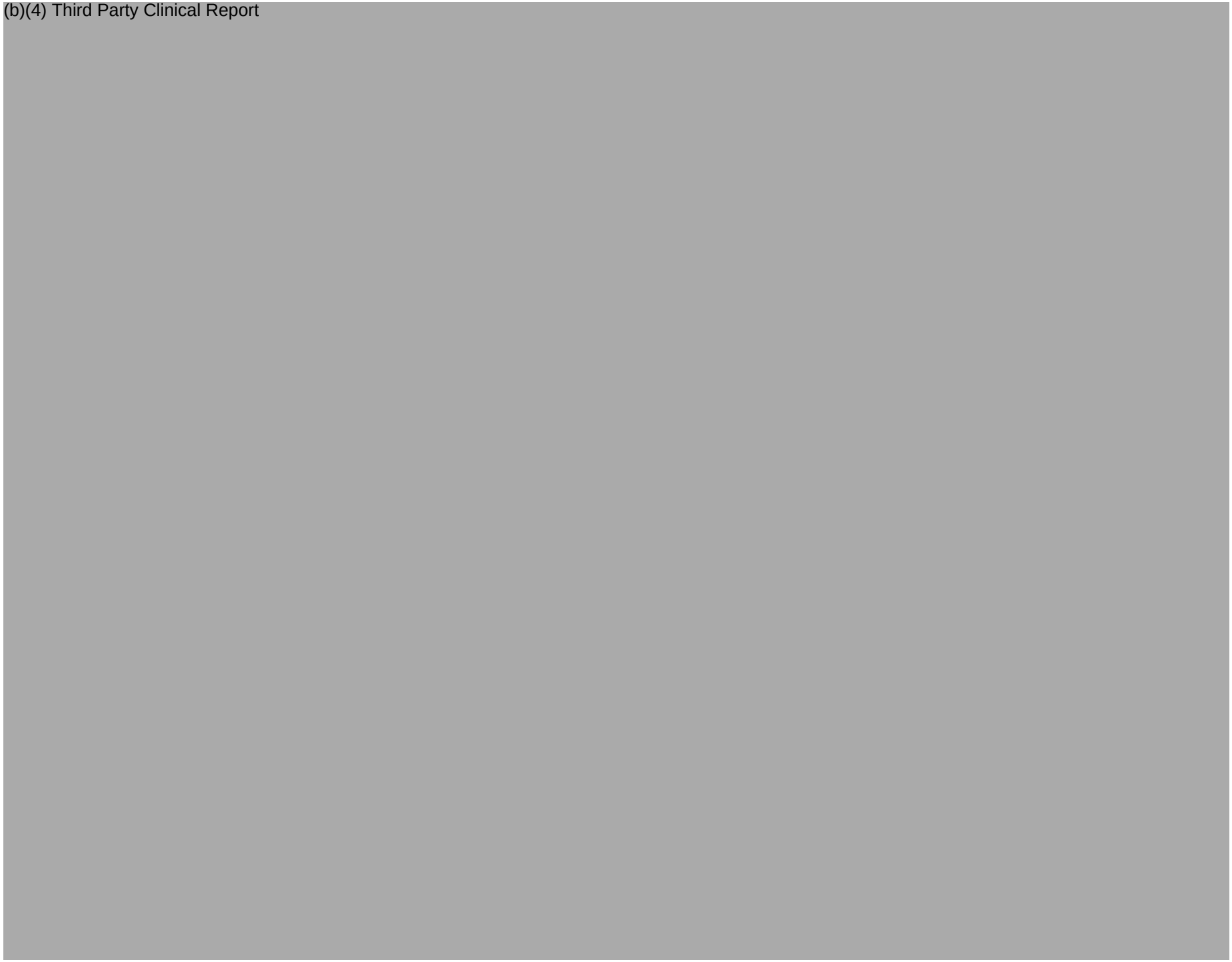
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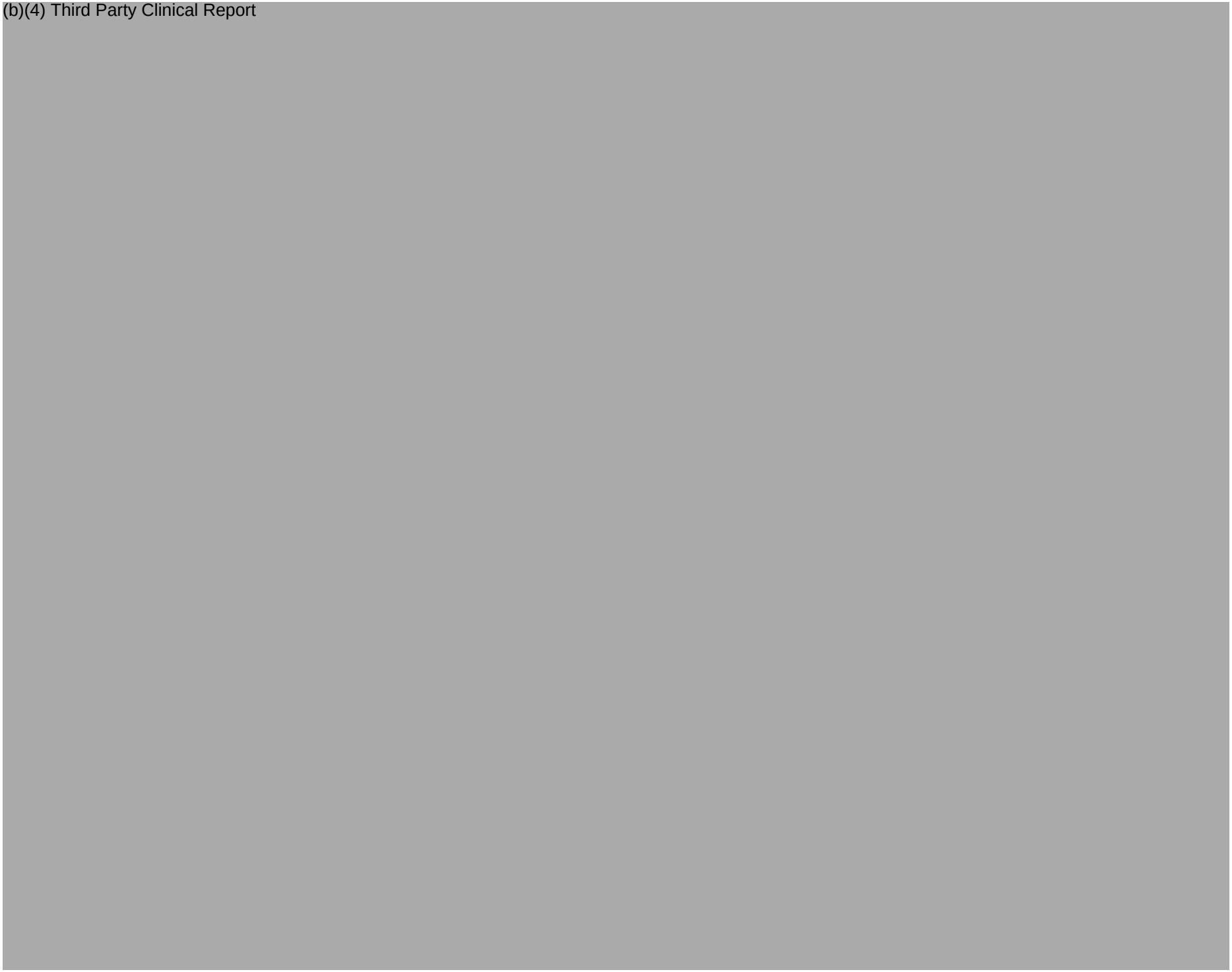
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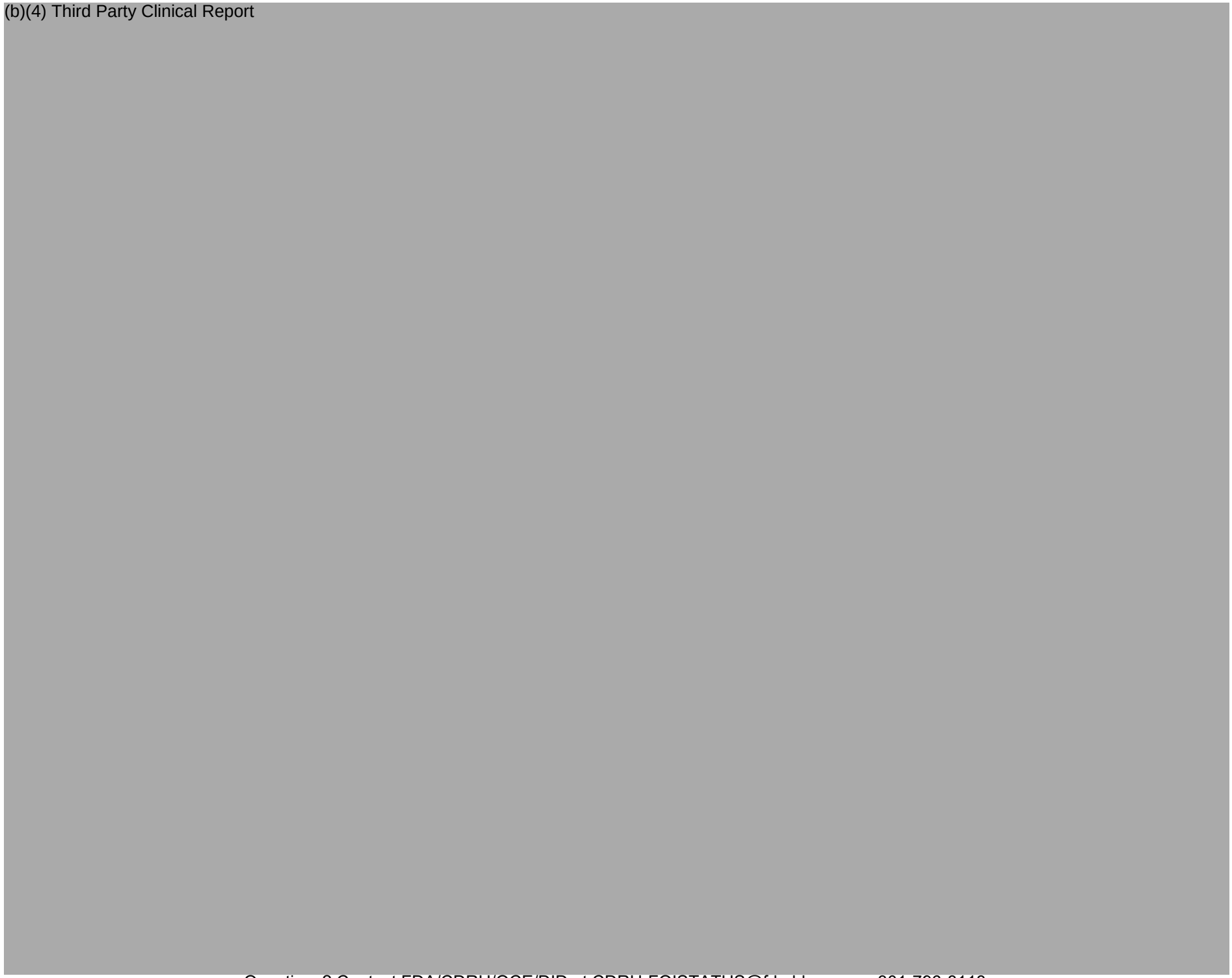
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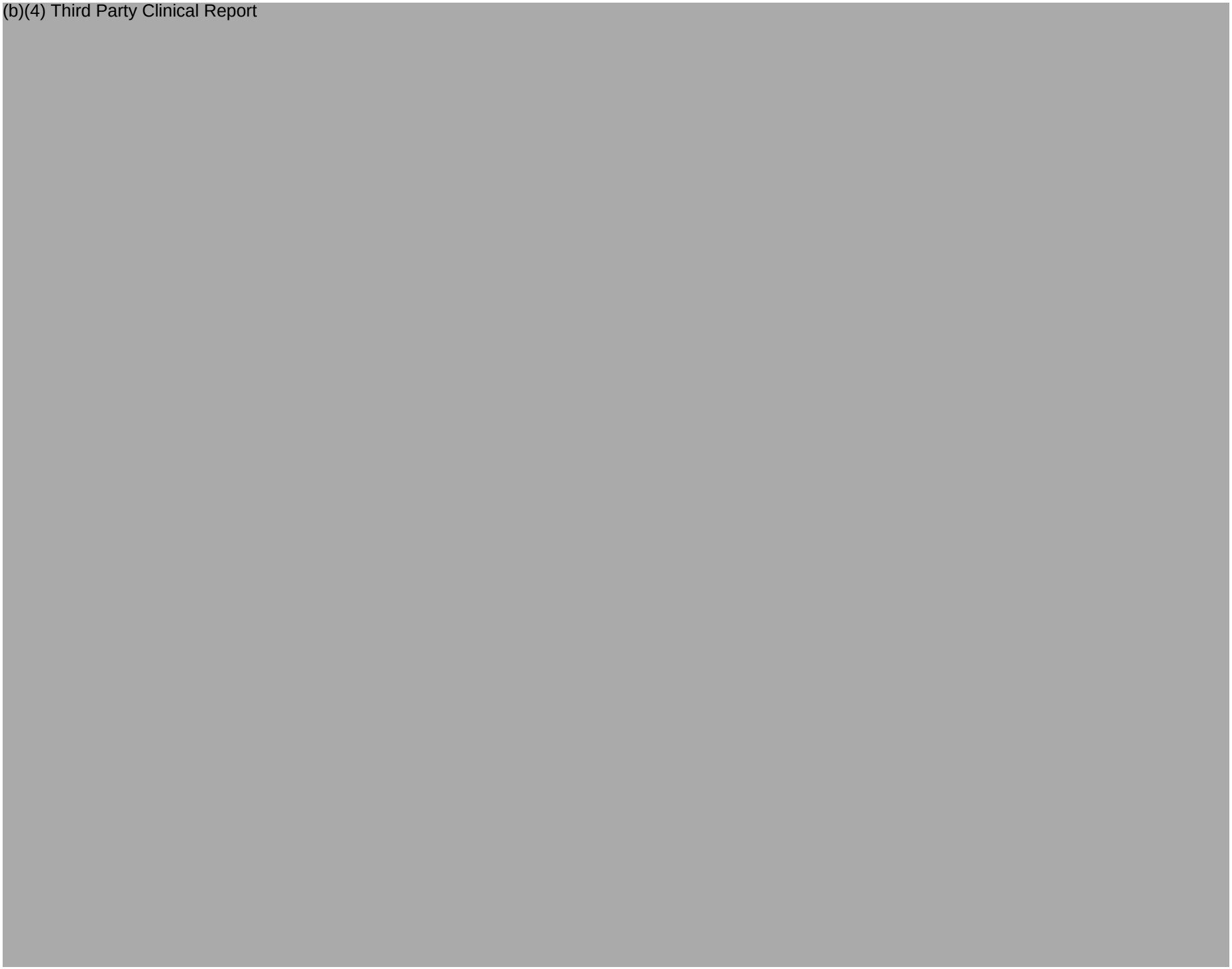
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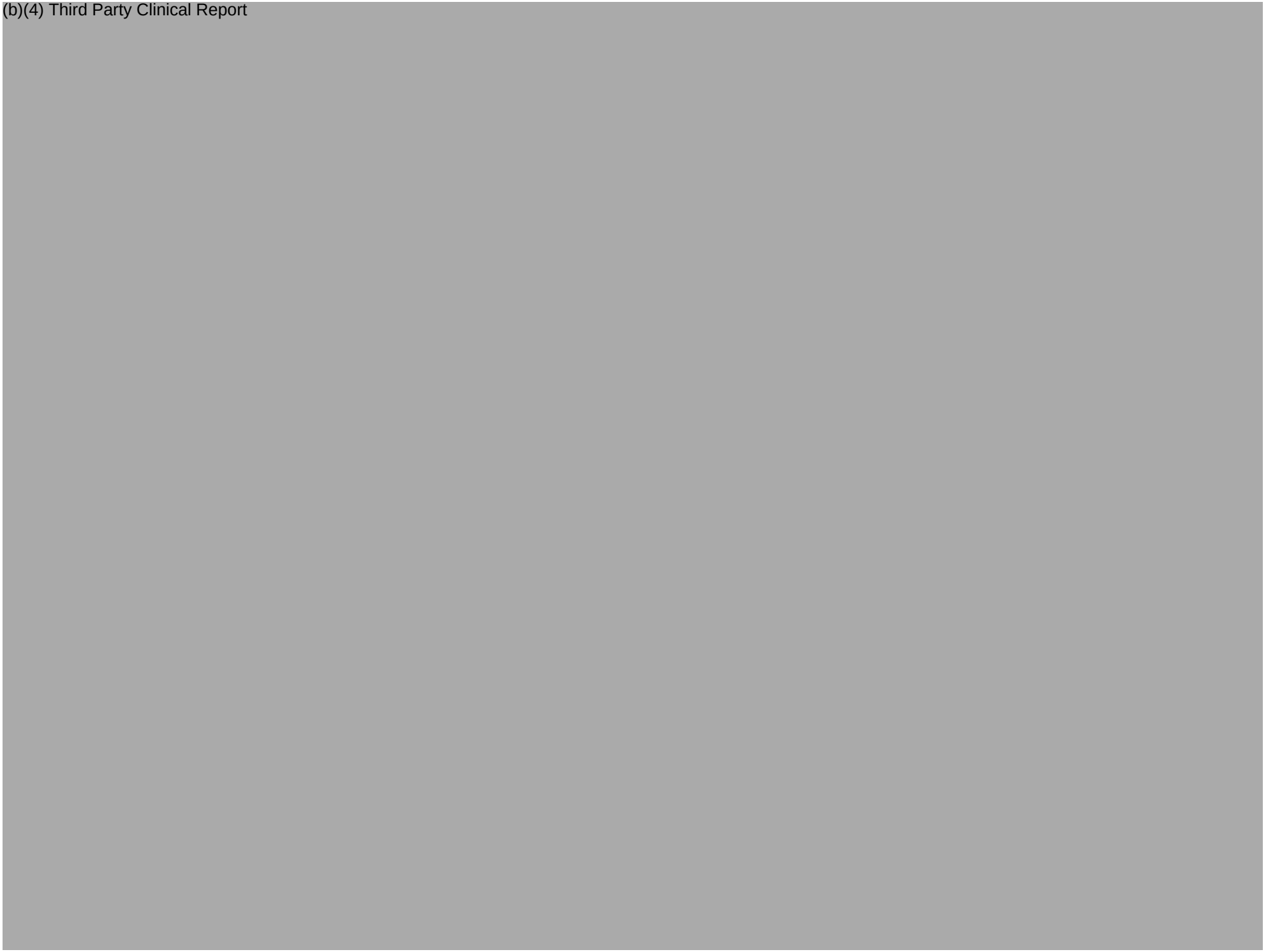
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(b)(4) Third Party Clinical Report



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Appendix H: Adverse Event Listing

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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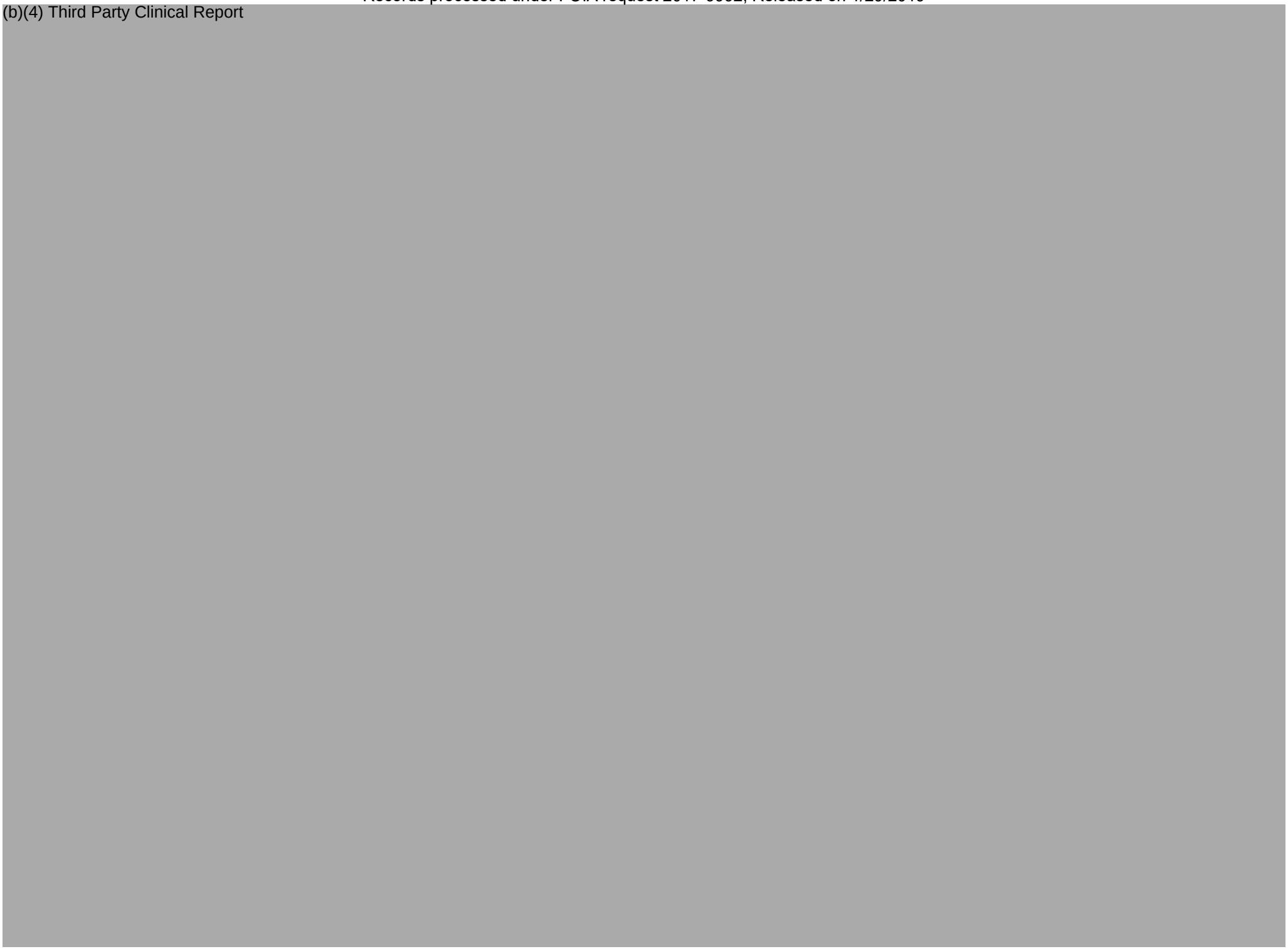
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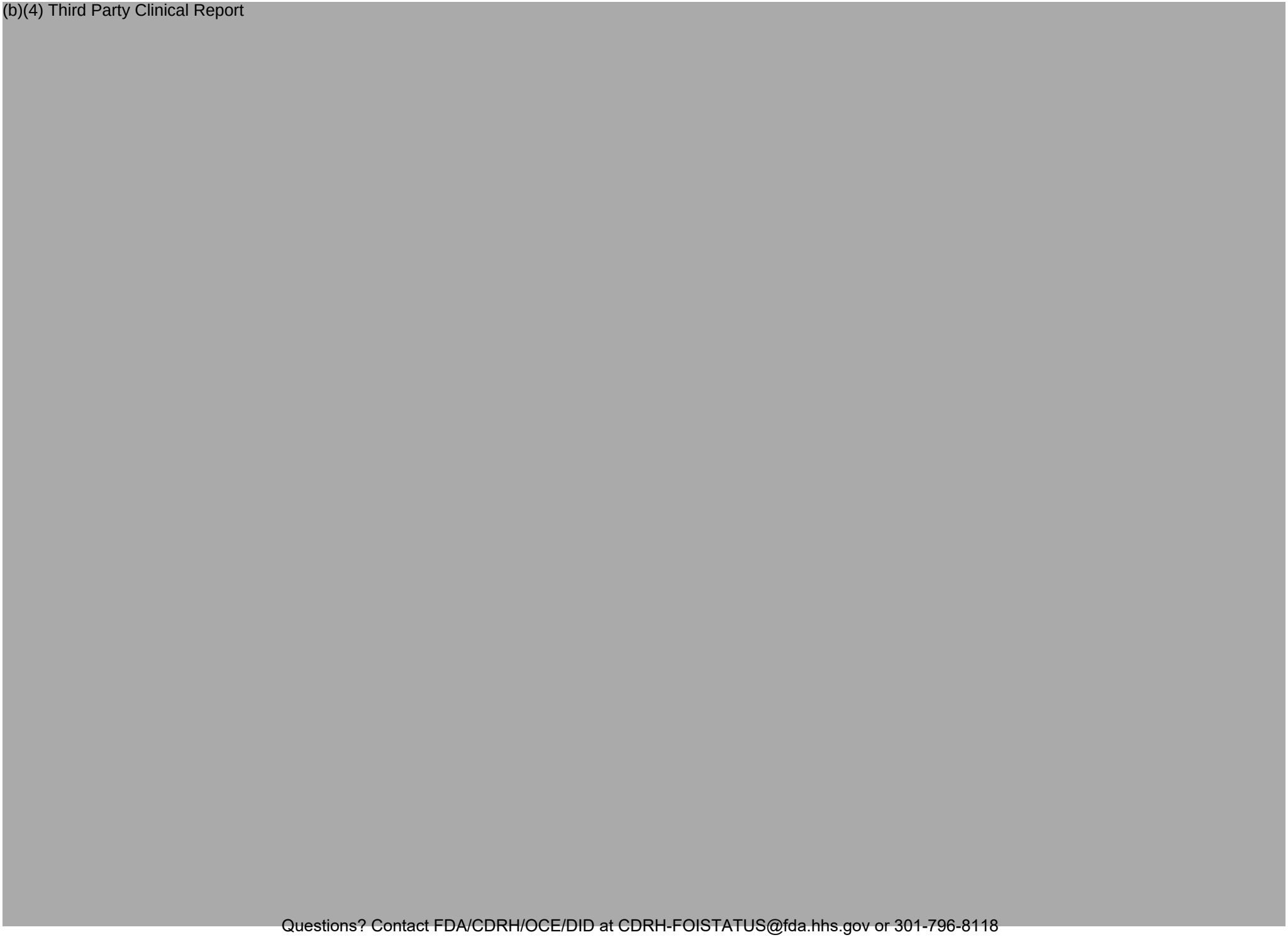
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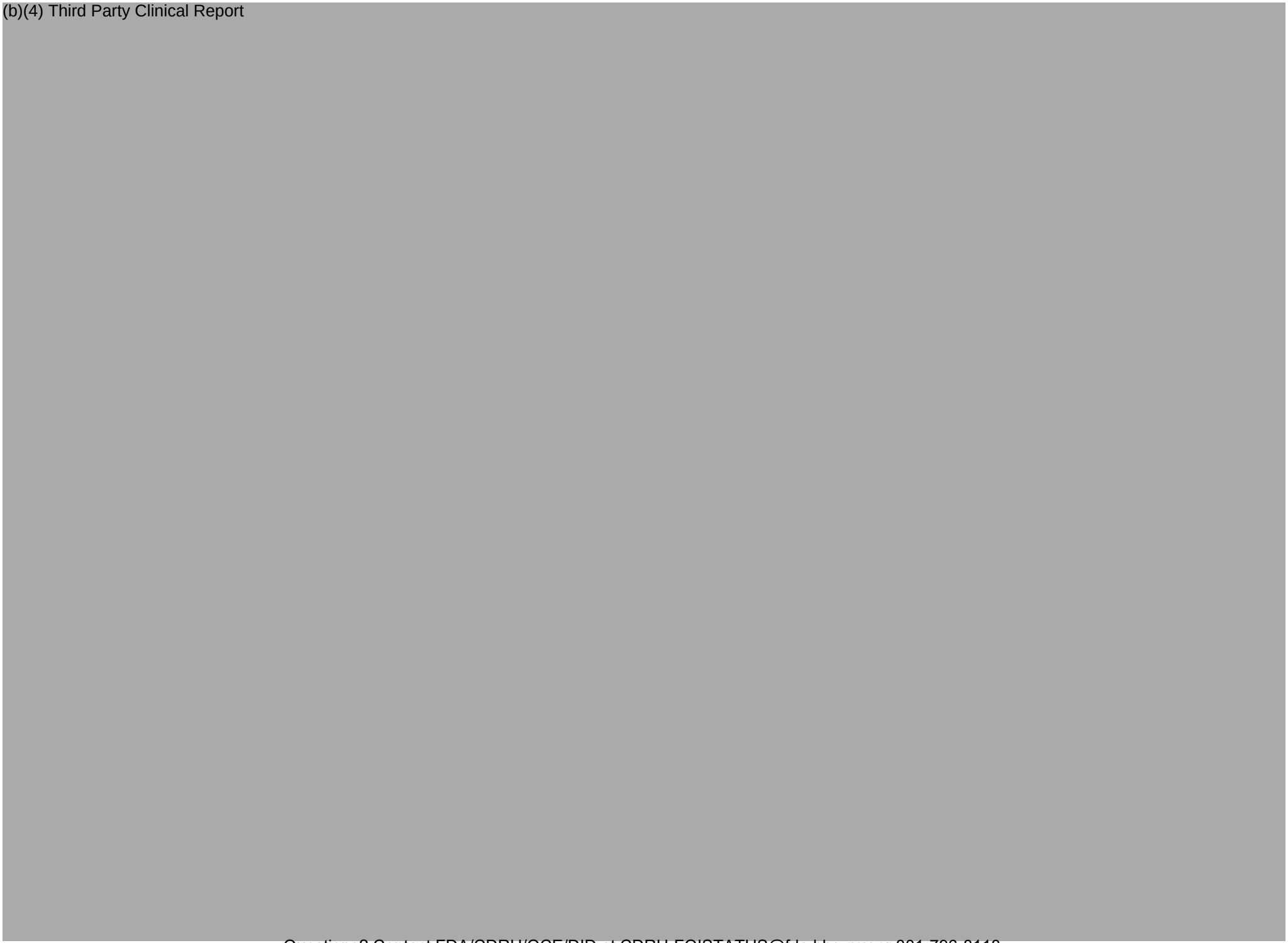
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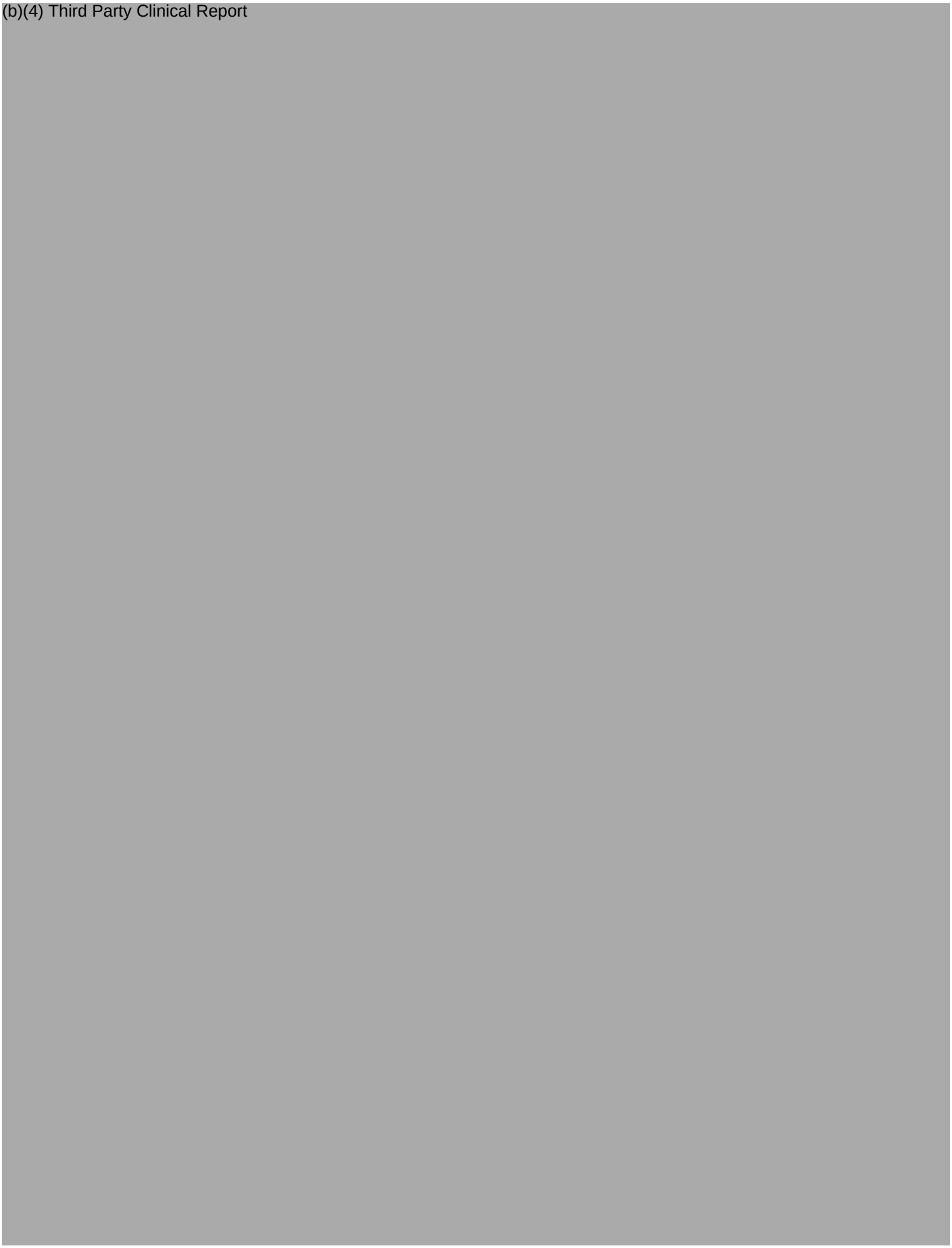
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Appendix I: Published Clinical Experience

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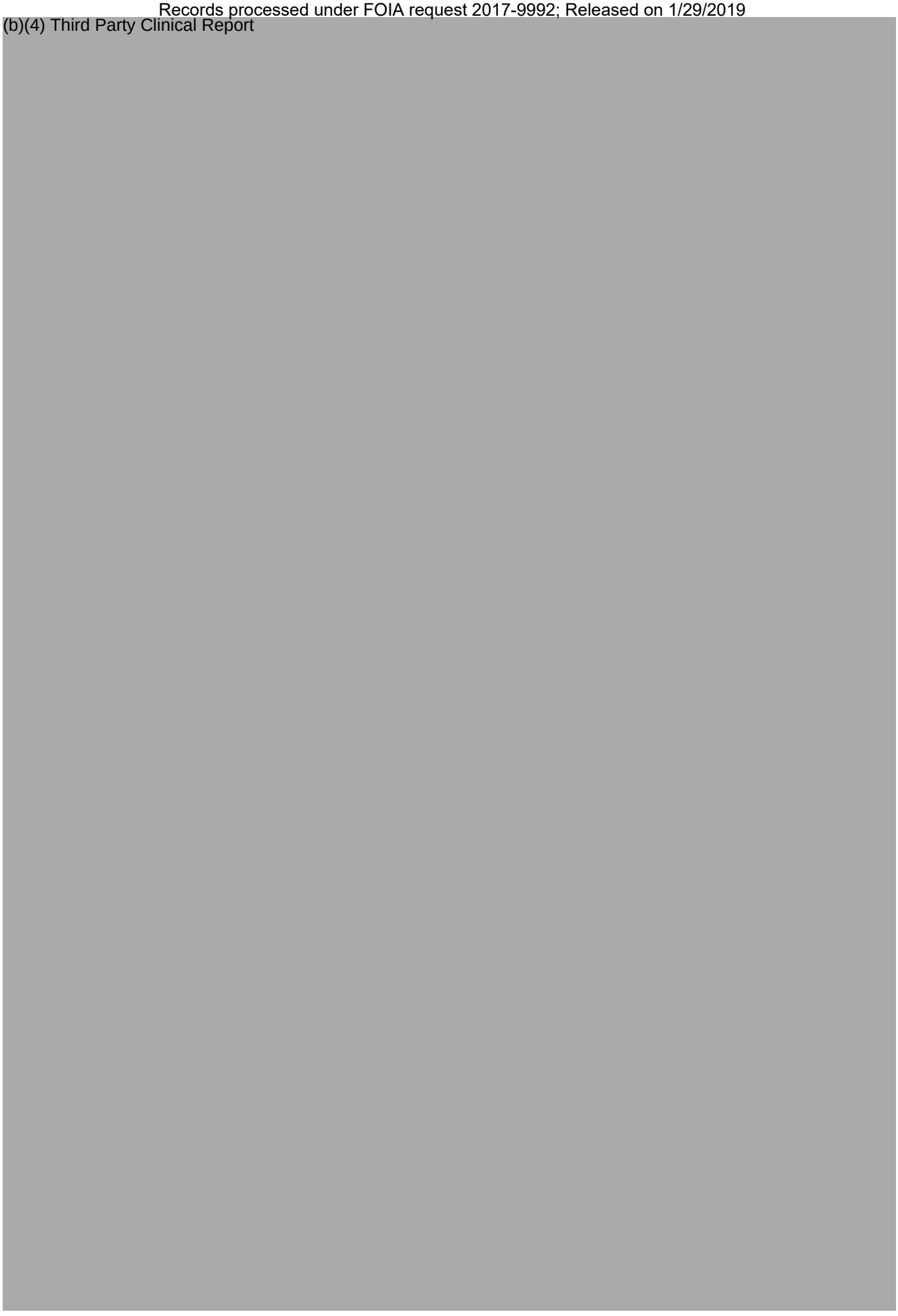
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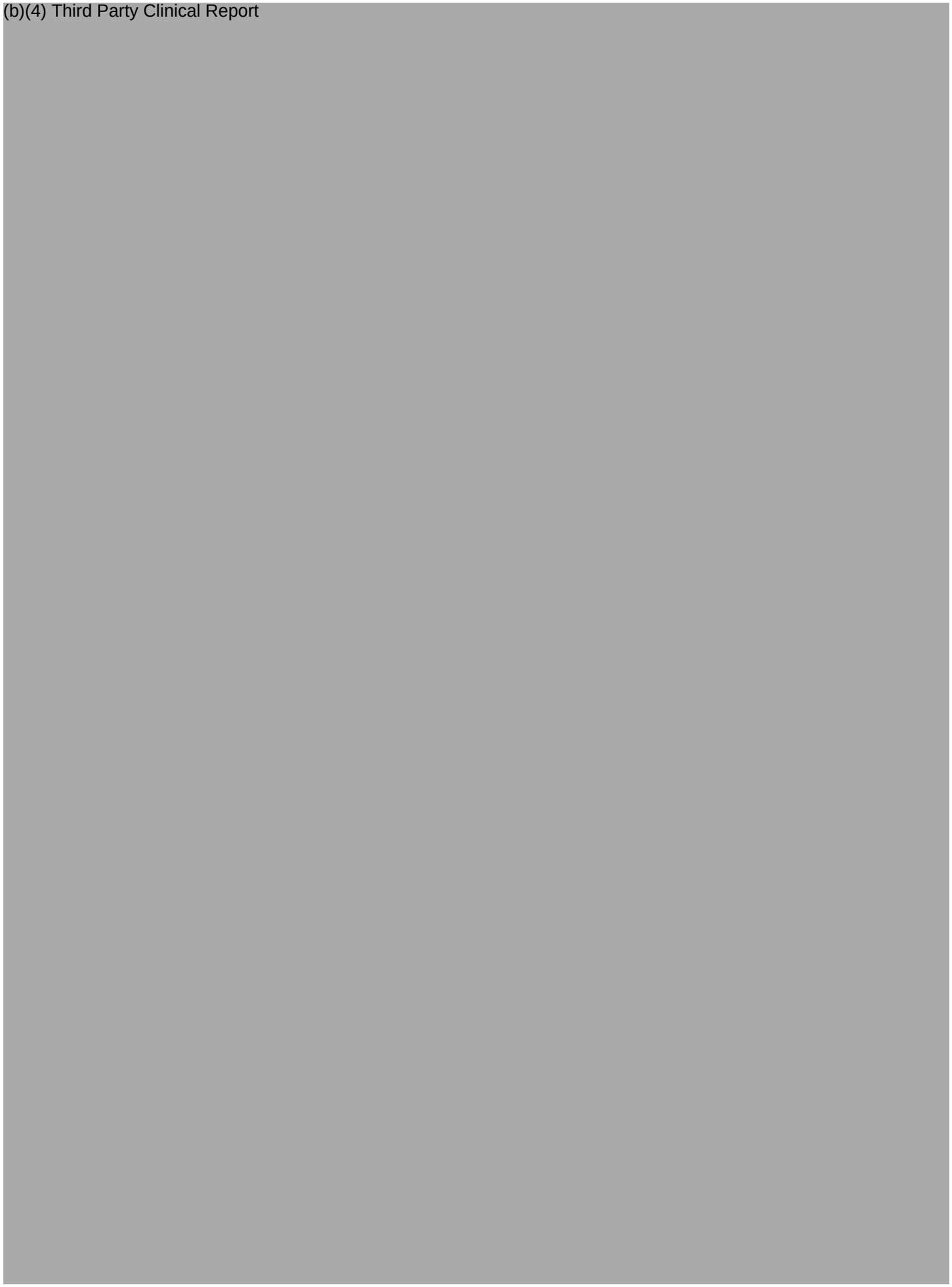
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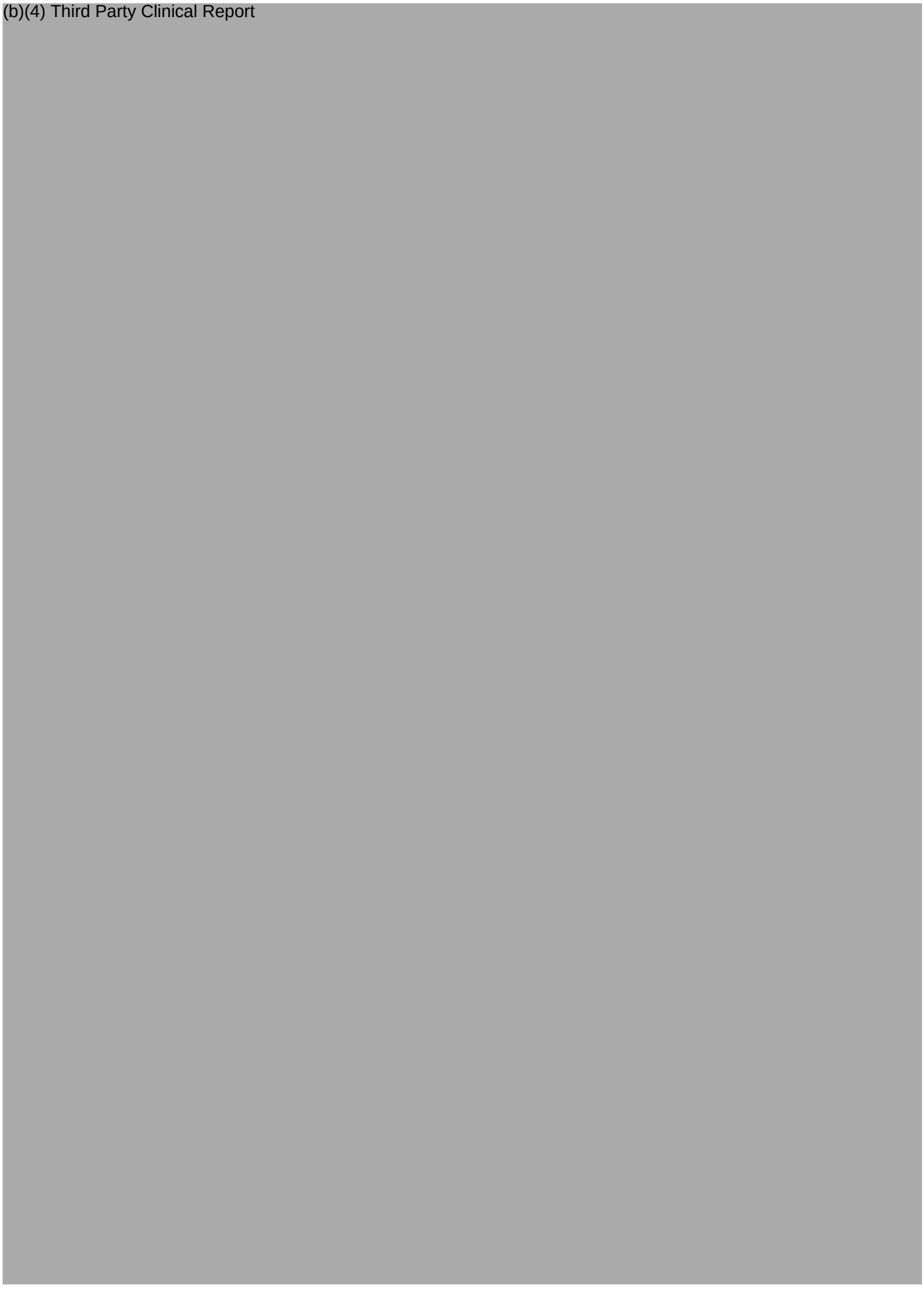
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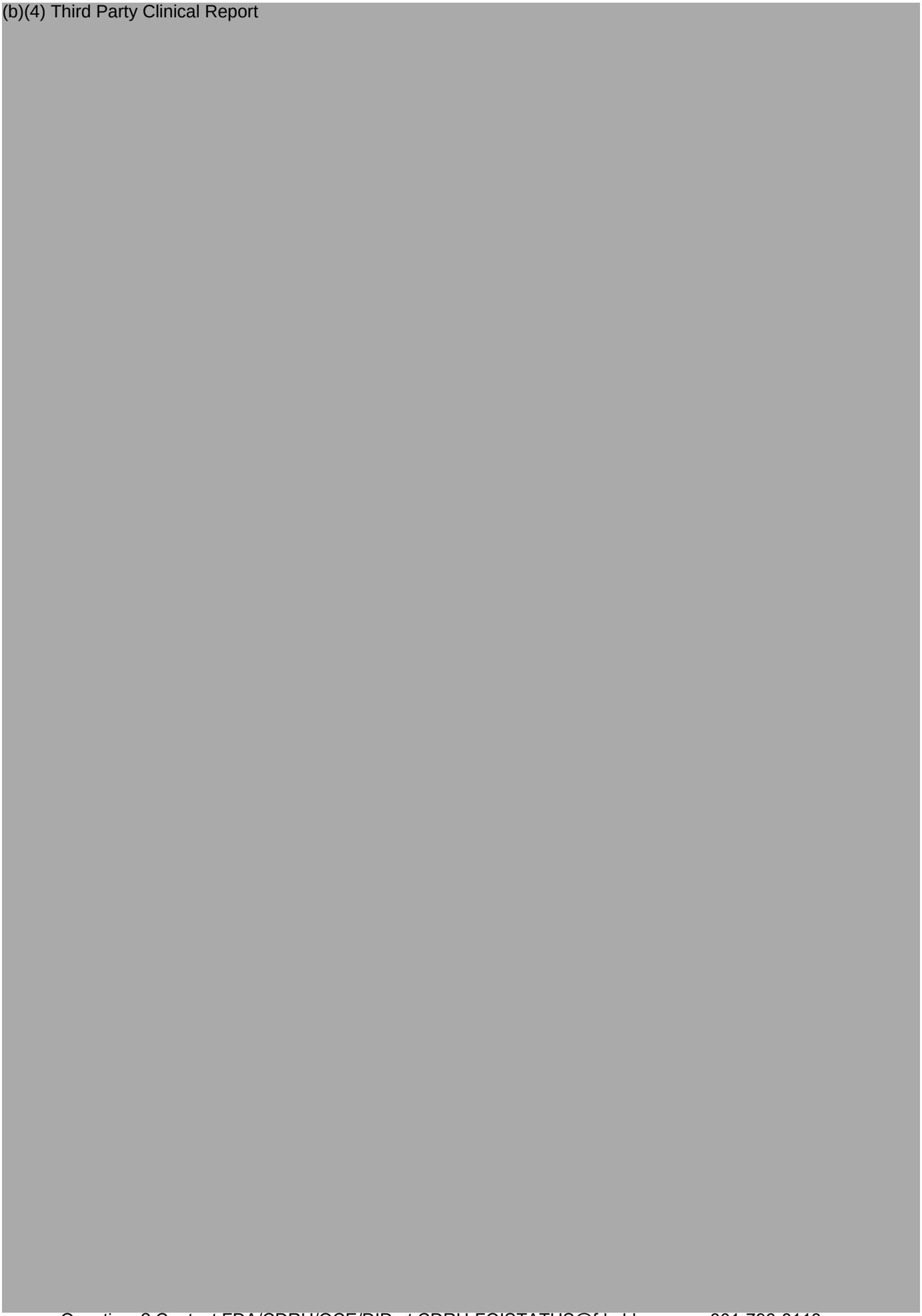
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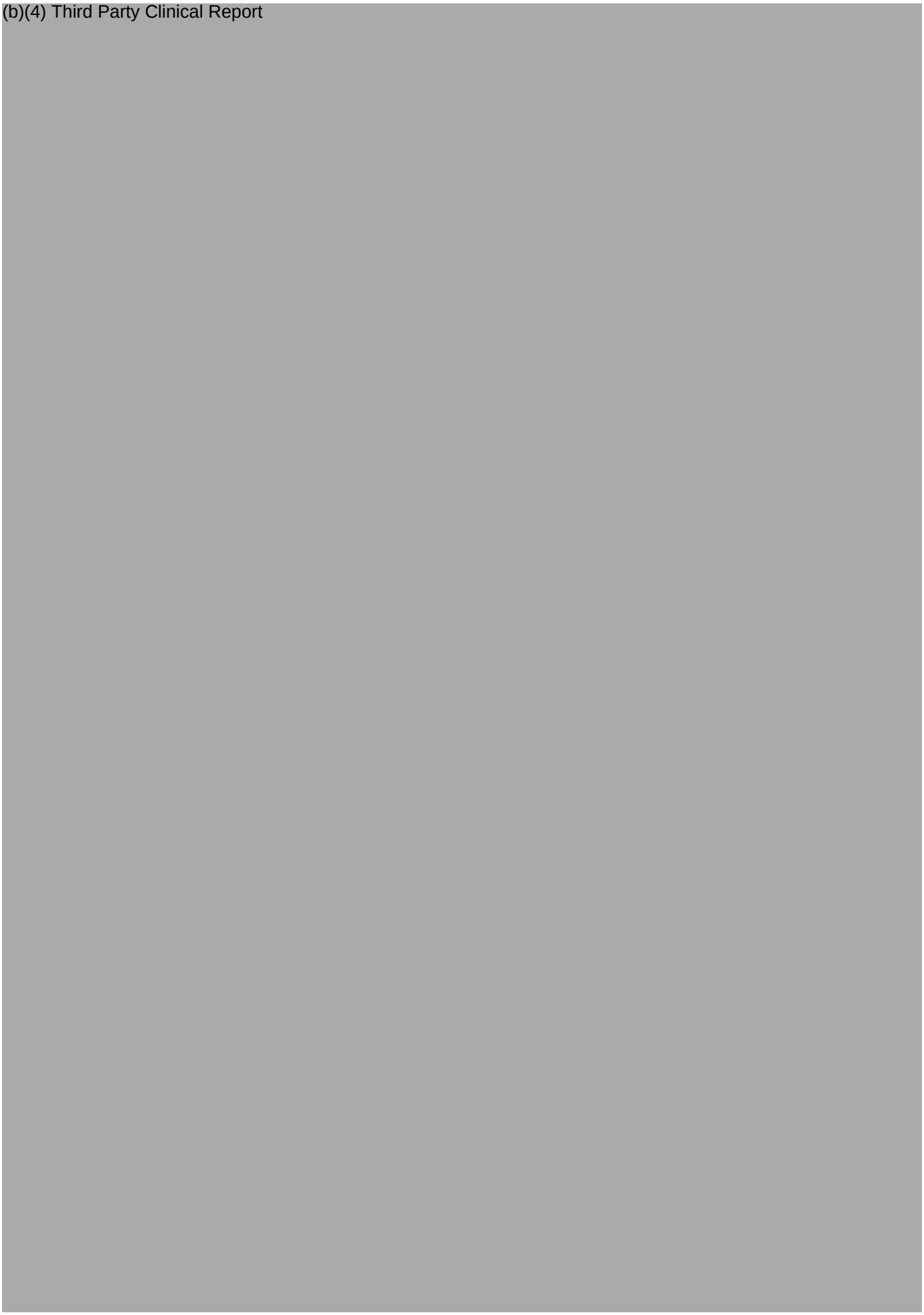
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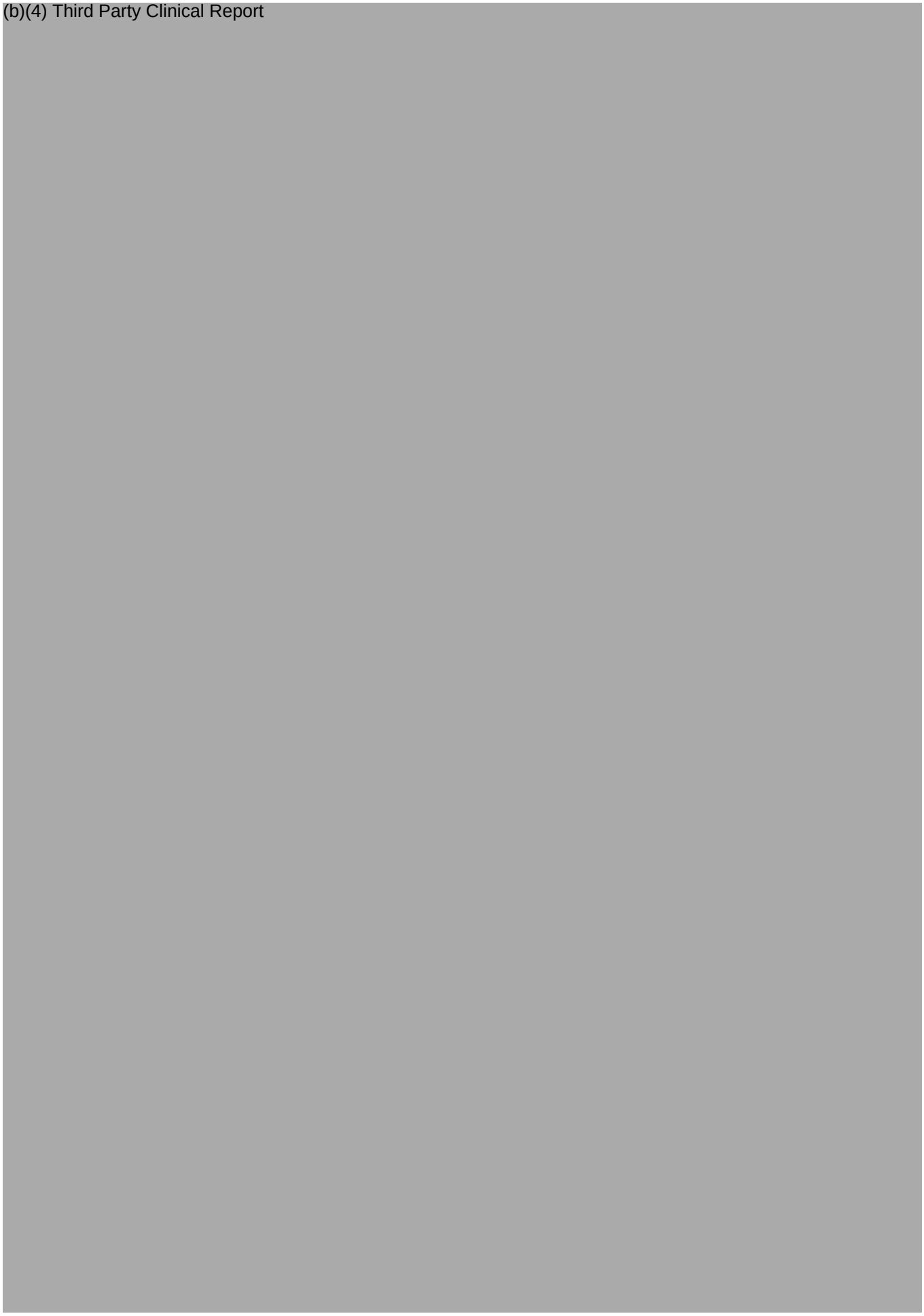
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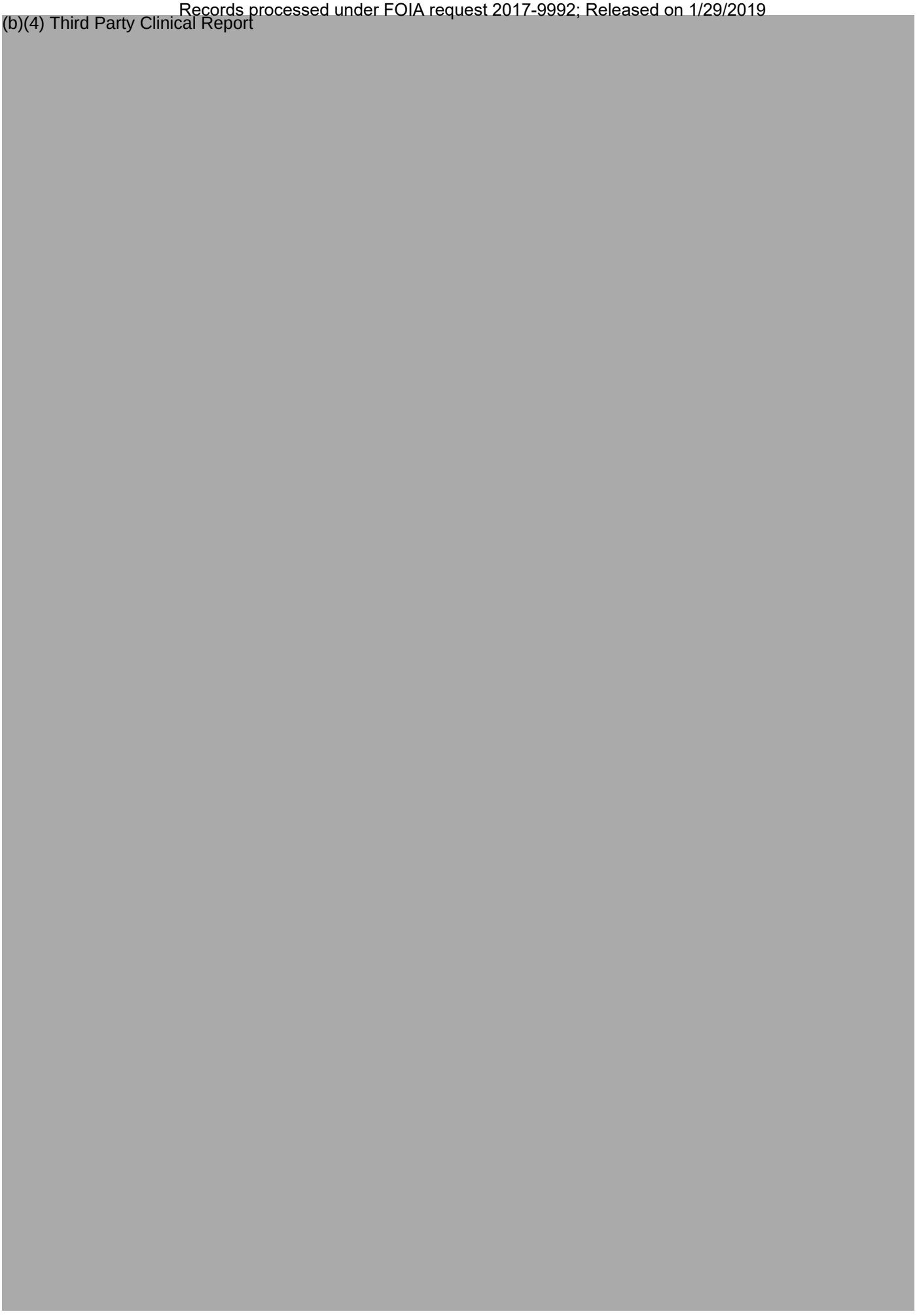
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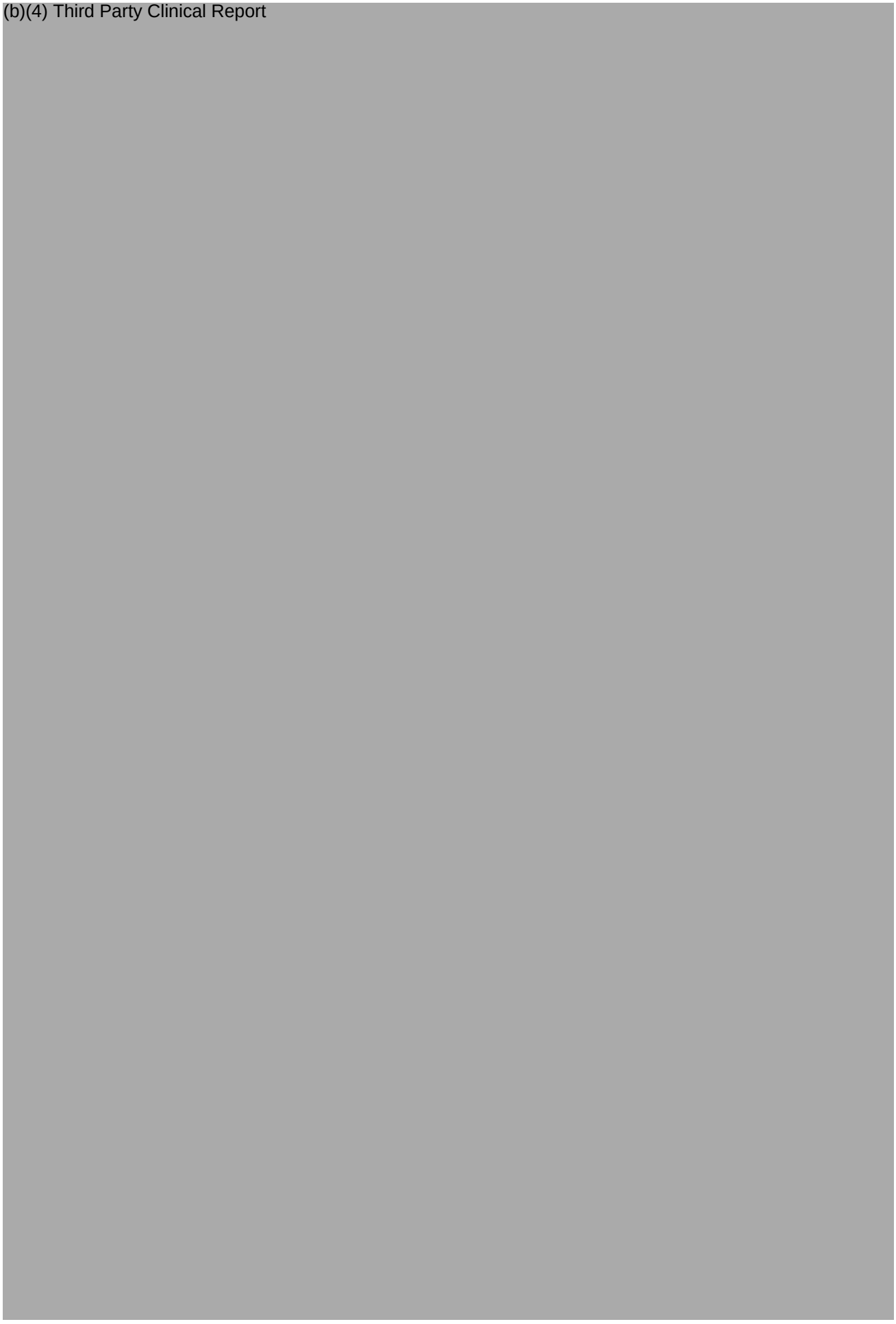
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TRADITIONAL
510(k) Premarket Notification for
SpiderFX Embolic Protection Device

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1 Medical Device User Fee Cover Sheet Form FDA 3601

The Medical Device User Fee Cover Sheet Form FDA 3601 is provided on the following page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-511. See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b) (4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

EV3 INC
3033 Campus Drive
Plymouth MN 55441
US

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
*****8586

2. CONTACT NAME
Deborah Shaffer
2.1 E-MAIL ADDRESS
dshaffer@ev3.net
2.2 TELEPHONE NUMBER (include Area code)
763-3987431
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
763-3987200

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] Annual Fee for Periodic Reporting (APR)
[ ] 30-Day Notice

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)
[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION
(b) (4)
07-Mar-2011

Form FDA 3601 (01/2007)

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2 CDRH Premarket Review Submission Cover Sheet

The CDRH Premarket Review Submission Cover Sheet is provided on the following pages.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
04/08/2011	(b) (4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
ev3 Inc.	2183870		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	763-398-7238		
Street Address	**FAX Number *(including area code)***		
3033 Campus Drive	763-591-3248		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Plymouth	MN	55441	USA
Contact Name			
Brenda Johnson			
Contact Title	**Contact E-mail Address**		
Principal Regulatory Affairs Specialist	brenda.johnson@ev3.net		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Graphics: (301) 443-6740 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☒ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	NTE	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K063204	1	SpiderFX Embolic Protection Device	1	ev3 Inc.
2	K052659	2	SpideRX Embolic Protection Device	2	ev3 Inc.
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Temporary Carotid Catheter for Embolic Capture

	Trade or Proprietary or Model Name for This Device		Model Number
1	SpiderFX® Embolic Protection Device	1	SPD2-US-050-190, SPD2-US-050-320,
2		2	SPD2-US-060-190, SPD2-US-060-320,
3		3	SPD2-US-070-190, SPD2-US-070-320
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	G080017	2	G080025	3	K063204	4	K063785	5	K052659	6	K053195
7	K062201	8	K070540 (NSE)	9	G030115	10	G020248	11		12	

Data Included in Submission

☒ Laboratory Testing ☒ Animal Trials ☒ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
NTE	21 CFR 870.1250	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Cardiovascular

Indications *(from labeling)*

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material during revascularization procedures of arteries in the lower extremities. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 6.0mm.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
ev3 Inc.	2183870
Division Name *(if applicable)*	**Phone Number *(including area code)***
	763-398-7000
Street Address	**FAX Number *(including area code)***
4600 Nathan Lane North	763-398-7200

City	State / Province	ZIP Code	Country
Plymouth	MN	55442	USA

Contact Name	Contact Title	Contact E-mail Address
Mike Geary	Director, Quality	mgeary@ev3.net

(b) (4)

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	**Phone Number *(including area code)***
Street Address	**FAX Number *(including area code)***

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1			Please see standards forms provided in Section 6.		
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

3 FDA-3674 Clinical Form

Form FDA 3674 is provided on the following page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 10-31-2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER
ev3 Inc.

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
April 2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
3033 Campus Drive, Suite N550
Plymouth, MN 55441

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 763-398-7238
(Fax) 763-591-3248 (attn: Brenda Johnson)

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Embolic Protection Device	SpiderFX Embolic Protection Device
Temporary Carotid Catheter for Embolic Capture 21 CFR 870.1250, Product Code NTE	SPD2-US-050-190, SPD2-US-050-320, SPD2-US-060-190, SPD2-US-060-320, SPD2-US-070-190, SPD2-US-070-320

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
☐ IND ☐ NDA ☐ ANDA ☐ BLA ☐ PMA ☐ HDE ☒ 510(k) ☐ PDP ☐ Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER *(If number previously assigned)*

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES *(See instructions for additional information and explanation)*

☐ A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

☐ B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

☒ C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/ SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES *(Attach extra pages as necessary)*
NCT Number(s): 00733135

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign)
June Eckhardt

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) June Eckhardt
(Title) Sr. Director, Clinical Affairs

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
3033 Campus Drive, Suite N550
Plymouth, MN 55441

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 763-591-3322
(Fax) 763-398-7200

15. DATE OF CERTIFICATION
Apr 4, 2011

Form FDA 3674 (11/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ev3™ Your endovascular company.™

April 8, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – W066 – G609
10903 New Hampshire Ave.
Silver Spring, Maryland 20993-0002

Contents: **One paper copy**
One eCopy – exact duplicate of paper copy

RE: Traditional 510(k) Submission for the
ev3 SpiderFX Embolic Protection Device, Peripheral Indication

To Whom It May Concern:

Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act and in accordance with 21 CFR 807.90(e), ev3 Endovascular Inc., doing business as ev3, is submitting the attached Premarket Notification. The basis for this submission is a modified indication for a legally marketed device. The legally marketed predicate devices are the SpiderFX Embolic Protection Device (K063204) and the SpideRX Embolic Protection Device (K052659).

This Traditional 510(k) Premarket Notification is supported by clinical data from the DEFINITIVE Ca^{++} study (G080017). The DEFINITIVE Ca^{++} study included class II devices from two separate product codes (embolic protection and plaque excision). Because each device requires a separate 510(k), this submission is exclusively for the SpiderFX Embolic Protection Device for use while performing revascularization of arteries in the lower extremities. ev3 plans to submit a separate 510(k) for the plaque excision devices that were used in the study together with the SpiderFX Embolic Protection Device.

The SpiderFX Embolic Protection Device is intended for use as a percutaneously delivered distal embolic protection device. The SpiderFX Device is designed to capture and remove dislodged debris during interventional procedures. The device Capture Wire is used as the 0.014” wire for interventional device delivery. The identical SpiderFX Embolic Protection Device currently has clearance for use during interventions in carotid arteries (K063204) and saphenous vein grafts (K063785).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

The proposed SpiderFX Device uses the identical design and materials as the legally marketed predicate SpiderFX Device. However, to support the IDE study (G080017), ev3 identified that compatibility testing needed to be completed with atherectomy, thrombectomy, and laser devices, because of their widespread use during lower extremity interventions in the United States. During the compatibility testing it was noted that it is advantageous to use a larger SpiderFX filter in a smaller vessel for two reasons: 1) to provide an increased filter capacity, and 2) to optimize filter stability during the peripheral intervention. Additionally, ev3 received feedback from physicians that in certain situations the current SpiderFX Catheter does not provide an ideal amount of support to initially cross the lesion and/or to recover the SpiderFX Capture Wire in lower extremity vessels. Preclinical bench and animal testing was completed to verify that the SpiderFX Device performed safely and as intended when used in lower extremity vessels with the revised sizing matrix, and testing verified the compatibility of commercially available catheters for delivery and/or recovery of the SpiderFX Capture Wire. This submission includes these changes in the proposed labeling and Instructions for Use.

Performance standards for Embolic Protection Devices have not been established under Section 514 of the Federal Food, Drug, and Cosmetic Act. Embolic Protection Devices are covered by the following regulations:

Trade Name	SpiderFX™ Embolic Protection Device
Common Name	Embolic Protection Device
Classification Name	Temporary Carotid Catheter for Embolic Capture
Classification Regulation	21 CFR 870.1250
Classification Panel	Cardiovascular
Device Class	II (two)
Product Code	NTE

The principal factors regarding the design and use of the proposed device are addressed in the table below.

Design and Use of the Device

Question	**YES**	**NO**
Is the device intended for prescription use (21 CFR 801 Subpart D)?	**X**	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		**X**
Does the device contain components derived from a tissue or other biologic source?	**X**	
Is the device provided sterile?	**X**	
Is the device intended for single use?	**X**	
Is the device a reprocessed single use device?		**X**
If yes, does this device type require reprocessed validation data?	**n/a**	
Does the device contain a drug?		**X**
Does the device contain a biologic?		**X**

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Design and Use of the Device

Question	**YES**	**NO**
Does the device use software?		**X**
Does the submission include clinical information?	**X**	
Is the device implanted?		**X**

This submission contains trade secret and confidential commercial information that should be protected in accordance with 21CFR Part 20 and 807.95. If additional information is required, please contact the undersigned.

Sincerely,

Brenda Johnson
Principal Regulatory Affairs Specialist
bjohnson@ev3.net
Direct: 763-398-7238
Fax: 763-591-3248

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

5 Indications for Use Statement

The Indications for Use Statement is provided on the following page.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Indications for Use Statement

510(k) Number (if known):_____

Device Name: SpiderFX® Embolic Protection Device

Indications for Use:

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material during revascularization procedures of arteries in the lower extremities. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 6.0mm.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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6 FDA-3654 Standards Form

FDA-3654 Standards Forms are provided on the following pages

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Sterilization Standards

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI ANSI ISO 10993-7 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals 2008

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	✓	
FDA Recognition number [3]	# 14-279	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

AAMI ANSI ISO 10993-7 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals 2008

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.4.6	Product Extraction	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

Option Selected: Simulated use extraction

DESCRIPTION

24 hour extraction using purified water

JUSTIFICATION

Represents the intended use of an externally communicating device

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services
Food and Drug Administration

STANDARDS DATA REPORT FOR 510(k)s

(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☑ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 11135-1, Sterilzation of health care products - Ethylene Oxide - Reqts for the development, validation, & routine process 2007

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	✓	
FDA Recognition number [3]	# 14-228	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☑	☐
Is a summary report [4] describing the extent of conformance of the standard used included in the 510(k)? If no, complete a summary report table.	☑	☐
Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?	☑	☐
Does this standard include acceptance criteria? If no, include the results of testing in the 510(k).	☑	☐
Does this standard include more than one option or selection of tests? If yes, report options selected in the summary report table.	☑	☐
Were there any deviations or adaptations made in the use of the standard?	☐	☑
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☑
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☑
Is there an FDA guidance [6] that is associated with this standard?	☐	☑
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

[5] The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[6] The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11135-1, Sterilzation of health care products - Ethylene Oxide - Reqts for the development, validation, & routine process 2007

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Annex B	Conserservative determination of lethal rate of sterilization process - Overkill	☑ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

Option Selected: Half-Cycle Appoarch: Method B.1.2-a

DESCRIPTION

A total of 3 consecutive experiments resulting in total inactivation of biological indicators to meet a sterility assurance level 10(-6)

JUSTIFICATION

Widely used by the medical device industry for externally communicating devices.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED*

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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7 510(k) Summary
SpiderFX Embolic Protection Device

The 510(k) Summary is provided on the following pages.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ev3™ Your endovascular company.™

510(k) Summary

SpiderFX® Embolic Protection Device

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1. Submitter Information

Applicant	ev3 Inc. 3033 Campus Drive Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Brenda Johnson Principal Regulatory Affairs Specialist
Date Prepared	April 7, 2011

2. Subject Device

Device Trade Name	SpiderFX® Embolic Protection Device
Device Common Name	Embolic Protection Device
Classification Name	Temporary Carotid Catheter for Embolic Capture 21 CFR 870.1250, Product Code NTE
Classification Panel	Cardiovascular

3. Predicate Devices

Device Trade Name	SpiderFX® Embolic Protection Device; SpideRX® Embolic Protection Device
510(k) Number	K063204; K052659
510(k) Clearance Date	November 14, 2006; February 17, 2006

4. Device Description

The SpiderFX® Embolic Protection Device is a percutaneously delivered distal embolic protection system that can be delivered over any 0.014" or 0.018" guidewire. The SpiderFX Embolic Protection Device contains a Capture Wire composed of a nitinol mesh filter mounted on a 190 cm or a convertible 320/190 cm PTFE-coated 0.014" stainless steel guidewire and a dual-ended SpiderFX Catheter for delivery and recovery.

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The SpiderFX® Embolic Protection Device uses the following materials: Pebax, Grilamid, Platinum/Iridium, Nitinol, Stainless Steel, PTFE coating, Gold Tungsten, and hydrophilic coating.

5. Indications for Use

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material during revascularization procedures of arteries in the lower extremities. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 6.0mm.

6. Comparison of Technological Characteristics

The SpiderFX® Embolic Protection Device is the identical device as the currently marketed SpiderFX Embolic Protection Device (K063204). The SpiderFX Embolic Protection Device for peripheral use and the predicate SpiderFX Embolic Protection Device for carotid use share the following technological characteristics:

- Intended use
- Fundamental scientific technology and operating principle
- Design & Dimensions
- Materials
- Manufacturing site and methods
- Sterilization site, method, parameters, and sterility assurance level
- Packaging
- Shelf Life

Additionally, the Indications for Use, labeling, and Instructions For Use are similar between the proposed and marketed devices. The differences include a revised sizing matrix for use during interventions in lower extremity vessels, allowing use of the SpiderFX Device with atherectomy, thrombectomy, and laser interventional devices, and allowing use of commercially available catheters, that are minimally 0.035" guide wire compatible, for delivery and/or recovery of the SpiderFX Capture Wire. Bench and animal testing was performed to demonstrate the proposed use of the device met pre-determined acceptance criteria.

7. Performance Testing Summary

To demonstrate substantial equivalence of the subject SpiderFX® Embolic Protection Device to the predicate device, the technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Analysis procedures, the following tests were performed:

- Stent Compatibility
- Filter Efficiency
- Radial Outward Force
- Simulated Use
- Deployment/Retrieval Forces
- *In Vivo* Animal Studies

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The following testing was leveraged from the predicate SpiderFX® and SpideRX® Embolic Protection Device submissions. Test results met the specified acceptance criteria and were included in K063204 or K052659:

- Embolic Capture Efficiency and Retrieval Ability
- Simulated Use
- Deployment/Retrieval Forces
- Filter Capacity
- Resistance to Filter Rupture During Removal of a Fully Loaded Filter
- Flow Characteristics
- Tip Flexibility
- Tensile Strength
- Torque Strength
- Torque Response
- Kink Resistance
- Dimensional Verification
- Package Integrity
- Sterilization
- Biocompatibility
- Shelf Life

The results from these tests demonstrate that the technological characteristics and performance criteria of the SpiderFX® Embolic Protection Device are comparable to the predicate device and that the SpiderFX® Embolic Protection Device performs in a manner equivalent to the predicate device currently on the market for the same intended use.

8. Conclusions

Based on the intended use, technological characteristics, safety and performance testing included in this submission, ev3 considers the proposed SpiderFX® Embolic Protection Device to be substantially equivalent to the currently marketed SpiderFX® Embolic Protection Device (K063204) and SpideRX® Embolic Protection Device (K052659).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8 Truthful and Accurate Statement

The Truthful and Accurate Statement is provided on the following page.

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PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT

[as required by 21 CFR 807.87(k)]

I certify that, in my capacity as Principal Regulatory Affairs Specialist at ev3, I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.



Brenda Johnson
Principal Regulatory Affairs Specialist

April 8, 2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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9 Class III Summary and Certification

This section does not apply to the SpiderFX Embolic Protection Device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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10 Financial Certification of Clinical Investigators

In accordance with 21 CFR 807.87(i), the following page provides a financial certification (Form FDA 3454) which is applicable to all DEFINITIVE Ca^{++} clinical investigators with the exception of one investigator. A complete listing of the applicable investigators is provided on the page following the form.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

CERTIFICATION: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

TO BE COMPLETED BY APPLICANT

With respect to all covered clinical studies (or specific clinical studies listed below (if appropriate)) submitted in support of this application, I certify to one of the statements below as appropriate. I understand that this certification is made in compliance with 21 CFR part 54 and that for the purposes of this statement, a clinical investigator includes the spouse and each dependent child of the investigator as defined in 21 CFR 54.2(d).

Please mark the applicable checkbox.

☒ (1) As the sponsor of the submitted studies, I certify that I have not entered into any financial arrangement with the listed clinical investigators (enter names of clinical investigators below or attach list of names to this form) whereby the value of compensation to the investigator could be affected by the outcome of the study as defined in 21 CFR 54.2(a). I also certify that each listed clinical investigator required to disclose to the sponsor whether the investigator had a proprietary interest in this product or a significant equity in the sponsor as defined in 21 CFR 54.2(b) did not disclose any such interests. I further certify that no listed investigator was the recipient of significant payments of other sorts as defined in 21 CFR 54.2(f).

Clinical Investigators		
	see attached listing	

☐ (2) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that based on information obtained from the sponsor or from participating clinical investigators, the listed clinical investigators (attach list of names to this form) did not participate in any financial arrangement with the sponsor of a covered study whereby the value of compensation to the investigator for conducting the study could be affected by the outcome of the study (as defined in 21 CFR 54.2(a)); had no proprietary interest in this product or significant equity interest in the sponsor of the covered study (as defined in 21 CFR 54.2(b)); and was not the recipient of significant payments of other sorts (as defined in 21 CFR 54.2(f)).

☐ (3) As the applicant who is submitting a study or studies sponsored by a firm or party other than the applicant, I certify that I have acted with due diligence to obtain from the listed clinical investigators (attach list of names) or from the sponsor the information required under 54.4 and it was not possible to do so. The reason why this information could not be obtained is attached.

NAME	TITLE
David Worrell	Director of Regulatory Affairs
FIRM/ORGANIZATION: ev3 Inc.	
SIGNATURE: 	DATE *(mm/dd/yyyy)*: April 7, 2011

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1350 Piccard Drive, 420A
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FORM FDA 3454 (10/09)

PSC Graphics (301) 443-1090 EF

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(b) (4)

Form FDA 3454, Clinical Investigator Listing

Name	Site

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

DISCLOSURE: FINANCIAL INTERESTS AND ARRANGEMENTS OF CLINICAL INVESTIGATORS

Form Approved: OMB No. 0910-0396
Expiration Date: August 31, 2012

TO BE COMPLETED BY APPLICANT

The following information concerning (b) (4) , who participated
Name of clinical investigator

as a clinical investigator in the submitted study (b) (4)
Name of

_____ is submitted in accordance with 21 CFR part 54. The
clinical study

named individual has participated in financial arrangements or holds financial interests that are required to be disclosed as follows:

Please mark the applicable check boxes.

☐ any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of the covered study, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;

☐ any significant payments of other sorts made on or after February 2, 1999, from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

☐ any proprietary interest in the product tested in the covered study held by the clinical investigator;

☒ any significant equity interest, as defined in 21 CFR 54.2(b), held by the clinical investigator in the sponsor of the covered study.

Details of the individual's disclosable financial arrangements and interests are attached, along with a description of steps taken to minimize the potential bias of clinical study results by any of the disclosed arrangements or interests.

NAME	TITLE
David Worrell	Director, Regulatory Affairs
FIRM/ORGANIZATION ev3 Inc.	
SIGNATURE	Date *(mm/dd/yyyy)* 04/07/2011

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REC'D JUL 16 2010

ENT'D JUL 19 2010

(b) (4)

ev3®

Appendix B: FINANCIAL DISCLOSURE STATEMENT

(b) (4) name) will be serving as a Clinical (the "Study") with FoxHollow Technologies and/or ev3 Inc. Pursuant to 21 CFR Part 54, I hereby disclose the following required financial information.

1. During the course of the Study, I was an employee or part-time employee of FoxHollow Technologies and/or ev3.

   ☐ Yes ☒ No

2. I have listed below details of any financial arrangement between myself (or my spouse and dependent children) and Sponsor, whereby the value of my compensation for conducting the Study could be influenced by the outcome of the Study. Compensation affect by the outcome of the clinical study means compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result, compensation in the form of an equity interest in Sponsor, or compensation tied to the sales for the product, such as a royalty interest.

☒ Neither I, nor my spouse or dependent children, has any financial arrangement with Sponsor whereby the value of my compensation for conducting the Study could be influenced by the outcome of the Study.

3. I have listed below details of any other significant payments (i.e., payments with a monetary value of more than $25,000) from Sponsor to me (or my spouse and dependent children), such as grants to fund ongoing research, compensation in the form of equipment, retainer for on-going consultation, or honoraria. I understand that this includes payments made by Sponsor to me or my institution to support my activities, exclusive of the costs of conducting the Study, during the time I am carrying out the Study and for 1 year following the completion of the Study.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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RECD JUL 16 2010

(b) (4)

☑ Neither I, nor my spouse or dependent children, have received any other significant payments from Sponsor.

4. I have listed below any proprietary interest I (or my spouse and dependent children) have in the product being tested in the Study. I understand that proprietary interest in the tested product means property or other financial interest in the product including, but not limited to, a patent, trademark, copyright or licensing agreement.

☒ Neither I, nor my spouse or dependent children, have received any proprietary interest in the product being tested in the Study.

5. I have listed below any significant equity interest I (or my spouse and dependent children) have in t Sponsor. I understand that significant equity interest means any ownership interest, stock option or other financial interest that exceeds $50,000 during the time the clinical investigator

(b) (4)

(b) (4)

either I, nor my spouse or dependent children, have received any other significant equity interest in Sponsor.

6. List any steps taken to minimize the potential for bias resulting from any of the disclosed arrangements, interest or payments above.

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11 Executive Summary

SpiderFX® Embolic Protection Device Traditional 510(k)

Applicant (Manufacturer)

Name	ev3 Inc.
Address	3033 Campus Drive | Plymouth | MN 55441
Telephone:	763-398-7000
Fax:	763-591-3248

Submitter

Name	ev3 Inc.
Company Address	3033 Campus Drive | Plymouth | MN 55441
Telephone:	763-398-7000
Fax:	763-591-3248

Contact Person

Name	Brenda Johnson
Company Address	3033 Campus Drive | Plymouth | MN 55441
Telephone	763-398-7238
Fax	763-591-3248
Summary Preparation Date	April 7, 2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Device Name and Classification

Trade Name	SpiderFX® Embolic Protection Device
Common Name	Embolic Protection Device
Classification Name	Catheter, Percutaneous
Classification	21 CFR 870.1250
Product Code	NTE

Predicate Device Identification

Name	ev3 Inc.
Product Name	SpiderFX® Embolic Protection Device; SpideRX® Embolic Protection Device
Clearance Number	K063204 K052659

Device Description

The SpiderFX Embolic Protection Device is a percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The SpiderFX Device Capture Wire is used as the 0.014 in. wire for interventional device delivery. The SpiderFX Device can be delivered over any 0.014 in. or 0.018 in. primary wire used to gain access to the lesion site. The SpiderFX Embolic Protection Device package contains the following three components:

- One **Capture Wire** composed of a nitinol mesh filter with a Distal Floppy Tip, mounted on a 190 cm or a convertible 190/320cm PTFE-coated 0.014" stainless steel wire. The filter is mounted in such a manner that the stainless steel wire is allowed to rotate freely under the radiopaque markers utilized to mount the filter. The filter is coated with heparin. The convertible Capture Wire is scored at the 190cm mark, allowing the wire to be snapped to a 190cm usable length for use with rapid exchange systems, if desired.

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- The **SpiderFX Catheter** is a single lumen tube with asymmetric ends with dual functions. The delivery end is colored green, and recovery end is colored blue at opposite ends of the catheter. The delivery end contains a double-port design to allow the rapid-exchange exit of the guidewire, as well as a separate location for the exit of the Capture Wire. The area proximal to the guidewire exit, designated as the garage, houses the filter while the catheter is advanced over the normal PTCA guidewire. The recovery end has only one port to allow the retrieval of the Capture Wire. The Capture Wire is preloaded into the SpiderFX Catheter at shipping.
  * As an alternative to using the SpiderFX Catheter for delivery and/or recovery of the Capture Wire, commercially available catheters that are compatible with 0.035" guide wires may be used for delivery and/or recovery of the SpiderFX Capture Wire.
- One **23 gauge blunt tip flushing needle** for use in flushing the delivery end of the catheter before use.

Indications For Use:

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material during revascularization procedures of arteries in the lower extremities. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 6.0mm.

Intended Use

Percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The device Capture Wire is used as the 0.014" wire for interventional device delivery.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.1 Substantial Equivalence Summary

Table 11 - 1: Substantial Equivalence Summary

	Proposed Device	Predicate Devices	
Device Name	**SpiderFX**	**SpiderFX**	**SpideRX**
Indication	**Use in Lower Extremity Interventions**	**Carotid Use**	**Carotid Use**
510(k) Number	K10XXXX	K063204	K052659
Intended Use			
Indications For Use	Indicated for use as a guidewire and embolic protection system to contain and remove embolic material during revascularization procedures of arteries in the lower extremities. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 6.0mm.	Indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.	
Intended Use	Percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The device Capture Wire is used as the 0.014" wire for interventional device delivery.		
Indicated Vessel Diameters	3.0 – 6.0 mm	3.0 – 7.0 mm	
Technological Characteristics			
System Components	SpiderFX Catheter Capture Wire Flushing Needle		SpideRX Catheter Capture Wire
Guide (Sheath) Compatibility	6F (5F) – min. 0.066"		
Primary Wire Compatibility	0.014" or 0.018"		
Wire Exit Location	22.5 cm (Primary guidewire) 40 cm (Capture Wire)		
Catheter Configuration	Dual-ended Rapid Exchange (Delivery End and Recovery End)		
Catheter Delivery End Nominal Diameter		(b) (4)	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11 - 1: Substantial Equivalence Summary

	Proposed Device	Predicate Devices	
Device Name	**SpiderFX**	**SpiderFX**	**SpideRX**
Indication	**Use in Lower Extremity Interventions**	**Carotid Use**	**Carotid Use**
Catheter Recovery End Nominal Diameter	(b) (4)		
Catheter Materials			
Capture Wire Lengths			
Filter Sizes			
Recommended Vessel Sizing			
Filter Materials			
Filter Design	Eccentric		
Recommended Distance Between Lesion and Filter	2.0 cm		1.5 cm

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11.2 Device History

The SpiderFX Device is commercially available in the United States with indications for both carotid (K063204) and saphenous vein graft (SVG) (K063785) interventions. The SpiderFX Device is also available commercially outside of the United States. In Europe and many other international markets the SpiderFX Device is approved with a general vascular indication, which includes carotid, SVG, and peripheral use. The design and materials of the device described in this 510(k) are identical to the device that is marketed under clearances K063204 and K063785 and sold internationally.

Device testing was initially performed on the SpiderFX Device to demonstrate compatibility and performance with balloons and stents. Atherectomy, thrombectomy, and laser devices were not included in initial bench testing, which resulted in the inclusion of a warning by ev3 in the SpiderFX IFU regarding use of the SpiderFX Device with those devices. To support the IDE study (G080017), ev3 considered the use of the SpiderFX Device in lower extremity vessels in the United States and identified that compatibility testing needed to be completed with atherectomy, thrombectomy, and laser devices, because of their widespread use during lower extremity interventions in the United States.

After considering the device interactions between many different types of atherectomy, thrombectomy, and laser devices, ev3 determined SilverHawk to be a worst-case device for demonstrating compatibility of the SpiderFX Device with atherectomy, thrombectomy, and laser devices. This determination was made because of the location of the functional portion of the device relative to its long nose-cone on the distal end and the unique eccentric design of the SilverHawk Device. Additionally, physician feedback indicated that the SilverHawk Device is the most frequently used atherectomy device in peripheral interventions in the United States. Therefore ev3 chose to complete testing with the SilverHawk device to demonstrate compatibility of the SpiderFX Device with atherectomy, thrombectomy, and laser devices.

During the compatibility testing it was noted that it is advantageous to use a larger SpiderFX filter in a smaller vessel for two reasons: 1) to provide an increased filter capacity, and 2) to optimize filter stability during the peripheral intervention. Preclinical bench and animal testing was completed to verify that the SpiderFX Device performed safely and as intended when used with worst-case atherectomy devices in lower extremity vessels with the revised sizing matrix. Therefore, ev3 is recommending the following sizing matrix when the SpiderFX Device is used in the peripheral vasculature.

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Table 11 - 2: Recommended SpiderFX Sizing Matrices

Filter Size (mm)	Recommended Vessel Diameter for SpiderFX placement during Peripheral Interventions (mm)	Current Vessel Diameter for SpiderFX placement during SVG & Carotid Interventions (mm)
3.0	n/a	3.0
4.0	n/a	3.1-4.0
5.0	3.0-4.0	4.1-5.0
6.0	3.5-5.0	4.5-6.0
7.0	4.5-6.0	5.5-6.0 (SVG) 5.5-7.0 (Carotid)

Additionally, ev3 received feedback from physicians that in certain situations the current SpiderFX Catheter does not provide an ideal amount of support to initially cross the lesion and/or to recover the SpiderFX Capture Wire in lower extremity vessels. Therefore, based on compatibility testing performed, ev3 will include in the proposed product labeling the use of commercially available catheters that are minimally 0.035" guide wire compatible, for delivery and/or recovery of the SpiderFX Capture Wire.

11.3 Performance Testing-Bench

The tests and test results presented in this submission previously were reviewed by FDA in one or more of the following submissions: G080017, G080025, G030115, G020248, K052659, K053195, K063204, K063785, K070540 (determined to be NSE). Because the tests and results are included by reference in this submission, the tests and test results are presented in summary tables rather than re-presenting the entire data set previously reviewed and cleared by FDA.

Multiple bench-level Design Verification and Validation Tests were performed to evaluate the performance of the SpiderFX System with respect to its intended use. A risk-based approach, Failure Mode Effect and Criticality Analysis (FMECA), initially was conducted to identify performance characteristics of the SpiderFX Device that required design verification and validation activities to support use of the SpiderFX Device during PTA and stenting interventions.

To support the addition of atherectomy, thrombectomy, and laser devices and the revised sizing matrix, bench testing models were developed to evaluate whether the SpiderFX Device performed as intended when used with worst-case atherectomy devices in peripheral vessels with the revised sizing matrix (previously described in Section 12.1). A Design/Interface FMECA was completed to identify the bench and animal testing necessary to demonstrate compatibility between the worst-case atherectomy devices and the SpiderFX Device. Separate testing also was completed to demonstrate that commercially available 0.035" guidewire compatible catheters could be used to deliver and/or recover the SpiderFX Capture Wire, if desired.

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All of the test methods utilized for SpiderFX testing and the resulting data previously were reviewed by FDA for the SpiderFX Device (G080017, G080025, K070540- determined to be NSE), and/or the predicate SpideRX Device (G020248, G030115, K052659, K053195). Please note: the SpiderFX Device Carotid and SVG submissions (K063204, K063785) were approved via Special 510(k), therefore the summaries of design control test methods and acceptance criteria were provided to FDA for review. The following design characteristics which were not affected by the SpiderFX design change were not re-tested for the SpiderFX Device: catheter tip flexibility, catheter bond tensile, catheter kink, catheter torque strength and torque response, Capture Wire tip flexibility, heparin coating durability, flow characteristics and filter capacity. These results from SpideRX testing included in K052659 and K053195 are applicable to the SpiderFX device.

11.3.1 Testing Recommended in FDA Guidance Document

FDA issued a Guidance Document titled "Coronary and Carotid Embolic Protection devices – Premarket Notification [510(k)] Submissions" on February 15, 2008. All testing for the SpiderFX Device already had been completed at that time, however, the guidance document was considered in conjunction with this Premarket Notification. Table 11-3 below lists the bench testing described in the guidance document, and provides references to the submission(s) previously reviewed by FDA which contained the identical test methods and/or data to support use with PTA catheters and stents. Table 11-4 summarizes the bench tests and provides the results achieved.

Table 11 - 3: References to Previous FDA Reviews; Testing Recommended in FDA Guidance Document - Use with PTA Catheters and Stents

#	Recommended Bench Test	References		Comments
		Test Method	Data Review	
1	**Embolic Capture Efficiency and Retrieval Ability**	Capture Efficiency: K052659, page 18-17 Retrieval Ability: K052659, page 18-41	K063204 (Attach. D, provided summary)	Previously referred to as Capture Efficiency and Debris Retention
2	**Stent Compatibility**	K052659, page 18-15	K063204 (Attach. D, provided summary)	Previously referred to as Stent Crossability;
3	**Simulated Use**	K052659, page 18-12	K063204 (Attach. D, provided summary)	
4	**Deployment/ Retrieval Forces**	K052659, page 18-12	K063204 (Attach. D, provided summary)	Previously referred to as Filter Advancement and Filter Deployment, within Simulated Use.
5	**Filter Capacity**	K052659, Page 18-46	K052659, Page 18-46	SpideRX data is applicable to SpiderFX
6	**Resistance to Filter Rupture During Removal of a Fully Loaded Filter**	K052659, page 18-32	K063204 (Attach. D, provided summary)	Previously referred to as Resistance to Rupture

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Table 11 - 3: References to Previous FDA Reviews; Testing Recommended in FDA Guidance Document - Use with PTA Catheters and Stents

#	Recommended Bench Test	References		Comments
		Test Method	Data Review	
7	**Flow Characteristics**	K052659, Page 18-47	K052659, Page 18-47	SpideRX data is applicable to SpiderFX
8	**Radial Outward Force**	K052659, Page 18-44	K063204 (Attach. D, provided summary)	Previously referred to as Radial Expansion Force
9a	**Tip Flexibility- Catheter**	K052659, Page 18-20	K052659, Page 18-20	SpideRX data is applicable to SpiderFX
9b	**Tip Flexibility- Wire**	K052659, Page 18-26	K052659, Page 18-26	SpideRX data is applicable to SpiderFX
10a	**Tensile Strength - Catheter**	K052659, Page 18-22	K052659, Page 18-22 K052659, Page 18-24 White strip at primary wire exit port: K063204 (Attach. D, provided summary)	SpideRX data is applicable to SpiderFX. SpiderFX has an additional bond at the primary wire exit port.
10b	**Tensile Strength – Capture Wire**	K052659, Page 18-27	K063204 (Attach. D, provided summary)	
11a	**Torque Strength - Catheter**	K052659, Page 18-37	K052659, Page 18-37	SpideRX data is applicable to SpiderFX
11b	**Torque Strength - Wire**	K052659, Page 18-29	K063204 (Attach. D, provided summary)	
12a	**Torque Response - Catheter**	K052659, Page 18-38	K052659, Page 18-39	SpideRX data is applicable to SpiderFX
12b	**Torque Response - Wire**	K052659, Page 18-30	K063204 (Attach. D, provided summary)	
13	**Kink Resistance - Catheter**	K052659, Page 18-40	K052659, Page 18-40	SpideRX data is applicable to SpiderFX
14	**Occlusion Balloon Characteristics**	N/A – the SpiderFX is not an occlusion balloon.		
15	**Dimensional Verification**	Catheter: K052659, Page 18-10 Capture Wire: K052659, Page 18-25	K063204 (Attach. D, provided summary)	Previously referred to as Visual/Dimensional Inspection
16	**Catheter Coating Integrity**	N/A – the SpiderFX Device has been commercially marketed since November 2006, with a very low rate of complaints related to coating integrity. More information is provided in Table 19-2.		
17	**Electromagnetic Compatibility**	N/A – the SpiderFX is not an electrically powered device.		
18	**Software Validation**	N/A – the SpiderFX does not rely on software for operation.		

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Table 11 - 4: Testing Recommended in FDA Guidance Document-Use With PTA Catheters and Stents

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

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Table 11 - 4: Testing Recommended in FDA Guidance Document-Use With PTA Catheters and Stents

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

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Table 11 - 4: Testing Recommended in FDA Guidance Document-Use With PTA Catheters and Stents

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11 - 4: Testing Recommended in FDA Guidance Document-Use With PTA Catheters and Stents

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11 - 4: Testing Recommended in FDA Guidance Document-Use With PTA Catheters and Stents

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.3.2 Additional Testing

Testing was completed in addition to the tests recommended in the FDA Guidance Document. Table 11-5 below provides references to submissions that were previously reviewed by FDA which contained the identical test methods and/or data and supported use with PTA catheters and stents. Table 11-6 summarizes the bench tests and provides the results achieved.

Table 11 - 5: Previous FDA Reviews; Additional Testing - Use with PTA Catheters and Stents

Bench Test	References		Comments
	Test Method	Data Review	
Packaging Visual Inspection	K063204, Attachment D, page 1	K063204 (Attach. D, provided summary)	
Heparin Coating Durability	K052659, Page 18-43	K052659, Page 18-43	SpideRX data is applicable to SpiderFX
Heparin Activity	K052659, Page 18-29	K063204 (Attach. D, provided summary)	
Wire Bias	K063204, Attachment D, page 5	K063204 (Attach. D, provided summary)	

Table 11 - 6: Additional Testing - Use with PTA Catheters and Stents

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.3.3 Revised Sizing Matrix and Compatibility with Atherectomy, Thrombectomy, and Laser Devices

To support the addition of atherectomy, thrombectomy, and laser devices and the revised sizing matrix, testing was completed to evaluate whether the SpiderFX Device performed as intended when used with worst-case atherectomy devices in peripheral vessels with the revised sizing matrix. A Design/Interface FMECA was completed to identify the bench and animal testing that was necessary to demonstrate compatibility between the worst-case atherectomy devices and the SpiderFX Device. Several of the identified bench tests required development of new testing models.

Table 11-7 below provides references to submissions that were previously reviewed by FDA which contained the identical test methods or data. Table 11-8 summarizes the bench tests and provides the results achieved.

Table 11 - 7: References to Previous FDA Reviews; Revised Sizing Matrix and Interventions with Atherectomy, Thrombectomy, and Laser Devices

Bench Test	References		Comments
	Test Method	Data Review	
(b) (4)			

Table 11 - 8: Testing to Support the Revised Sizing Matrix and Interventions with Atherectomy, Laser, and Thrombectomy Devices

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

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Table 11 - 8: Testing to Support the Revised Sizing Matrix and Interventions with Atherectomy, Laser, and Thrombectomy Devices

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

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11.3.4 Compatibility with Commercially Available 0.035" Catheters

Testing was completed to demonstrate that commercially available 0.035" guidewire compatible catheters could be used to deliver and/or recover the SpiderFX Capture Wire, if desired. The table below provides references to submissions that were previously reviewed by FDA which contained the identical test methods or data.

Table 11 - 9: Reference to Previous FDA Review - Use with Commercially Available Catheter

Bench Test	References		Comments
	Test Method	Data Review	
Simulated Use	G080017, Page 29, and Tab III-XI, page 6	G080017, Page 29, and Tab III-XI, page 6	

The following table summarizes the testing that was completed to support the use of commercially available catheters to deliver and/or recover the SpiderFX Capture Wire. Four representative, commercially available, 0.035" guidewire compatible catheters were selected for testing to demonstrate compatibility.

Table 11 - 10: Testing to Support Use with Commercially Available Catheters

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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11.4 Performance Testing - Animal

(b) (4)

[redacted]

11.4.1 Acute Animal Study

(b) (4)

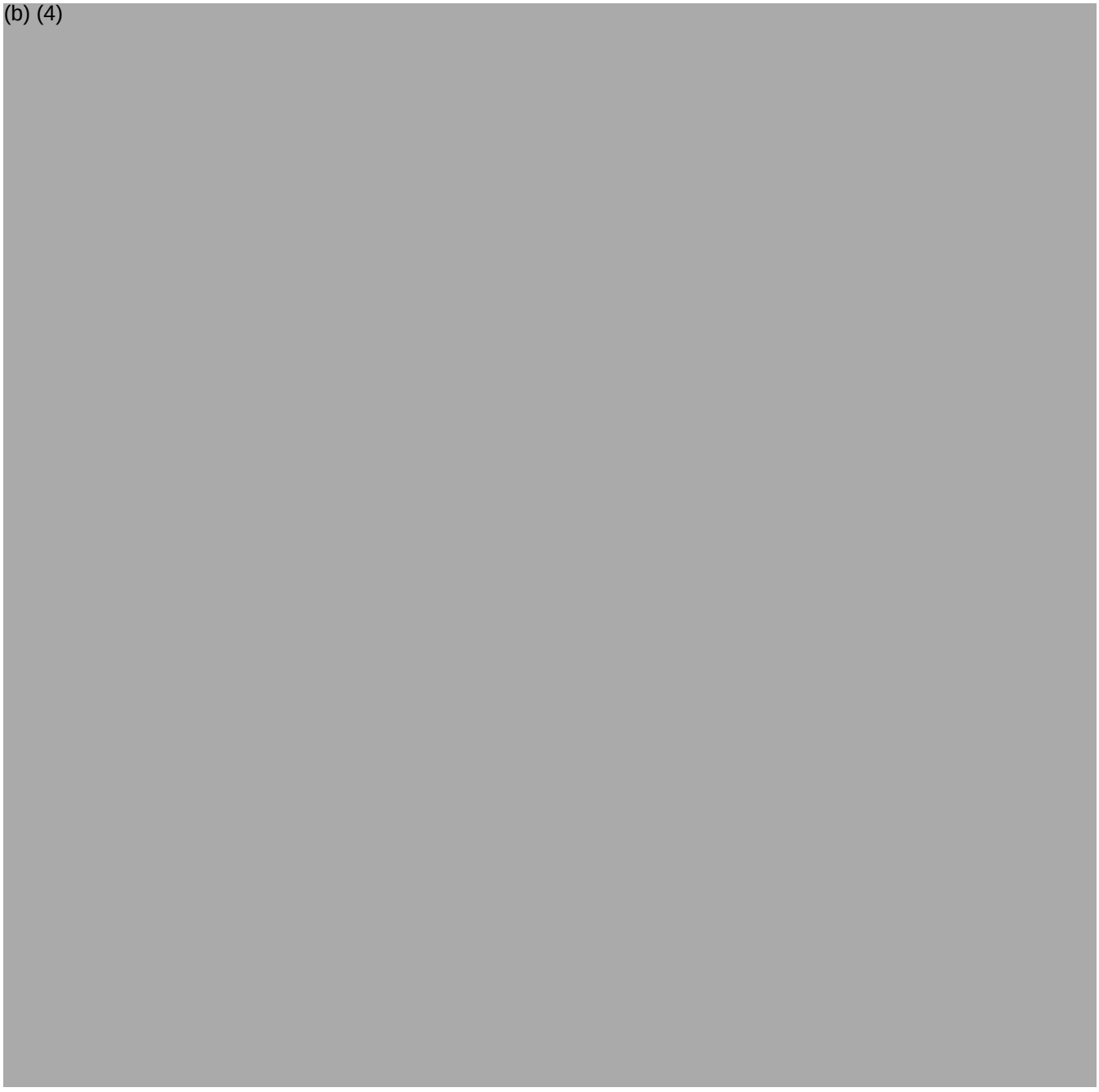
[redacted]

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11.4.2 Chronic Animal Study

(b) (4)

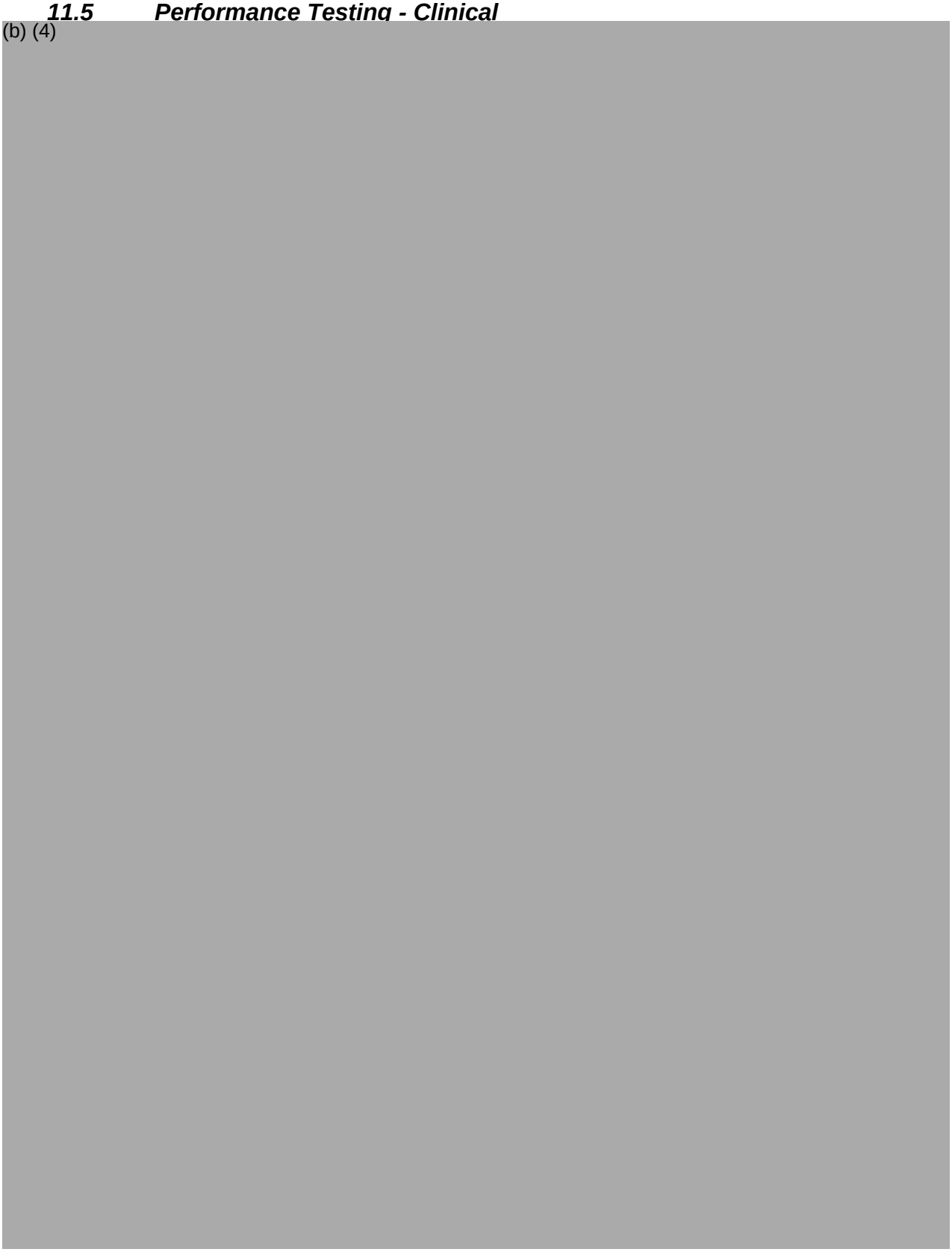


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11.5 Performance Testing - Clinical

(b) (4)



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(b) (4)

Primary Safety Endpoint

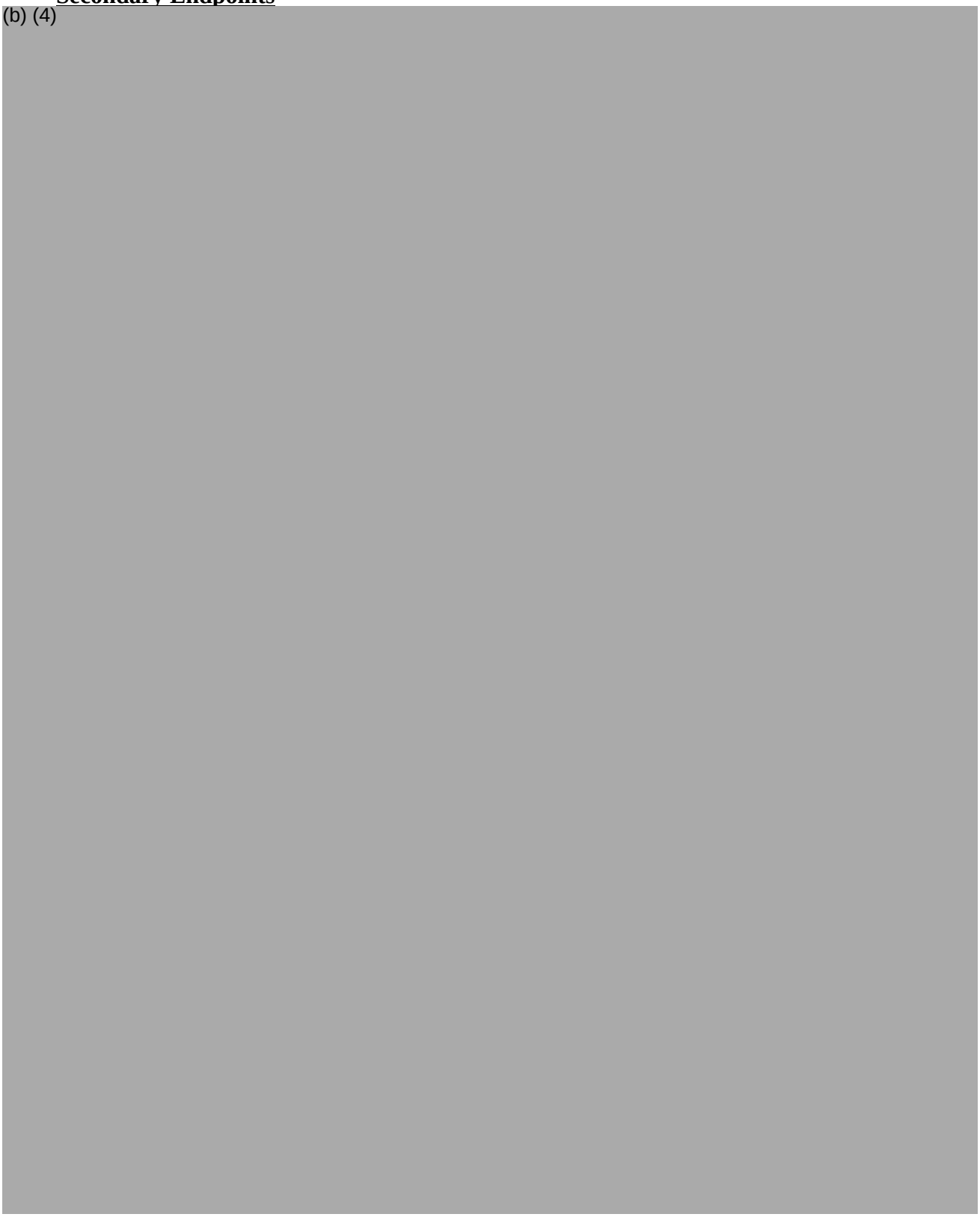
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Secondary Endpoints

(b) (4)



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(b) (4)

11.5.2 Discussion and Conclusion

(b) (4)

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11.6 Conclusions

The proposed SpiderFX Device has the identical intended use, technological characteristics, materials and operating principle as the predicate SpiderFX Device. Based on results from bench, animal and clinical safety and performance testing, the SpiderFX Embolic Protection Device is considered substantially equivalent to the SpiderFX Embolic Protection Device (K063204) and the SpideRX Embolic Protection Device (K052659).

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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12 Device Description

12.1 Device History

The SpiderFX Device is commercially available in the United States with indications for both carotid (K063204) and saphenous vein graft (SVG) (K063785) interventions. The SpiderFX Device is also available commercially outside of the United States. In Europe and many other international markets the SpiderFX Device is approved with a general vascular indication, which includes carotid, SVG, and peripheral use. The design and materials of the device described in this 510(k) are identical to the device that is marketed under clearances K063204 and K063785 and sold internationally.

Device testing was originally performed on the SpiderFX Device to demonstrate compatibility and performance with balloons and stents. Atherectomy, thrombectomy, and laser devices were not included in initial bench testing, which resulted in the inclusion of a warning by ev3 in the SpiderFX IFU regarding use of the SpiderFX Device with those devices. To support the peripheral IDE study, ev3 considered the use of the SpiderFX Device in lower extremity vessels in the United States and identified that compatibility testing needed to be completed with atherectomy, thrombectomy, and laser devices, because of their widespread use during lower extremity interventions in the United States.

The following table summarizes the different types of devices, their interactions with guidewires, and determination of compatibility with distal embolic protection devices. Two atherectomy devices, Rotablator ® (Boston Scientific) and Diamondback 360º (Cardiovascular Systems) are not compatible with SpiderFX. These devices require the use of specific guidewires, therefore, were not included in the evaluation.

Table 12 - 1: Device Interactions with Capture Wire

Device Type	Example of Device	Orientation	Interaction With Capture Wire	Position of Functional Component
(b) (4)				

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Table 12 - 1: Device Interactions with Capture Wire

Device Type	Example of Device	Orientation	Interaction With Capture Wire	Position of Functional
(b) (4)				

After considering the device interactions between many different types of atherectomy, thrombectomy, and laser devices, ev3 determined SilverHawk to be a worst-case device for demonstrating compatibility of the SpiderFX Device with atherectomy, thrombectomy, and laser devices. This determination was made because of the location of the functional portion of the device relative to its long nose-cone on the distal end and the unique eccentric design of the SilverHawk Device. Additionally, physician feedback indicated that the SilverHawk Device is the most frequently used atherectomy device in peripheral interventions in the United States. Therefore ev3 chose to complete testing with the SilverHawk device to demonstrate compatibility of the SpiderFX Device with atherectomy, thrombectomy, and laser devices.

During the compatibility testing it was noted that it is advantageous to use a larger SpiderFX filter in a smaller vessel for two reasons: 1) to provide an increased filter capacity, and 2) to optimize filter stability during the peripheral intervention. Preclinical bench and animal testing was completed to verify that the SpiderFX Device performed safely and as intended when used with worst-case atherectomy devices in lower extremity vessels with the revised sizing matrix. Therefore, ev3 is recommending the following sizing matrix when the SpiderFX Device is used in the peripheral vasculature.

Table 12 - 2: Recommended SpiderFX Sizing Matrices

Filter Size (mm)	Recommended Vessel Diameter for SpiderFX placement during Peripheral Interventions (mm)	Current Vessel Diameter for SpiderFX placement during SVG & Carotid Interventions (mm)
(b) (4)		

Additionally, ev3 received feedback from physicians that in certain situations the current SpiderFX Catheter does not provide an ideal amount of support to initially cross the lesion and/or to recover the SpiderFX Capture Wire in lower extremity vessels. Therefore, based on compatibility testing performed, ev3 will include in the proposed product labeling the use of commercially available catheters that are minimally 0.035" guide wire compatible, for delivery and/or recovery of the SpiderFX Capture Wire.

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12.2 Device Description

The SpiderFX Embolic Protection Device is a percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The SpiderFX Device Capture Wire is used as the 0.014" wire for interventional device delivery. The SpiderFX Device can be delivered over any 0.014" or 0.018" primary wire used to gain access to the lesion site. The SpiderFX Embolic Protection Device package contains the following:

- One **Capture Wire** composed of a (b) (4) mesh filter with a Distal Floppy Tip, mounted on a 190 cm or a convertible 190/320cm PTFE-coated 0.014" stainless steel wire. The filter is mounted in such a manner that the stainless steel wire is allowed to rotate freely under the radiopaque markers utilized to mount the filter. The filter is coated with heparin. The convertible Capture Wire is scored at the 190cm mark, allowing the wire to be snapped to a 190cm usable length for use with rapid exchange systems, if desired.

- The **SpiderFX Catheter** is a single lumen tube with asymmetric ends with dual functions. The delivery end is colored green, and recovery end is colored blue at opposite ends of the catheter. The delivery end contains a double-port design to allow the rapid-exchange exit of the guidewire, as well as a separate location for the exit of the Capture Wire. The area proximal to the guidewire exit, designated as the garage, houses the filter while the catheter is advanced over the normal PTCA guidewire. The recovery end has only one port to allow the retrieval of the Capture Wire. The Capture Wire is preloaded into the SpiderFX Catheter at shipping.

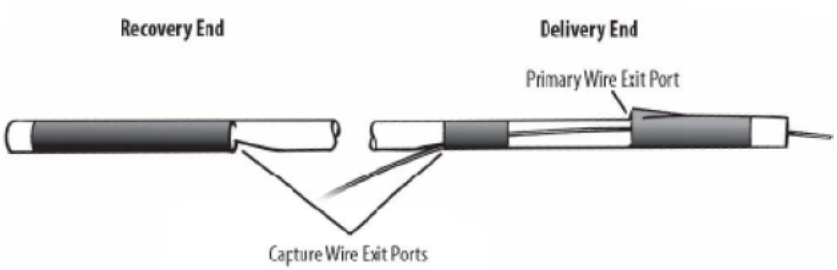
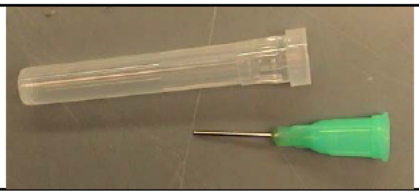
    * As an alternative to using the SpiderFX Catheter for delivery and/or recovery of the Capture Wire, commercially available catheters that are compatible with 0.035" guide wires may be used for delivery and/or recovery of the SpiderFX Capture Wire.

- One **23 gauge blunt tip flushing needle** accessory for use in flushing the delivery end of the catheter before use.

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Table 12 - 3: SpiderFX System Components and Accessory

Component	Diagram
SpiderFX Capture Wire	
SpiderFX Catheter	
Blunt tip flushing needle accessory	

Engineering drawings of the SpiderFX Device are provided in **Attachment A**.

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12.3 Device Materials

The device materials used in the proposed SpiderFX Device are identical to the device materials used in the predicate SpiderFX Device. The following table summarizes the materials used in the SpiderFX Device and the blunt tip flush needle accessory.

Table 12 - 4: Summary of SpiderFX Materials

Part Name	Raw Material	Identical to Material in:	
		SpiderFX (K063204)	SpideRX (K052659)
(b) (4)			

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12.4 Performance Specifications and Device Design Requirements

The SpiderFX Device is designed to capture and remove debris from the artery during endovascular procedures using a rapid exchange approach. The components of the System are compatible with most standard interventional devices.

The SpiderFX Device is a percutaneous system. The unique design and shape of the nitinol filter allows the filter to collapse within the Delivery Catheter for positioning, and then resume its shape when deployed within a target vessel. The porous design of the nitinol mesh filter allows blood to flow through the filter while capturing debris.

When the interventional procedure has been completed, the Recovery Catheter is used to remove the filter and its contents from the vessel.

The following table describes design features and specifications for the proposed device, which are identical to the currently marketed SpiderFX Device (K063204).

Table 12 - 5: Design Features and Specifications

Design Feature	Specification		
SpiderFX Capture Wire			
Filter Diameter (mm)	5.0	6.0	7.0
Capture Wire Length RX (cm)	190	190	190
Capture Wire Length OTW/RX (cm)	320/190	320/190	320/190
Wire Diameter (in./mm)	0.014/0.36	0.014/0.36	0.014/0.36
Distal Wire Tip Coil Length (cm)	1.2	1.2	1.2
SpiderFX Catheter – Delivery End (green)			
Nominal Diameter (in./mm)	0.040/1.02	0.040/1.02	0.040/1.02
Functional Length (cm)	140	140	140
SpiderFX Catheter – Recovery End (blue)			
Diameter (Fr)	4.2	4.2	4.2
Functional Length (cm)	140	140	140
Total Catheter Length (cm)	180	180	180

12.5 Design Changes From Currently Marketed Device

The proposed SpiderFX Device uses the identical design as the currently marketed SpiderFX Device (K063204). There are no design changes for this device.

Note that several design changes have been implemented to the SpiderFX Embolic Protection Device (K063204) via documentation to file following device clearance. Those changes are described in Section 22 of this submission.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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13 Substantial Equivalence

The proposed SpiderFX Embolic Protection Device for peripheral use is the identical device and has the identical intended use as the SpiderFX Embolic Protection Device (K063204, cleared November 14, 2006) and SpideRX Embolic Protection Device (K052659, cleared February 17, 2006) for carotid use. The indication for use of the proposed SpiderFX Embolic Protection Device reflects the different anatomical location for use of the device compared with the predicate. Currently, the IFU for product distributed in the United States warns against use in the peripheral vasculature.

Because the SpiderFX Embolic Protection Device was designed and developed for peripheral vascular use (the SpiderFX indication in Europe includes peripheral vascular use), modifying the indication in the United States to include use in peripheral vessels does not affect the risk profile of the device.

13.1 Substantial Equivalence Summary Table

The following table shows the similarities and differences between the proposed SpiderFX Embolic Protection Device and the predicate devices to which substantial equivalence is claimed.

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Table 13- 1: Substantial Equivalence Summary

	Proposed Device	Predicate Devices	
Device Name	**SpiderFX**	**SpiderFX**	**SpideRX**
Indication	**Use in Lower Extremity Interventions**	**Carotid Use**	**Carotid Use**
510(k) Number	K10XXXX	K063204	K052659
Intended Use			
Indications For Use	Indicated for use as a guidewire and embolic protection system to contain and remove embolic material during revascularization procedures of arteries in the lower extremities. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 6.0mm.	Indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.	
Intended Use	Percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The device Capture Wire is used as the 0.014" wire for interventional device delivery.		
Indicated Vessel Diameters	3.0 – 6.0 mm	3.0 – 7.0 mm	
Technological Characteristics			
System Components	SpiderFX Catheter Capture Wire Flushing Needle		SpideRX Catheter Capture Wire
Guide (Sheath) Compatibility	6F (5F) – min. 0.066"		
Primary Wire Compatibility	0.014" or 0.018"		
Wire Exit Location	(b) (4)		
Catheter Configuration	Dual-ended Rapid Exchange (Delivery End and Recovery End)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 13- 1: Substantial Equivalence Summary

<table>
<tr><th></th><th>Proposed Device</th><th colspan="2">Predicate Devices</th></tr>
<tr><td>Device Name</td><td>SpiderFX</td><td>SpiderFX</td><td>SpideRX</td></tr>
<tr><td>Indication</td><td>Use in Lower Extremity Interventions</td><td>Carotid Use</td><td>Carotid Use</td></tr>
<tr><td>Catheter Delivery End Nominal Diameter</td><td colspan="3">(b) (4)</td></tr>
<tr><td>Catheter Recovery End Nominal Diameter</td><td colspan="3"></td></tr>
<tr><td>Catheter Materials</td><td colspan="3"></td></tr>
<tr><td>Capture Wire Lengths</td><td colspan="2">190 cm
320 cm, convertible to 190 cm</td><td>320 cm, convertible to 190 cm</td></tr>
<tr><td>Filter Sizes</td><td>5, 6, 7 mm</td><td colspan="2">3, 4, 5, 6, 7 mm</td></tr>
<tr><td>Recommended Vessel Sizing</td><td>
<table>
<tr><th>Filter Size (mm)</th><th>Target Vessel Size (mm)</th></tr>
<tr><td>5.0</td><td>3.0 – 4.0</td></tr>
<tr><td>6.0</td><td>3.5 – 5.0</td></tr>
<tr><td>7.0</td><td>4.5 – 6.0</td></tr>
</table>
</td><td colspan="2">
<table>
<tr><th>Filter Size (mm)</th><th>Target Vessel Size (mm)</th></tr>
<tr><td>3.0</td><td>3.0</td></tr>
<tr><td>4.0</td><td>3.1 – 4.0</td></tr>
<tr><td>5.0</td><td>4.1 – 5.0</td></tr>
<tr><td>6.0</td><td>4.5 – 6.0</td></tr>
<tr><td>7.0</td><td>5.5 – 7.0</td></tr>
</table>
</td></tr>
</table>

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Table 13- 1: Substantial Equivalence Summary

	Proposed Device	Predicate Devices	
Device Name	**SpiderFX**	**SpiderFX**	**SpideRX**
Indication	**Use in Lower Extremity Interventions**	**Carotid Use**	**Carotid Use**
Filter Materials	(b) (4)		
Filter Design	Eccentric		
Recommended Distance Between Lesion and Filter	2.0 cm		1.5 cm

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13.2 Intended Use Comparison to Predicate Devices

The intended use of the proposed SpiderFX Device is identical to the currently marketed SpiderFX Device (K063204) and SpideRX Device (K052659) for carotid use, in addition to the currently marketed SpiderFX Device (K063785, cleared January 19, 2007) and SpideRX Device (K053195, cleared June 23, 2006) for use in Saphenous Vein Grafts (SVGs). The reason for this submission is to modify the Indication for Use for the SpiderFX Device to allow use in peripheral vessels.

13.3 Technological Comparison to Predicate Devices

The proposed SpiderFX Device uses the identical design and materials as the currently marketed SpiderFX Device. The reason for this submission is to modify the Indication for Use for the SpiderFX Device to allow use in peripheral vessels.

Although the proposed SpiderFX Device uses the identical design and materials, SpiderFX Device testing was initially performed to demonstrate compatibility and performance with balloons and stents. Atherectomy, thrombectomy, and laser devices were not included in initial bench testing, which resulted in the inclusion of a warning by ev3 in the SpiderFX IFU regarding use of the SpiderFX Device with those devices. To support the (b) (4)), ev3 considered the use of the SpiderFX Device in lower extremity vessels in the United States and identified that compatibility testing needed to be completed with atherectomy, thrombectomy, and laser devices, because of their widespread use during lower extremity interventions in the United States.

After considering the device interactions between many different types of atherectomy, thrombectomy, and laser devices, ev3 determined SilverHawk to be a worst-case device for demonstrating compatibility of the SpiderFX Device with atherectomy, thrombectomy, and laser devices. This determination was made because of the location of the functional portion of the device relative to its long nose-cone on the distal end and the unique eccentric design of the SilverHawk Device. Additionally, physician feedback indicated that the SilverHawk Device is the most frequently used atherectomy device during interventions of the lower extremities in the United States. Therefore ev3 chose to complete testing with the SilverHawk device to demonstrate compatibility of the SpiderFX Device with atherectomy, thrombectomy, and laser devices.

Recommended Sizing Matrix

During the compatibility testing it was noted that it is advantageous to use a larger SpiderFX filter in a smaller vessel for two reasons: 1) to provide an increased filter capacity, and 2) to optimize filter stability during the intervention. Preclinical bench and animal testing was completed to verify that the SpiderFX Device performed safely and as intended when used with worst-case atherectomy devices in lower extremity vessels with the revised sizing matrix. Therefore, ev3 is recommending the following sizing matrix when the SpiderFX Device is used in lower extremity vessels.

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Table 13- 2: Recommended SpiderFX Sizing Matrices

Filter Size (mm)	Recommended Vessel Diameter for SpiderFX placement during Lower Extremity Interventions (mm)	Current Vessel Diameter for SpiderFX placement during SVG & Carotid Interventions (mm)
3.0	n/a	3.0
4.0	n/a	3.1-4.0
5.0	3.0-4.0	4.1-5.0
6.0	3.5-5.0	4.5-6.0
7.0	4.5-6.0	5.5-6.0 (SVG) 5.5-7.0 (Carotid)

Delivery/Recovery Through Commercially Available Catheters

Additionally, ev3 received feedback from physicians that in certain situations the current SpiderFX Catheter does not provide an ideal amount of support to initially cross the lesion and/or to recover the SpiderFX Capture Wire in lower extremity vessels. Therefore, based on compatibility testing performed, ev3 will include in the proposed product labeling the use of commercially available catheters that are minimally 0.035" guide wire compatible, for delivery and/or recovery of the SpiderFX Capture Wire.

13.4 Conclusions

The proposed SpiderFX Device is identical to the currently marketed SpiderFX Device, and the intended use is also identical. The reason for this submission is to modify the Indication for Use to allow use in the peripheral vessels.

The principles of operation for the SpiderFX Device in the periphery are the same as in the carotids and SVG. The lower extremity peripheral vessels are considered lower risk vessels compared to the carotid vessels and SVGs, due to the less critical nature of the end organ. Performance bench and animal testing was completed to verify that the SpiderFX Device functions as intended, and similarly to the predicate use of the SpiderFX Device, when sized according to the Recommended Sizing Matrix for use in the lower extremities. Testing also demonstrated that commercially available catheters that are minimally 0.035" guide wire compatible are acceptable to use for delivery and/or recovery of the SpiderFX Capture Wire.

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14 Proposed Labeling

A draft of the proposed instructions for peripheral use is provided together with drafts of the proposed pouch and box labels in **Attachment B**.

Labeling for the predicate SpiderFX Device and SpideRX Device for carotid use is provided in **Attachment C**.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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15 Sterilization and Shelf Life

15.1 Sterilization

The SpiderFX Device is provided to the user sterile and labeled for single use only. The device is not intended for sterilization or reprocessing by the user. The SpiderFX Device will be sterilized using the identical ethylene oxide sterilization cycles as the currently marketed SpiderFX Device (K063204) and SpideRX Device (K052659).

The SpiderFX Device is ethylene oxide (EO) sterilized in a fixed chamber at the contract sterilization facility of Steris-Isomedix and meets a sterility assurance level (SAL) of 10^{-6}. The contract sterilization facility sterilizes all ev3 Peripheral Vascular Division products. General information for the contract sterilization facility follows:

(b) (4)

15.1.1 EtO Sterilization Validation

Based on the similarities between the SpideRX and SpiderFX Devices and because no changes were proposed for the validated sterilization cycle, the SpiderFX Device was adopted into the existing cycle at Steris-Isomedix Services. No additional validation testing was required.

(b) (4)

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(b) (4)

15.1.2 Sterilization Residue

(b) (4)

15.1.3 Pyrogenicity

(b) (4)

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15.2 Packaging Information

15.2.1 Packaging Description

The SpiderFX single barrier Tyvek/polyethylene pouch packaging is identical to the packaging used for the commercially-available SpiderFX and SpideRX Devices. The Capture Wire is pre-loaded into the SpiderFX Catheter. The hooped SpiderFX device is placed into the Tyvek/polyethylene pouch which is then heat sealed. The sealed pouch is placed into a paperboard shelf carton and sterilized.

The packaging for the proposed device is identical to the packaging from the previously cleared version of the same device and the test data of the predicate devices is applicable to this version of SpiderFX. The information summarized below was previously included in the SpideRX Original 510(k) (K052659, page 14-1).

15.2.2 Packaging Testing

Testing Leveraged from Predicate SpideRX Device (K052659)
Packaging validation was conducted. Both product functional testing and packaging testing were completed to verify that the packaging materials can withstand the stresses of Ethylene Oxide (EtO) sterilization and transportation, after accelerated aging to two years. A summary of the tests performed is provided below.

Distribution Simulation Testing
Testing subjected the product and packaging materials to a series of tests to simulate the forces encountered during shipping. The testing was performed based on the method outlined in ASTM D4169-01; DC 13, Assurance Level I. Testing was conducted with sixty (60) units accelerated aged to two years. Distribution simulations were performed prior to conducting design verification tests. All devices were required to pass the established acceptance criteria for the specified performance evaluation.

Bubble Leak Test
The package leak test was conducted with units accelerated aged to two years in conjunction with the distribution simulation testing. Pouches were tested in accordance with ASTM F2096-02 to determine the effects of transportation simulation on the seal integrity of the pouches. All thirty (30) units passed the bubble leak test.

Pouch Physical Testing:
Testing measured the maximum force required to separate a test strip of material containing the seal. A minimum of 4 one inch wide strips were cut from each pouch for this testing. Testing was conducted with ten (10) units (n=40 test strips) accelerated aged to five years. All units passed the peel strength test.

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15.3 Shelf Life

(b) (4)



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16 Biocompatibility

Biocompatibility for the SpiderFX Device was assessed in accordance with ISO 10993-1 Part 1: 2003 "Biological Evaluation of Medical Devices". The SpiderFX Device is considered an externally communicating device in circulating blood, with a limited duration of contact (≤ 24 hrs).

16.1 Device Materials

The following figures and table summarize the components, materials, and patient/blood contact for the SpiderFX Device and accessory.

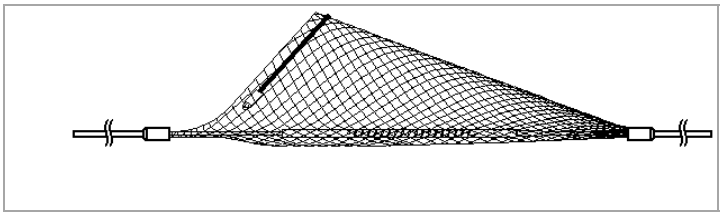


Figure 16- 1: SpiderFX Capture Wire

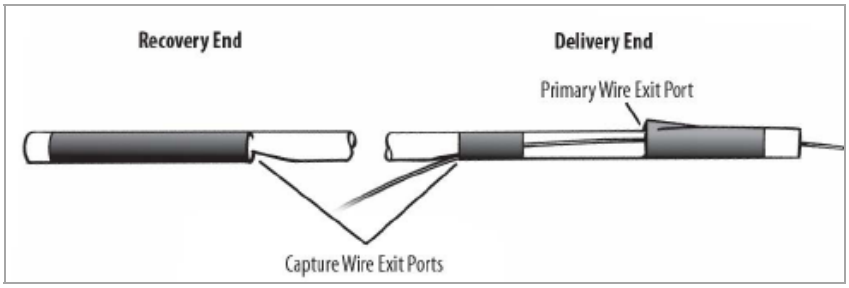


Figure 16-2: SpiderFX Catheter

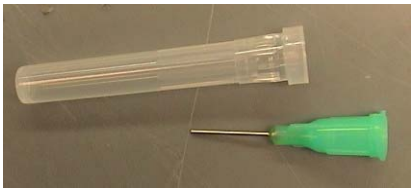


Figure 16-3: Blunt Tip Flushing Needle

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Table 16- 1: Materials for the SpiderFX Device and Accessory

Part Name	Raw Material	Blood Contact	Identical to Material in:	
			SpiderFX (K063204)	SpideRX (K052659)
(b) (4)				

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16.2 Biocompatibility Testing

All biocompatibility testing described in this section was performed on fully finished 2X sterile test samples that represented the final materials and exposure areas for the SpiderFX Device. All samples were provided to an ev3 approved biocompatibility testing laboratory after being submitted for sterilization with EtO gas per the validated Steris ev3 cycle #EV3-014 used for commercial devices. Samples were prepared and Design Inputs were established per the test lab protocols.

16.2.1 SpiderFX Device

The device materials in the proposed SpiderFX Device are identical to the materials in the commercially available SpideRX Device (K052659) and SpiderFX Device (K063204). Therefore, no new biocompatibility testing was performed.

(b) (4)



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Table 16- 2: SpiderRX Biocompatibility Test Results, Applicable to the SpiderFX Catheter and Capture Wire

Test Performed/ Report Number	Result / Comment	Pass/Fail
(b) (4)		

16.2.2 Flush Needle Accessory

Testing Leveraged from Predicate SpiderFX Device (K063204)

The SpiderFX Device provides a blunt tip flush needle accessory that was not provided with the SpideRX Device. The flush needle does not have direct contact with the patient during normal use, but may have limited indirect contact due to interaction with the distal catheter tip during catheter prep and flushing. Based on an assessment of biological risks, several biocompatibility tests were identified to confirm that there are no material interactions and no additional biological risks due to use of the flush needle accessory.

As summarized in the table below, the flush needle accessory met the requirements for biocompatibility testing outlined in ISO 10993-1 Part 1: 2003 "Biological Evaluation of Medical Devices" after exposure to the validated ethylene oxide Sterilization Cycle. The biocompatibility test reports summarized in the following table previously were reviewed and approved in the Definitive CA^{++} IDE (G080017, pages 40-42 and Attachment IV,

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tab XVII) and were summarized in the SpiderFX Special 510(k) submission (K063204, Attachment D). The test reports are available upon request.

Table 16- 3: Biocompatibility Test Results, Distal Flushing Tool Accessory

Test Performed/ Report Number	Result / Comment	Pass/Fail
(b) (4)		

16.3 Conclusion

The SpiderFX Device and its flush needle accessory were tested and shown to be biocompatible within the meaning of ISO 10993-1 Part 1: 2003 "Biological Evaluation of Medical Devices".

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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17 Software

This section does not apply to the SpiderFX Embolic Protection Device.

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18 Electromagnetic Compatibility and Electrical Safety

This section does not apply to the SpiderFX Embolic Protection Device.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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19 Performance Testing – Bench

The tests and test results presented in this submission previously were reviewed by FDA in one or more of the following submissions: G080017, G080025, G030115, G020248, K052659, K053195, K063204, K063785, K070540 (determined to be NSE). Because the tests and results are included by reference in this submission, the tests and test results are presented in summary tables rather than re-presenting the entire data set previously reviewed and cleared by FDA.

Multiple bench-level Design Verification and Validation Tests were performed to evaluate the performance of the SpiderFX System with respect to its intended use. A risk-based approach, Failure Mode Effect and Criticality Analysis (FMECA), initially was conducted to identify performance characteristics of the SpiderFX Device that required design verification and validation activities to support use of the SpiderFX Device during PTA and stenting interventions.

To support the addition of atherectomy, thrombectomy, and laser devices and the revised sizing matrix, bench testing models were developed to evaluate whether the SpiderFX Device performed as intended when used with worst-case atherectomy devices in peripheral vessels with the revised sizing matrix (previously described in Section 12.1). A Design/Interface FMECA was completed to identify the bench and animal testing necessary to demonstrate compatibility between the worst-case atherectomy devices and the SpiderFX Device. Separate testing also was completed to demonstrate that commercially available 0.035" guidewire compatible catheters could be used to deliver and/or recover the SpiderFX Capture Wire, if desired.

All of the test methods utilized for SpiderFX testing and the resulting data previously were reviewed by FDA for the SpiderFX Device (G080017, G080025, K070540-determined to be NSE), and/or the predicate SpideRX Device (G020248, G030115, K052659, K053195). Please note: the SpiderFX Device Carotid and SVG submissions (K063204, K063785) were approved via Special 510(k), therefore the summaries of design control test methods and acceptance criteria were provided to FDA for review. The following design characteristics which were not affected by the SpiderFX design change were not re-tested for the SpiderFX Device: catheter tip flexibility, catheter bond tensile, catheter kink, catheter torque strength and torque response, Capture Wire tip flexibility, heparin coating durability, flow characteristics and filter capacity. These results from SpideRX testing included in K052659 and K053195 are applicable to the SpiderFX device.

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19.1 Test Sample Preparation

All SpiderFX Devices used for bench testing were fully processed, sterile devices that had gone through shipping simulation per ASTM D 4169-01 *Standard Practice for Performance Testing of Shipping Containers and Systems*. (Note: the SpiderFX Devices used for catheter compatibility testing were not exposed to shipping simulation.) Most test samples were exposed to two sterilization cycles, except as noted in the attached reports. Products were built with full traceability by manufacturing staff and are equivalent to the final product.

The SpideRX testing that is referenced was completed on full units, with the exception of Catheter bond and tip flex testing. In these instances subassemblies, encompassing the physical attribute to be evaluated (i.e., the bond or the tip) were used for testing. All full unit devices were sterilized and subjected to shipping simulation. Subassemblies were sterilized, but were not subjected to coating or ship-testing. Since the bonds are thermally formed, no effects from the lubricious coating process or simulated shipping were expected.

Commercially available SilverHawk Devices and 0.035" guidewire compatible catheters were obtained for testing to demonstrate compatibility with the SpiderFX Capture Wire: FoxHollow SilverHawk, Spectranetics Quick-Cross, Terumo Glidecath, Cook Slip-Cath, and the ev3 Amplatz Gooseneck Snare Replacement Catheter.

19.2 Test Sample Size

Sample sizes for variable data were determined based on pre-DVT sample size and sample standard deviation. Attribute data was evaluated based on the Confidence/Reliability level identified in the FMECA. A bracketing strategy was utilized, where appropriate, with the smallest and largest filter used for evaluations. The SpideRX Device was used as the predicate device for SpiderFX, and a smaller sample size of 10 was established for control unit baseline data and informational testing where appropriate.

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19.3 Performance Bench Testing

19.3.1 Testing Recommended in FDA Guidance Document

FDA issued a Guidance Document titled "Coronary and Carotid Embolic Protection devices – Premarket Notification [510(k)] Submissions" on February 15, 2008. All testing for the SpiderFX Device already had been completed at that time, however, the guidance document was considered in conjunction with this Premarket Notification. No additional testing was required based on the assessment of the tests recommended within the guidance document.

Table 19-1 below lists the bench testing described in the guidance document, and provides references to the submission(s) previously reviewed by FDA which contained the identical test methods and/or data to support use with PTA catheters and stents. Table 19-2 summarizes the bench tests and provides the results achieved.

Table 19- 1: References to Previous FDA Reviews; Testing Recommended in FDA Guidance Document - Use with PTA Catheters and Stents

#	Recommended Bench Test	References		Comments
		Test Method	Data Review	

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Table 19- 1: References to Previous FDA Reviews; Testing Recommended in FDA Guidance Document - Use with PTA Catheters and Stents

#	Recommended Bench Test	References		Comments
		Test Method	Data Review	
(b) (4)				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The following table summarizes the testing that was completed to demonstrate compatibility between the SpiderFX Device and PTA Catheters and Stents.

Table 19- 2: Testing Recommended in FDA Guidance Document - Use With PTA Catheters and Stents

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 19- 2: Testing Recommended in FDA Guidance Document - Use With PTA Catheters and Stents

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 19- 2: Testing Recommended in FDA Guidance Document - Use With PTA Catheters and Stents

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Table 19- 2: Testing Recommended in FDA Guidance Document - Use With PTA Catheters and Stents

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 19- 2: Testing Recommended in FDA Guidance Document - Use With PTA Catheters and Stents

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Table 19- 2: Testing Recommended in FDA Guidance Document - Use With PTA Catheters and Stents

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

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(b) (4)			

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(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 19- 2: Testing Recommended in FDA Guidance Document - Use With PTA Catheters and Stents

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Table 19- 2: Testing Recommended in FDA Guidance Document - Use With PTA Catheters and Stents

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

19.3.2 Additional Testing

Testing was completed in addition to the tests recommended in the FDA Guidance Document. Table 19-3 below provides references to submissions that were previously reviewed by FDA which contained the identical data and supported use with PTA catheters and stents. Table 19-4 summarizes the bench tests and provides the results achieved.

Table 19- 3: References to Previous FDA Reviews; Additional Testing - Use with PTA Catheters and Stents

Bench Test	References		Comments
	Test Method	Data Review	
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

The following table summarizes the additional testing that was completed to support the use of the Spider Device with PTA catheters and stents.

Table 19- 4: Additional Testing - Use with PTA Catheters and Stents

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Table 19- 4: Additional Testing - Use with PTA Catheters and Stents

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

19.3.3 Revised Sizing Matrix and Compatibility with Atherectomy, Thrombectomy, and Laser Devices

To support the addition of atherectomy, thrombectomy, and laser devices and the revised sizing matrix, testing was completed to evaluate whether the SpiderFX Device performed as intended when used with worst-case atherectomy devices in peripheral vessels with the revised sizing matrix (previously described in Section 12.1). A Design/Interface FMECA was completed to identify the bench and animal testing that was necessary to demonstrate compatibility between the worst-case atherectomy devices and the SpiderFX Device. Several of the identified bench tests required development of new testing models.

Table 19-5 below provides references to submissions that were previously reviewed by FDA which contained the identical test methods or data. Table 19-6 summarizes the bench tests and provides the results achieved.

Table 19- 5: References to Previous FDA Reviews; Revised Sizing Matrix and Interventions with Atherectomy, Thrombectomy, and Laser Devices

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

The following table summarizes the testing that was completed to demonstrate compatibility between the SpiderFX Device and atherectomy, laser, and thrombectomy devices, and to address the revised sizing matrix. This testing was completed utilizing the worst-case compatibility scenario of the SilverHawk Device.

Table 19- 6: Testing to Support the Revised Sizing Matrix and Interventions with Atherectomy, Laser, and Thrombectomy Devices

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Table 19- 6: Testing to Support the Revised Sizing Matrix and Interventions with Atherectomy, Laser, and Thrombectomy Devices

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Table 19- 6: Testing to Support the Revised Sizing Matrix and Interventions with Atherectomy, Laser, and Thrombectomy Devices

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

19.3.4 Compatibility with Commercially Available 0.035" Catheters

Testing was completed to demonstrate that commercially available 0.035" guidewire compatible catheters could be used to deliver and/or recover the SpiderFX Capture Wire, if desired. Table 19-7 below provides references to submissions that were previously reviewed by FDA which contained the identical test methods or data. Table 19-8 summarizes the bench tests and provides the results achieved.

Table 19- 7: Reference to Previous FDA Review - Use with Commercially Available Catheter

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

The following table summarizes the testing that was completed to support the use of commercially available catheters to deliver and/or recover the SpiderFX Capture Wire. Four representative, commercially available, 0.035" guidewire compatible catheters were selected for testing to demonstrate compatibility.

Table 19- 8: Testing to Support Use with Commercially Available Catheters

Test Name/Qty:	Test Method:	Acceptance Criteria:	Test Results:
(b) (4)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

19.4 Conclusion

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

20 Performance Testing – Animal

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

20.2 Chronic Animal Study

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

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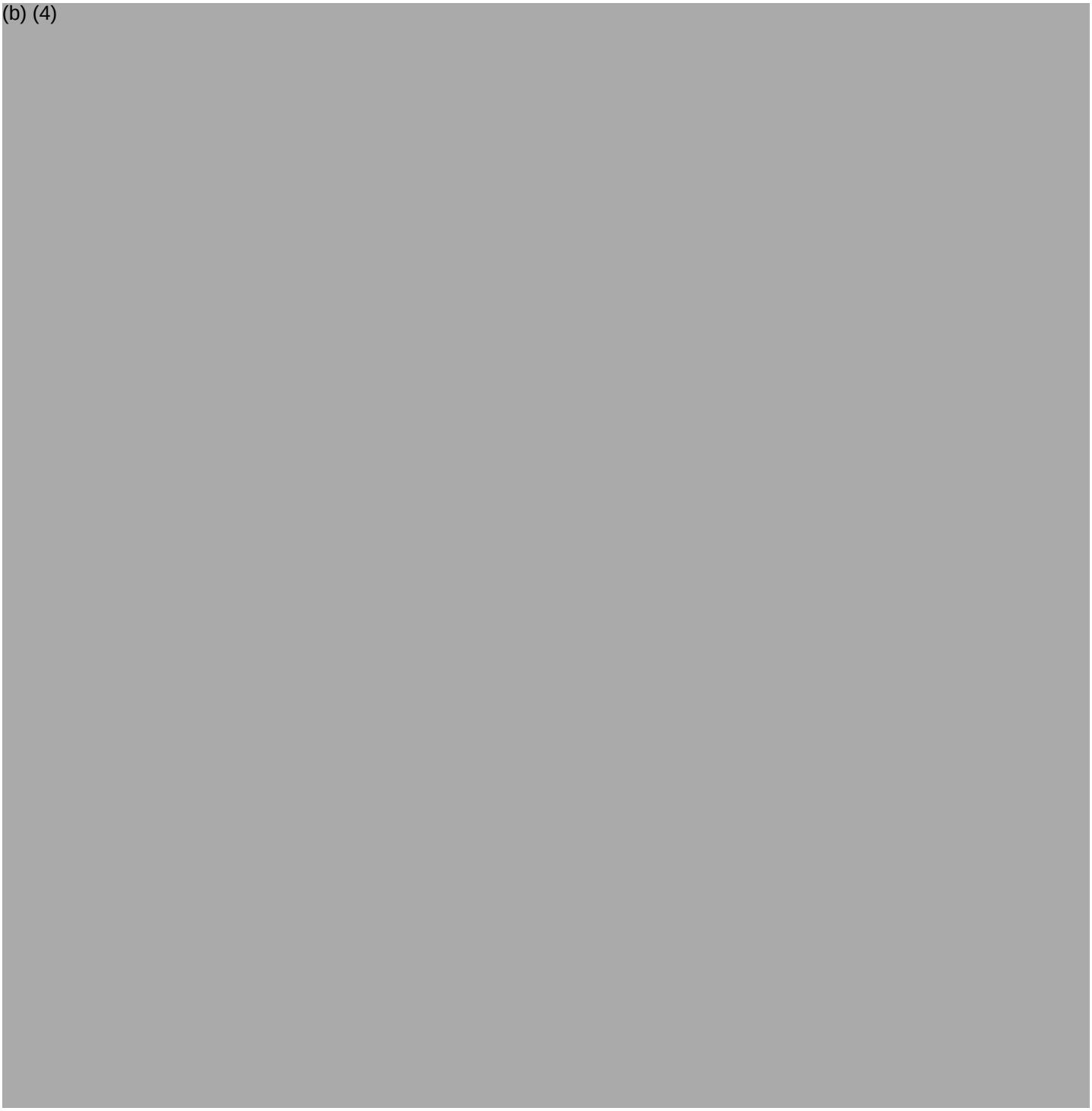
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

21 Performance Testing – Clinical

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

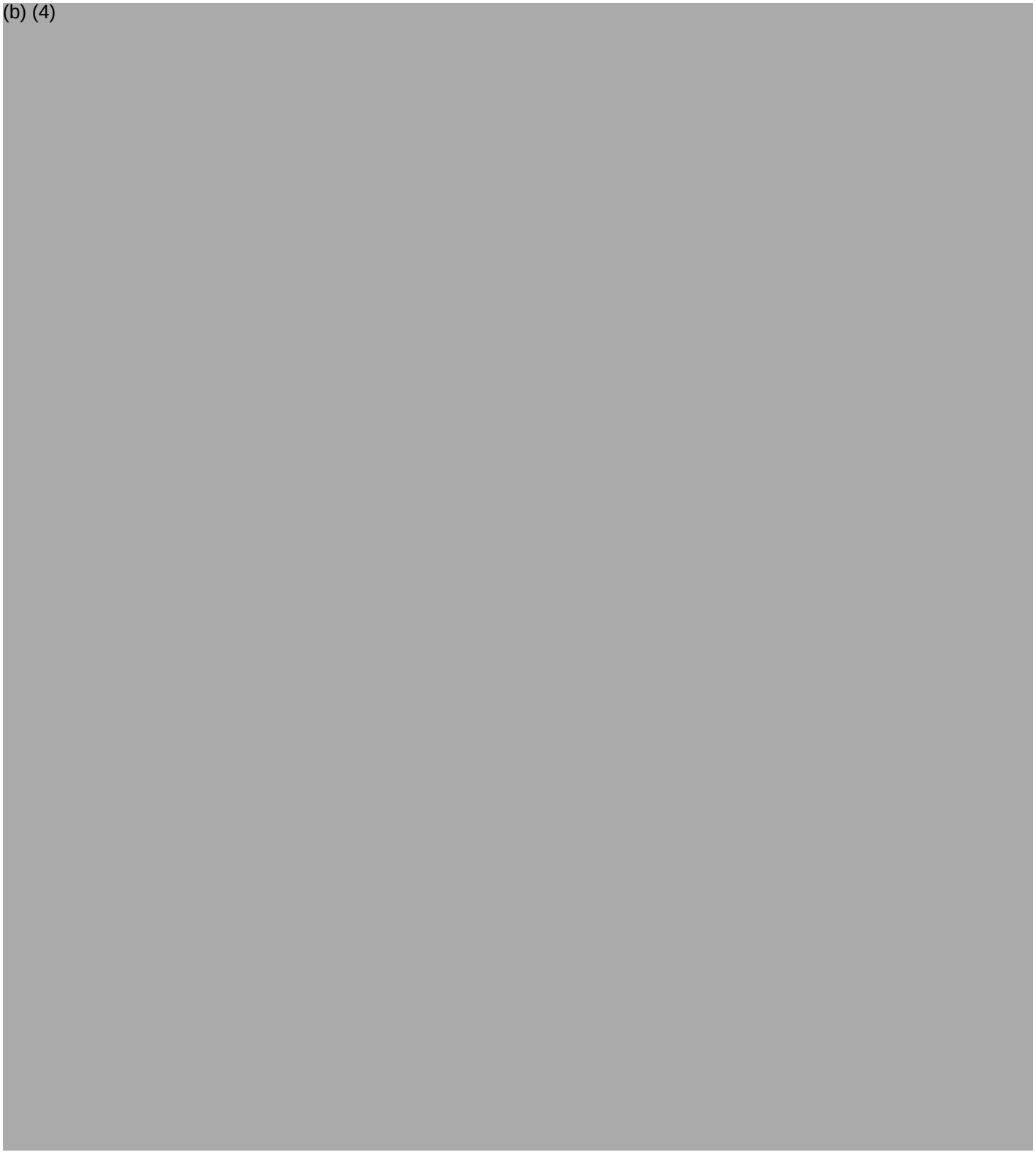
(b) (4)

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

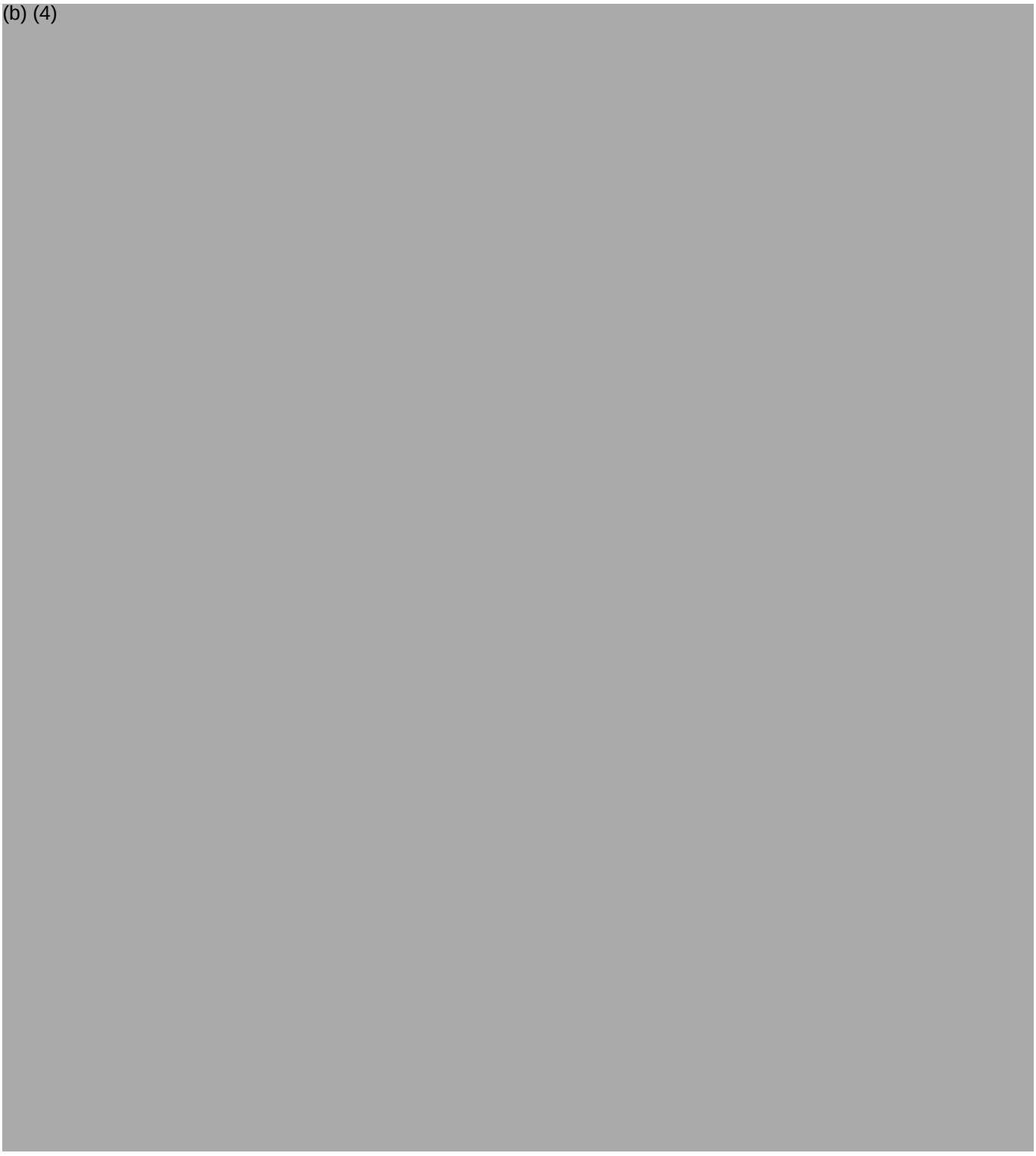
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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

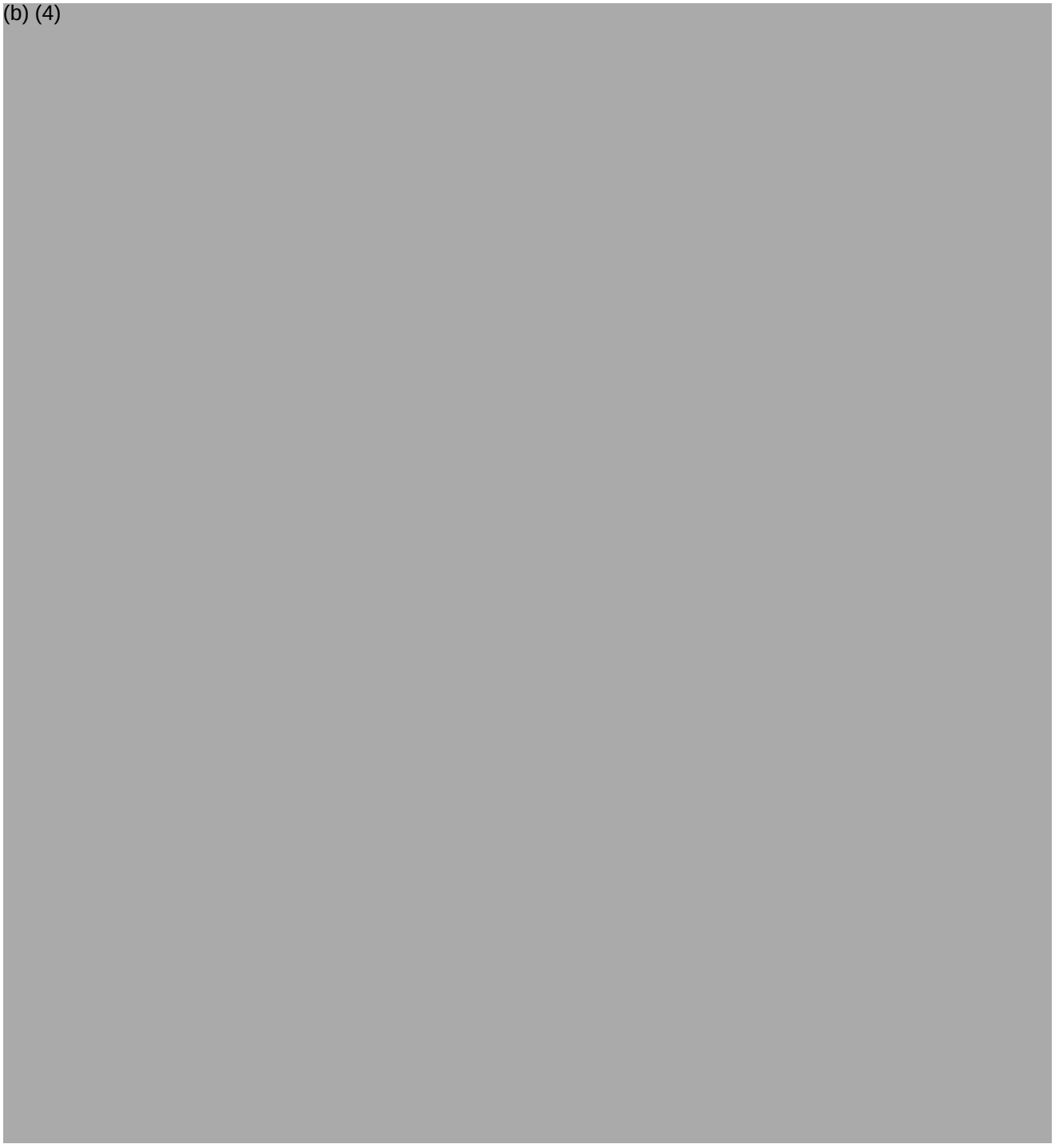
(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)



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Records processed under FOIA request 2017-9992; Released on 1/29/2019

(b) (4)



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Records processed under FOIA request 2017-9992; Released on 1/29/2019

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

22 Device Disclosure

Since receiving 510(k) clearance, the following design and process modifications were implemented to the SpiderFX Embolic Protection Device (K063204) via documentation to file, based on FDA Guidance *Deciding When to Submit a 510(k) for a Change to an Existing Device*.

22.1 Marker Band Outer Diameter Change

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

22.4 PTFE Material Formulation Change for Supplier to ev3's Supplier

The Environmental Protection Agency recently mandated that suppliers reformulate their products to reduce PFOA emissions. Accordingly, ev3's PTFE suppliers changed their supplier and manufacturing processes to allow the use of low PFOA as a processing aid in the manufacturing of PTFE. ev3 performed an assessment of the change. (b) (4)

22.5 Additional Model Numbers

The SpiderFX Device is currently cleared for two indications in the United States: carotid and SVG. For several years, Volcano Corporation had an agreement with ev3 to distribute SpiderFX Devices in the SVG market. New model numbers were added to identify product that was intended for distribution by Volcano. The product is identical to the product distributed by ev3, with the exception of the model number.

The agreement with Volcano Corporation has since been terminated, however, product bearing a Volcano Model Number may still exist in customer inventories.

22.6 Administrative Change - Incorrect Material Listed in Submissions

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

23 Attachments

The following documents are included as attachments:

- Attachment A: Engineering Drawings

(b) (4)

- Attachment B: Proposed Labeling
  - SpiderFX Device (peripheral use) box and pouch label
  - SpiderFX Device (peripheral use) Instructions for Use

- Attachment C: Predicate Labeling
  - SpiderFX Device (carotid use) box and pouch label
  - SpiderFX Device (carotid use) Instructions for Use
  - SpideRX Device (carotid use) box and pouch label
  - SpideRX Device (carotid use) Instructions for Use

- Attachment D: Acute Animal Study

(b) (4)

- Attachment E: Chronic Animal Study

(b) (4)

- Attachment F: Final Clinical Report

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Todd Courtney

Subject: 510(k) Number K111010 | S1

To: The Record

Please list CTS decision code SE

x Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

x Hold (Additional Information or Telephone Hold).

(x) Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

x	NO	NSE for lack of predicate
x	NI	NSE for new intended use
x	NQ	NSE for new technology that raises new questions of safety and effectiveness
x	NP	NSE for lack of performance data
x	NM	NSE requires PMA
x	NS	NSE no response
x	NH	NSE for another reason

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*	✓	
510(k) Summary /510(k) Statement	*Attach Summary*	✓	
Truthful and Accurate Statement.	*Must be present for a Final Decision*	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	*Must be present for a Final Decision*	—	
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)?		✓	
For United States-based clinical studies **only**: Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If study was conducted in the United States, and FORM FDA 3674 was not included or incomplete, then applicant must be contacted to obtain completed form.)		✓	
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age<=21			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Neonate/Newborn (Birth to 28 days)		
Infant (29 days -< 2 years old)		
Child (2 years -< 12 years old)		
Adolescent (12 years -< 18 years old)		
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)		
Transitional Adolescent B (18 -<= 21; No special considerations compared to adults => 21 years old)		
Nanotechnology		X
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	*Contact OC.*	X

Regulation Number	**Class***	**Product Code**
870.1250	II	NTE

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____ PDB 10/27/11
(Branch Chief) (Branch Code) (Date)

Final Review: _____ 10/27/11
(Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K111010.S001

Date: 10/26/2011
To: The Record
From: Todd Courtney

Office: ODE
Division: DCD

510(k) Holder: ev3
Device Name: SpiderFX Embolic Protection Device
Contact: Brenda Johnson
Phone: 763-398-7238
Fax: 763-591-3248
Email: bjohnson@ev3.net

I. Purpose and Submission Summary

ev3 would like to introduce the SpiderFX Embolic Protection Device into interstate commerce. The SpiderFX Embolic Protection Device is a percutaneously-delivered distal embolic protection device, designed to capture and remove dislodged debris during peripheral interventional procedures. The device is identical to the device that is marketed in the US for carotid (K063204) and saphenous vein graft (K063785) indications. Thus the sponsor leveraged pre-clinical testing from those submissions to support clearance of the device for the proposed indication. The sponsor also conducted a clinical study with the SpiderFX and TurboHawk atherectomy device. The sponsor is seeking an indication for embolic protection in the lower peripheral vasculature with any device. Since the study was specific to calcific lesions with the TurboHawk, the SpiderFX will be limited to use in those situations.

AI is the recommendation, as there are several deficiencies that need to be addressed.

Update via Supplement 1
The sponsor addressed all the deficiencies and there are no outstanding deficiencies remaining.

Dr. Steve Brooks provided the clinical review.
Dr. Tory Hampshire provided the animal review.

SE is the recommendation, as all deficiencies have been addressed.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

	Yes	No	N/A
Standards Form	X		

III. Device Description

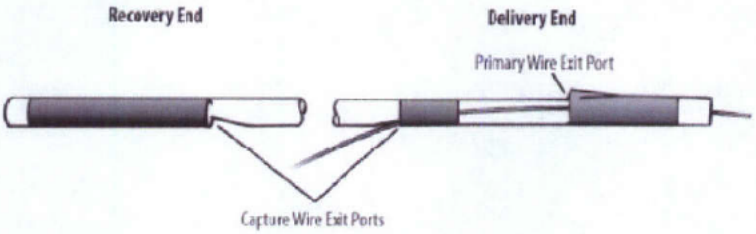
	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?			X

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Table 12 - 3: SpiderFX System Components and Accessory

Component	Diagram
SpiderFX Capture Wire	
SpiderFX Catheter	
Blunt tip flushing needle accessory	

IV. Indications for Use

The SpiderFX has the following indications for use.

> The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material during revascularization procedures of arteries in the lower extremities. The diameter of the artery at the site of filter basket placement should be between 3.0 mm and 6.0 mm.

The SpiderFX device was investigated along with the TurboHawk atherectomy device in moderate or severely calcified lesions. The indications for use should state that the SpiderFX device is indicated for use alongside the TurboHawk in patients with moderate to severely calcified lesions.

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

(b) (4)

V. Predicate Device Comparison

The predicate device has the following indications for use.

Indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0 mm and 7.0 mm.

Device Name	SpiderFX – K111010	SpiderFX – K063204	SpiderFX – K052659
Indication	Lower extremities	Carotid	Carotid
Indications for Use	The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities.	Indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0 mm and 7.0 mm.	
Indicated Vessel Diameters	3.0 – 6.0 mm	3.0 – 7.0 mm	
System Components	SpiderFX Catheter Capture Wire Flushing Needle	SpiderRX Catheter Capture Wire	
Guide (Sheath) Compatibility	6F (5F) – min 0.066"		
Guidewire Compatibility	0.014" or 0.018"		
Wire Exit Location	22.5 cm (Primary Guidewire) 40 cm (Capture Guidewire)		
Catheter Configuration	Dual-ended Rapid Exchange (Delivery End and Recovery End)		
Catheter Delivery End Nominal Diameter	(b) (4)		
Catheter Recovery End Nominal Diameter			
Catheter Materials			
Capture Wire Lengths	190 cm; 320 cm convertible to 190 cm		320 cm convertible to 190 cm
Filter Size	5, 6, 7 mm	3, 4, 5, 6, 7 mm	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

<table>
<tr><td>Device Name</td><td colspan="2">SpiderFX – K111010</td><td>SpiderFX – K063204</td><td>SpiderFX – K052659</td></tr>
<tr><td>Recommended Vessel Size</td><td colspan="2"><table><tr><th>Filter Size (mm)</th><th>Target Vessel Size (mm)</th></tr><tr><td>5.0</td><td>3.0 – 4.0</td></tr><tr><td>6.0</td><td>3.5 – 5.0</td></tr><tr><td>7.0</td><td>4.5 – 6.0</td></tr></table></td><td colspan="2"><table><tr><th>Filter Size (mm)</th><th>Target Vessel Size (mm)</th></tr><tr><td>3.0</td><td>3.0</td></tr><tr><td>4.0</td><td>3.1 – 4.0</td></tr><tr><td>5.0</td><td>4.1 – 5.0</td></tr><tr><td>6.0</td><td>4.5 – 6.0</td></tr><tr><td>7.0</td><td>5.5 – 7.0</td></tr></table></td></tr>
<tr><td>Filter Materials</td><td colspan="4">(b) (4)</td></tr>
<tr><td>Filter Design</td><td colspan="4">Eccentric</td></tr>
<tr><td>Recommended Distance between Lesion and Filter</td><td colspan="3">2.0 cm</td><td>1.5 cm</td></tr>
</table>

VI. Labeling

The sponsor provided a copy of the proposed and predicate labeling. The warnings and contraindications are appropriate and consistent with those found in the predicate labeling.

With the exception of the issue with the indications for use detailed above, I have no concerns with the labeling.

Update via Supplement 1
In response to deficiency #5, the sponsor has addressed the indications for use deficiency.

VII. Sterilization/Shelf Life/Reuse

The SpiderFX Device is provided to the user sterile and labeled for single use only. The device is not intended for sterilization or reprocessing by the user. The SpiderFX Device is sterilized using the identical ethylene oxide sterilization cycles as the currently marketed SpiderFX Device (K063204) and SpideRX Device (K052659).

The SpiderFX Device is ethylene oxide (EO) sterilized in a fixed chamber at Steris-Isomedix and meets a sterility assurance level (SAL) of 10^{-6}. Sterilization validation and associated revalidation activities are performed based on ISO 11135 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization, using Method C: Half-cycle Method. Ethylene oxide sterilization residue levels post-aeration are in compliance with the ISO 10993-7:2008 standard. The sterility assurance level (SAL) is 10^{-6}.

The packaging for the proposed device is identical to the packaging from the previously cleared version of the same device and the test data of the predicate devices is applicable to this version of SpiderFX.

The SpiderFX Device has the identical two-year shelf life as its predicate devices, SpiderFX (K063204, K063785) and SpideRX (K052659, K053195). No further shelf life testing was needed to support the peripheral indication.

As the device is identical to an already marketed device and the sterilization, packaging and shelf-life have not changed, I have no concerns with the sterilization, packaging, or shelf-life.

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VIII. Biocompatibility

The device materials in the proposed SpiderFX Device are identical to the materials in the commercially available SpideRX Device (K052659) and SpiderFX Device (K063204). Therefore, no new biocompatibility testing was performed.

I have no concerns with the lack of additional biocompatibility testing.

IX. Software

Not applicable

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable

XI. Performance Testing – Bench

Device testing was initially performed on the original SpiderFX Device (for carotid use) to demonstrate compatibility and performance with balloons and stents. Atherectomy, thrombectomy, and laser devices were not included in initial bench testing, which resulted in the inclusion of a warning by ev3 in the SpiderFX IFU regarding use of the SpiderFX Device with those devices. To support the IDE study (G080017), ev3 considered the use of the SpiderFX Device in lower extremity vessels in the United States and identified that compatibility testing needed to be completed with atherectomy, thrombectomy, and laser devices, because of their widespread use during lower extremity interventions in the United States.

After considering the device interactions between many different types of atherectomy, thrombectomy, and laser devices, ev3 determined SilverHawk to be a worst-case device for demonstrating compatibility of the SpiderFX Device with atherectomy, thrombectomy, and laser devices. This determination was made because of the location of the functional portion of the device relative to its long nose-cone on the distal end and the unique eccentric design of the SilverHawk Device. Additionally, physician feedback indicated that the SilverHawk Device is the most frequently used atherectomy device in peripheral interventions in the United States. Therefore ev3 chose to complete testing with the SilverHawk device to demonstrate compatibility of the SpiderFX Device with atherectomy, thrombectomy, and laser devices.

In section 11 of the submission, the sponsor provided a summary of the bench testing that was leveraged to support clearance of this device. This testing is shown below and can be found in the following submissions: G080017, G080025, G030115, G020248, K052659, K053195, K063204, K063786, and K070540 (NSE'd). All of the data shown below was reviewed in either K052659 or K063204.

The sponsor conducted the following tests on the device:

(b) (4)

The following testing was leveraged from the predicate SpiderFX® and SpideRX® Embolic Protection Device submissions. Test results met the specified acceptance criteria and were included in K063204 or K052659:

(b) (4)

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(b) (4)

[redacted]

References to Previous FDA reviews: Testing Recommended in FDA Guidance Document - Use with PTA Catheters and Stents

Test	Submission where Data Reviewed
Embolic Capture Efficiency and Retrieval Ability	K063204
Stent Compatibility	K063204
Simulated Use	K063204
Deployment/ Retrieval Forces	K063204
Filter Capacity	K052659
Resistance to Filter Rupture During Removal of a Fully-Loaded Filter	K063204
Flow Characteristics	K052659
Radial Outward Force	K063204
Tip Flexibility- Catheter	K052659
Tip Flexibility- Wire	K052659
Tensile Strength – Catheter	K052659
Torque Strength - Catheter	K052659
Torque Strength - Wire	K063204
Torque Response - Catheter	K052659
Torque Response - Wire	K063204
Kin Resistance - Catheter	K052659
Dimensional Verification	K063204
Packaging Visual Inspection	K063204
Heparin Coating Durability	K052659
Heparin Activity	K063204
Wire Bias	K063204

Testing to Support the Revised Sizing Matrix and Interventions with Atherectomy, Laser, and Thrombectomy Devices

Test Name/Qty:	Acceptance Criteria:	Test Results:

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Testing to Support the Revised Sizing Matrix and Interventions with Atherectomy, Laser, and Thrombectomy Devices

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Testing to Support the Revised Sizing Matrix and Interventions with Atherectomy, Laser, and Thrombectomy Devices

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

I have no concerns with the sponsor leveraging testing from previous clearances of the device for the carotid and saphenous vein graft indications. I also have no concerns with the testing conducted to support the revised sizing matrix and interventions with atherectomy, laser, and thrombectomy devices.

XII. Performance Testing – Animal

(b) (4)

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(b) (4)



XIII. Performance Testing – Clinical

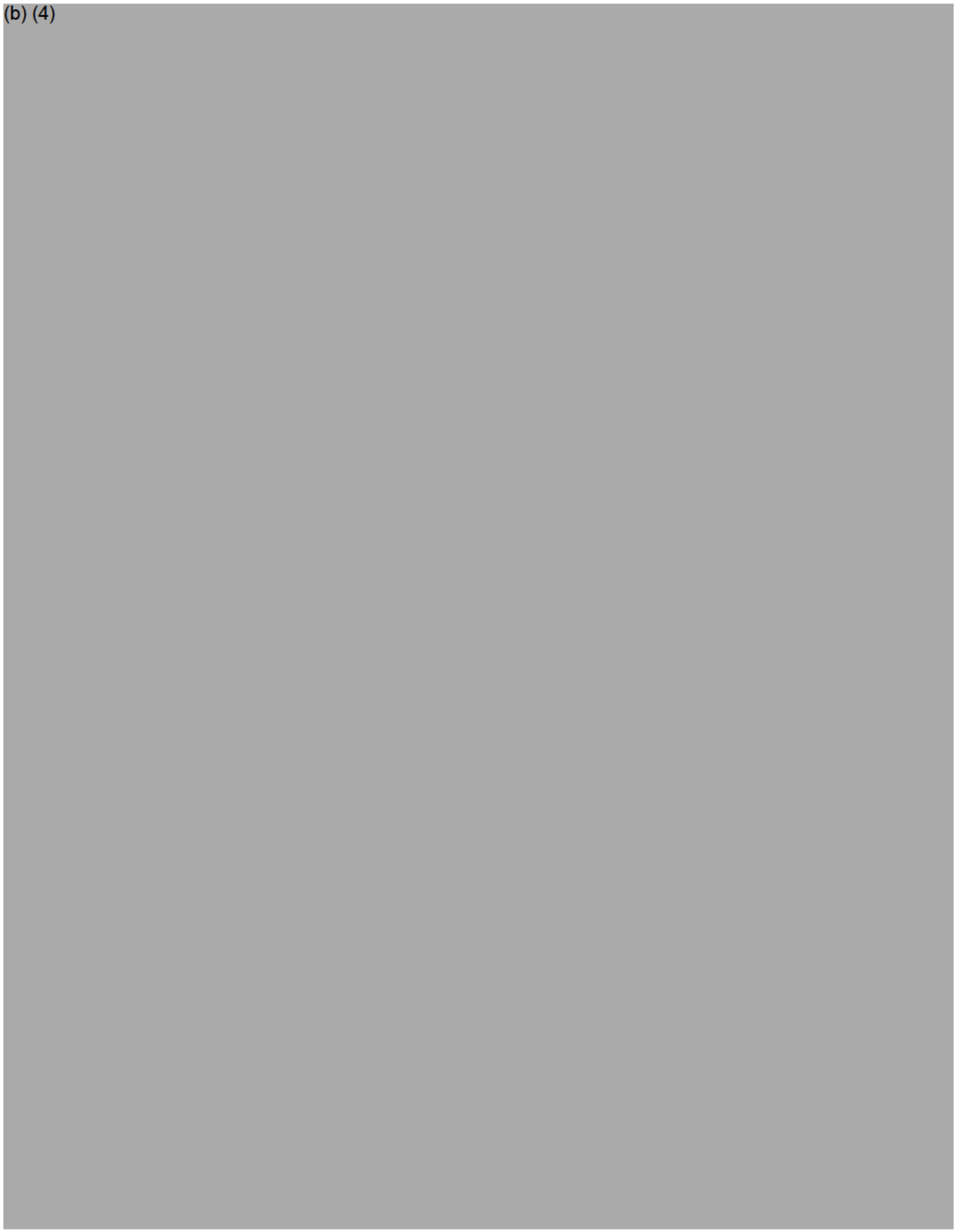
(b) (4)



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(b) (4)



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(b) (4)



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XIV. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?		N	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		N	If **YES** = Stop **NSE**
3. Same Technological Characteristics?	Y		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		N	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	Y		If **NO** = Request Data
9. Data Demonstrate Equivalence?	Y		Final Decision: SE

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1) Explain how the new indication differs from the predicate device's indication:

   The sponsor is proposing expanding the indications for use to the peripheral vasculature.

2) Explain why there is or is not a new effect or safety or effectiveness issue:

   The SpiderFx is the same device, only being used in the peripheral vasculature. The risks associated with use in the peripherals are less than the risks of use in the carotids, which the device is indicated for currently.

3) Describe the new technological characteristics:

4) Explain how new characteristics could or could not affect safety or effectiveness:

5) Explain how descriptive characteristics are not precise enough:

   The sponsor provided a limited device description. Performance and clinical data are needed to demonstrate substantial equivalence.

6) Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7) Explain why existing scientific methods can not be used:

8) Explain what performance data is needed:

9) Explain how the performance data demonstrates that the device is or is not substantially equivalent:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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The sponsor has addressed the outstanding deficiencies.

XV. Deficiencies

(b) (4)

[redacted]

Animal Studies

(b) (4)

[redacted]

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(b) (4)

Labeling

(b) (4)

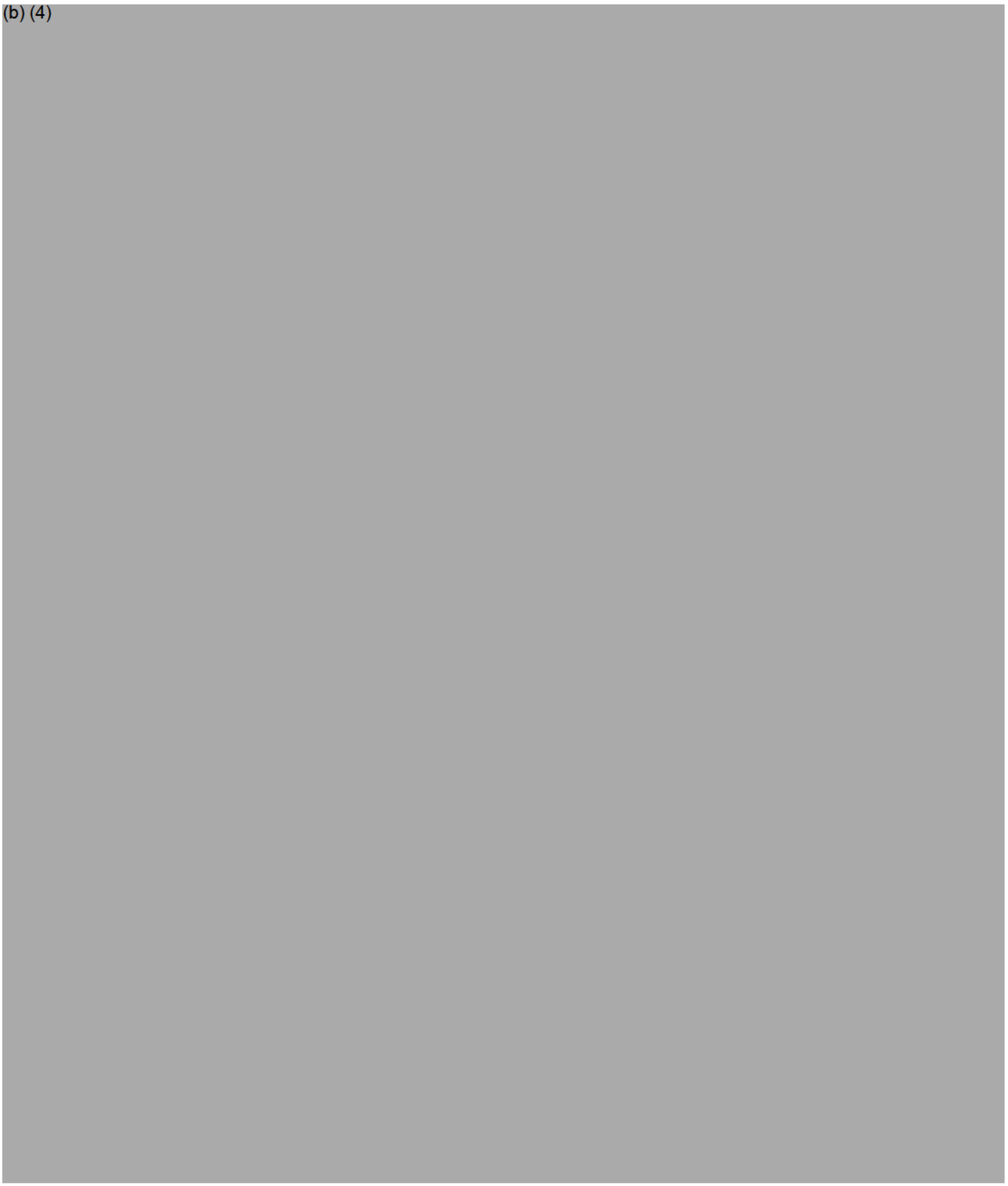
Animal Studies

(b) (4)

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(b) (4)

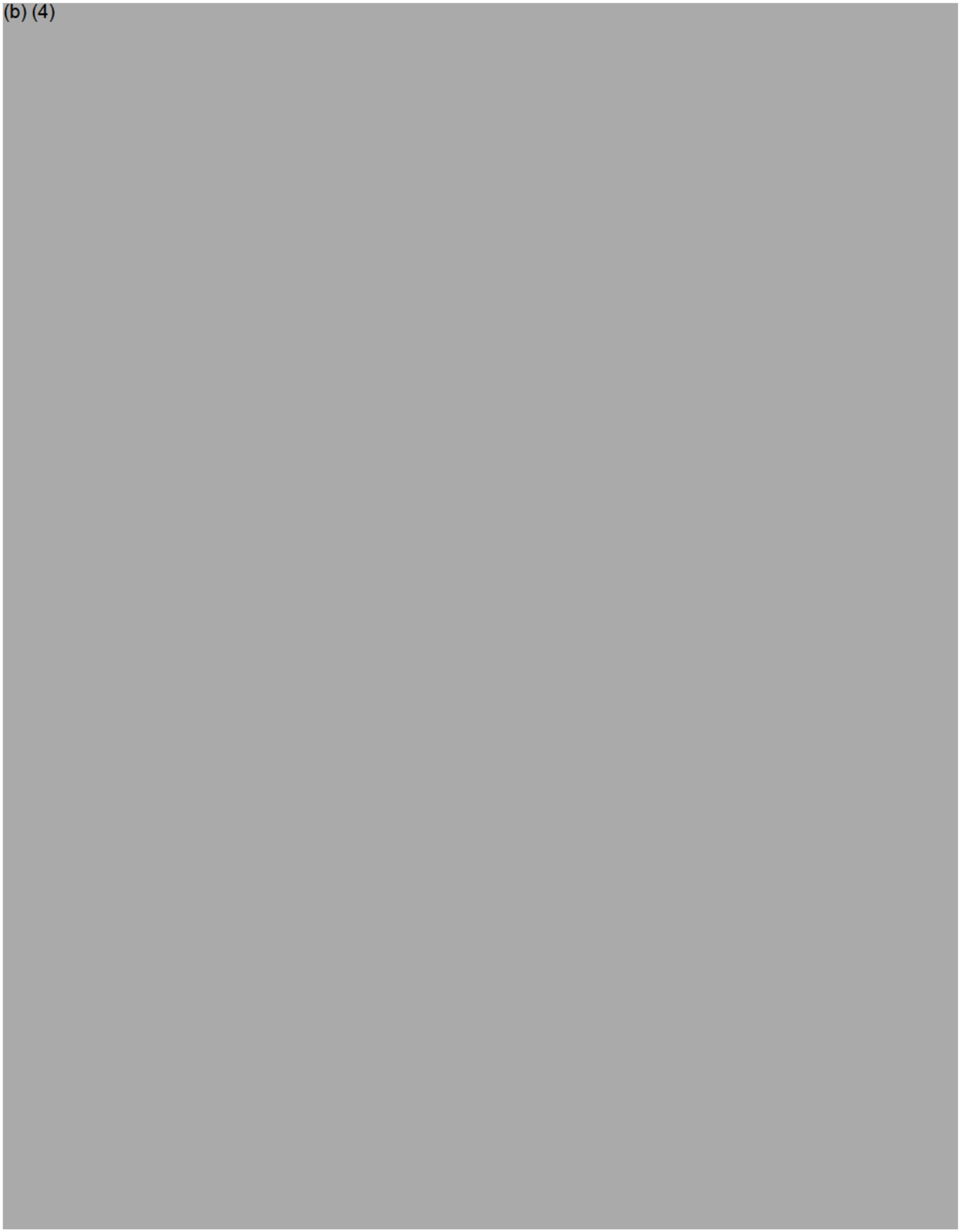


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Labeling

(b) (4)



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(b) (4)

[redacted]

XVI. Contact History

10/26/2011 – Interactive review to request ev3 to make a modification to their indications for use statement and to provide a new Indications for use statement and 510(k) Summary.

XVII. Recommendation

Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: NTE

Recommendation: SE

for Todd Courtney

Reviewer — Date: 10/27/11

Branch Chief — Date: 10/27/11

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Lim, Lisa

From: Courtney, Todd D
Sent: Thursday, October 27, 2011 10:51 AM
To: Lim, Lisa
Subject: FW: K111010 Indications
Attachments: Revised 510(k) Summary.docx; Revised Indications for Use.docx; Revised IFU.pdf

Lisa,

Here is a copy of the agreement for the indications.

Todd

From: Johnson, Brenda [mailto:bjohnson@ev3.net]
Sent: Wednesday, October 26, 2011 3:28 PM
To: Courtney, Todd D
Subject: RE: K111010 Indications

Hi Todd-

(b) (4)

[redacted]

Brenda Johnson
Principal Regulatory Affairs Specialist
Peripheral Vascular

COVIDIEN | ev3

3033 Campus Drive | Suite N550 | Plymouth, MN 55441 | USA

Main: +1 763 398 7000
Fax: +1 763 591 3248
Direct: +1 763 398 7238
Email: bjohnson@ev3.net

From: Courtney, Todd D [mailto:Todd.Courtney@fda.hhs.gov]

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10/27/2011

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sent: Wednesday, October 26, 2011 1:03 PM
To: Johnson, Brenda
Subject: K111010 Indications

(b) (4)



Todd Courtney, MS | Scientific Reviewer | Biomedical Engineer
Peripheral Vascular Devices Branch | FDA/CDRH/ODE/DCD
todd.courtney@fda.hhs.gov | p: 301-796-6371 | f: 301-847-8114
10903 New Hampshire Ave. WO66-1551, Silver Spring, MD 20993

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10/27/2011

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Indications for Use Statement

510(k) Number (if known): K111010

Device Name: SpiderFX® Embolic Protection Device

Indications for Use:

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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ev3

SpiderFX™

Embolic Protection Device

Instructions for Use

PRODUCT DESCRIPTION

The SpiderFX™ Embolic Protection Device is a percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The SpiderFX Device Capture Wire is used as the 0.014 in. wire for interventional device delivery. The SpiderFX Device can be delivered over any 0.014 in. or 0.018 in. primary wire used to gain access to the lesion site.

The SpiderFX Embolic Protection Device package contains the following components:

- One **Capture Wire** composed of a nitinol mesh Filter with a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter features a heparin-coating designed to maintain patency during Filter deployment[1]. This Capture Wire acts as the primary guidewire for other interventional devices compatible with a 0.014 in. wire. The convertible 320/190 cm Capture Wire is scored, allowing the wire to be snapped to a 190 cm usable length for use with rapid exchange systems, if desired. The distal portion of the Capture Wire for rapid exchange use is gold. The proximal portion for standard over-the-wire use is black.

  [1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.

- One dual-ended **SpiderFX Catheter** used to exchange the primary access guidewire with the Capture Wire, deploy the Capture Wire at the desired location, and recover the Capture Wire at the end of the procedure.
- One 23 gauge Blunt Needle for attachment to a syringe with Luer connector for priming and flushing the Catheter.

Components are delivered sterile, for use within a single vessel only. Do not re-sterilize or reuse.

***NOTE:** Commercially available catheters may also be used for delivery/recovery of the SpiderFX Capture Wire. Confirm that the Catheter of Choice is 0.035" guidewire compatible and is compatible with the Capture Wire length, guide catheter/sheath, and primary guidewire prior to use.*

INDICATIONS FOR USE

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities.

CONTRAINDICATIONS

Use of the SpiderFX Embolic Protection Device is contraindicated under these circumstances:

- Do not use with patients in whom anticoagulant and antiplatelet therapy is contraindicated
- Do not use in vessels with excessive tortuosity
- Do not use in patients with uncorrected bleeding disorders
- Do not use in the renal arteries

WARNINGS

The SpiderFX Embolic Protection Device should be used only by physicians who are trained in the proper use of the device.

- This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilizing could increase the risk of patient infection and risk of compromised device performance.
- Refer to the instructions supplied with all interventional devices to be used in conjunction with the SpiderFX Embolic Protection Device for their intended uses, contraindications and potential complications.
- The safety and effectiveness of this device as an embolic protection system have not been established in the renal or iliac arteries.
- The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure in accordance with standard medical practice.
- Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 2 Sizing Guide).
- Do not grip the Catheter at the distal white tips of either end. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.
- Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.
- Maintain the Capture Wire exit port of the SpiderFX Delivery Catheter within Guide Catheter/Sheath. This results in a 38 cm maximum distance from distal tip of Guide Catheter/Sheath to distal tip of Delivery Catheter. Failure to maintain this port within the Guide Catheter/Sheath may result in increased Filter advancement/deployment forces and vessel and/or device damage.
- Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.
- Do not apply excessive force to the Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.
- Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.
- Do not place the SpiderFX Capture Wire tip in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.
- Do not deploy the Filter within a previously implanted stent.
- Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX (or comparable) Catheter. This may lead to embolization of debris, and vessel and/or device damage.
- Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow. If slow/no flow should occur, the Filter should be recovered (See *Recovery and Removal*).
- Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.
- Do not use mechanical rotational thrombectomy with the Capture Wire.
- Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow flow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).
- After recovering the Filter, do not attempt to flush the Filter and/or reintroduce the Filter into the patient. The Filter must be discarded and a new Filter used if embolic protection is still needed.
- Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the SpiderFX (or comparable) Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

PRECAUTIONS

- Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.
- Do not use the product if the packaging sterile barriers have been damaged or compromised.
- If using the SpiderFX Delivery Catheter for filter delivery, the Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.
- Improper bending of the SpiderFX Catheter at the Primary Wire Exit Port could result in damage to the Catheter.
- If using the SpiderFX Catheter for filter delivery, DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.
- Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the catheter.
- Do not advance the Filter while the primary wire is still within the catheter lumen.
- Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without coming within 2 cm of the Filter proximal end.

Summary of DEFINTIVE Ca++ Study

DEFINITIVE Ca++ was a prospective, multi-center, non-randomized, single-arm study to compare the SilverHawk TurboHawk and the SpiderFX to performance goals derived from an observational multi-center registry (TALON) of subjects with lower extremity PAD who underwent revascularization with catheter-based plaque excision. The purpose of this study was to evaluate the safety and effectiveness of the SilverHawk/TurboHawk and the SpiderFX for the treatment of moderate to severely calcified peripheral arterial disease (PAD) in the superficial femoral and/or the popliteal arteries.

A total of 133 subjects were enrolled. Subject demographics are provided in Table1.

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Table 1: Subject Demographics and Baseline Clinical Characteristics

Subject Characteristics	N=133
Age (yrs.)	
Mean ± SD (N)	69.7 ± 9.8 (133)
Range (min, max)	(41.0, 95.0)
Male	71.4% (95/133)
Diabetes	47.4% (63/133)
History of hypertension requiring medication	91.7% (122/133)
History of MI	30.8% (41/133)
Hyperlipidemia	88.0% (117/133)
History of CABG or PCI	52.6% (70/133)
History of major amputation	0.8% (1/133)
Family history of CAD	49.6% (66/133)
History of peripheral intervention	57.1% (76/133)
History of smoking	78.9% (105/133)
CVA/TIA	15.8% (21/133)
Renal insufficiency	24.8% (33/133)
Rutherford clinical category score	
2	31.6% (42/133)
3	52.6% (70/133)
4	15.8% (21/133)

MI- myocardial infarction, CABG- coronary artery bypass graft, PCI- percutaneous coronary intervention, CAD- coronary artery disease, CVA- cerebrovascular accident, TIA - transient ischemic attack

The primary safety endpoint of the DEFINITIVE Ca++ study was freedom from major adverse event (MAE) rate. MAE was defined as a serious adverse event that results in death, acute myocardial infarction, dissection (grade C or greater), clinical perforation, pseudo-aneurysm, thrombosis, distal embolism (clinically relevant), amputation, or clinically-driven TVR, through 30 days post-procedure, as adjudicated by the clinical events committee (CEC). The 30-day freedom from MAE rate was 93.1% (122/131). The 95% lower confidence limit was 88.3% (as calculated by the Exact method), greater than the performance goal of 85.5%. Therefore, the primary safety endpoint was met. A summary of the MAEs is provided in Table 2.

Table 2: Summary of Major Adverse Events

Major Adverse Event	
Total	6.8% (9/133) [9]
Death	0.0% (0/133) [0]
Acute myocardial infarction	0.8% (1/133) [1]
Dissection, target vessel (C)	0.0% (0/133) [0]
Dissection, target vessel (grade D or greater)	0.8% (1/133) [1]
Vessel clinical perforation, target vessel	2.3% (3/133) [3]
Pseudoaneurysm, target vessel	0.0% (0/133) [0]
Thrombosis, target vessel	0.8% (1/133) [1]
Distal embolism	2.3% (3/133) [3]
Amputation, above metatarsal line	0.0% (0/133) [0]
Clinically Driven TVR	0.0% (0/133) [0]

Presence of debris in the SilverHawk/TurboHawk and SpiderFX by visual inspection at time of procedure was assessed. Debris (excised plaque) was present in the nosecone of the SilverHawk/ TurboHawk devices in 97.0% (129/133) of cases. Debris was present in 88.4% (122/138) of deployed SpiderFX filters upon recovery. Preservation of run-off distal to SpiderFX was determined by angiography of run-off vessels at the end of the procedure, as adjudicated by the angiographic core laboratory. Preservation of run-off was verified by the angiographic core laboratory in 98.3% (113/115) of subjects with available data. The proportion of asymptomatic subjects increased from 0% at baseline to 52.3% at the 30-day follow-up visit. Likewise, the proportion of subjects with severe claudication decreased from 52.6% at baseline to 6.2% at 30 days

Adverse Events

A summary of device- and procedure-related adverse events is provided in Table 3. There were no Unanticipated Adverse Device Effects or deaths.

Table 3: Summary of Device and Procedure-Related Adverse Events and Serious Adverse Events

Adverse Event	Procedure-Related	Study Requirement-Related	SilverHawk-Related	TurboHawk-Related	SpiderFX-Related	% of subjects [# of events]
All Related Events	38.3% (51/133) [64]	1.5% (2/133) [2]	18.4% (14/76) [14]	19.3% (11/57) [11]	3.8% (5/133) [5]	39.8% (53/133) [66]
Access site adverse event	6.0% (8/133) [8]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	6.0% (8/133) [8]
AV fistula, target vessel	0.8% (1/133) [1]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	0.8% (1/133) [1]
Dissection, grade A or B; non-target vessel	0.8% (1/133) [1]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	0.8% (1/133) [1]
Dissection, grade A or B; target vessel	19.5% (26/133) [26]	0.0% (0/133)	13.2% (10/76) [10]	10.5% (6/57) [6]	0.0% (0/133)	19.5% (26/133) [26]
Dissection, grade D or greater; target vessel	1.5% (2/133) [2]	0.0% (0/133)	13.2% (10/76) [10]	3.5% (2/57) [2]	0.0% (0/133)	1.5% (2/133) [2]
Distal embolism; plaque, thrombus (blood clot) or debris distal to the filter, clinically relevant	2.3% (3/133) [3]	0.0% (0/133)	2.6% (2/76) [2]	1.8% (1/57) [1]	2.3% (3/133) [3]	2.3% (3/133) [3]
GI bleeding due to antico-agulation	0.0% (0/133)	0.8% (1/133) [1]	2.6% (2/76) [2]	1.8% (1/57) [1]	2.3% (3/133) [3]	0.8% (1/133) [1]
Hypotension or hypertension	1.5% (2/133) [2]	0.8% (1/133) [1]	2.6% (2/76) [2]	1.8% (1/57) [1]	2.3% (3/133) [3]	2.3% (3/133) [3]
Myocardial infarction, acute	0.8% (1/133) [1]	0.8% (1/133) [1]	2.6% (2/76) [2]	1.8% (1/57) [1]	2.3% (3/133) [3]	0.8% (1/133) [1]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 3: Summary of Device and Procedure-Related Adverse Events and Serious Adverse Events

Adverse Event	Procedure-Related	Study Requirement-Related	SilverHawk-Related	TurboHawk-Related	SpiderFX-Related	% of subjects [# of events]
Pseudoaneurysm, non-target vessel	0.8% (1/133) [1]	0.0% (0/133)	0.0% (0/076)	0.0% (0/057)	0.0% (0/133)	0.8% (1/133) [1]
Renal insufficiency	1.5% (2/133) [2]	0.0% (0/133)	0.0% (0/076)	0.0% (0/057)	0.0% (0/133)	1.5% (2/133) [2]
Thrombosis (acute and subacute); target vessel	0.8% (1/133) [1]	0.0% (0/133)	1.3% (1/76) [1]	0.0% (0/057)	0.0% (0/133)	0.8% (1/133) [1]
Vasospasm	1.5% (2/133) [2]	0.0% (0/133)	1.3% (1/76) [1]	0.0% (0/057)	1.5% (2/133) [2]	1.5% (2/133) [2]
Vessel clinical perforation, target vessel	2.3% (3/133) [3]	0.0% (0/133)	1.3% (1/76) [1]	3.5% (2/57) [2]	1.5% (2/133) [2]	2.3% (3/133) [3]
Other, respiratory	0.8% (1/133) [1]	0.0% (0/133)	1.3% (1/76) [1]	3.5% (2/57) [2]	1.5% (2/133) [2]	0.8% (1/133) [1]
Other	5.3% (7/133) [9]	0.0% (0/133)	1.3% (1/76) [1]	3.5% (2/57) [2]	1.5% (2/133) [2]	5.3% (7/133) [9]

The results of the DEFINITIVE Ca++ study demonstrate that the SilverHawk/TurboHawk device is safe and effective in the endovascular treatment of moderate to severely calcified lesions in the superficial femoral and/or popliteal arteries when used with the SpiderFX embolic protection device. The data also showed that utilizing the SpiderFX embolic protection device resulted in preservation of run-off in 98.3% of subjects, further supporting that the use of the SpiderFX device is a safe and effective means of embolic protection in subjects undergoing endovascular treatment for peripheral arterial disease.

POTENTIAL COMPLICATIONS

Complications associated with the use of the SpiderFX Embolic Protection Device may include, but are not limited to:

- Access site adverse event (e.g., av fistula, hematoma, hemorrhage, pseudoaneurysm, puncture site infection)
- Adjunct device entanglement
- Adverse reaction to antiplatelet/anticoagulation agents or contrast media
- Allergic reaction to device materials
- Amputation
- Aneurysm
- Arterial dissection
- Death
- Device(s) deformation, collapse, fracture, or rupture
- Device(s) thrombosis (acute and subacute)
- Dissection
- Embolization of air, debris, plaque or thrombus (evidenced by slow or no-flow) from mechanical disruption by the intervention
- Embolization or migration of the interventional device(s)
- Emergency surgery
- GI bleeding due to anticoagulation
- Hemodynamic compromise (e.g., prolonged hypotension requiring treatment with intravenous medications)
- Hypotension or hypertension
- Infection
- Ischemia
- Myocardial infarction
- Renal insufficiency
- Renal failure requiring dialysis
- Repeat intervention to treatment site
- Sepsis
- Significant cardiac arrhythmia requiring treatment with medications and/or transvenous pacing
- Stent entanglement
- Stroke
- Thrombosis (acute and subacute)
- Transient Ischemia Attack (TIA)
- Vasospasm
- Vessel dissection, perforation, rupture or intimal flap
- Vessel/filter occlusion

DEVICE COMPONENTS

The SpiderFX Embolic Protection Device package contains one each of the following components:

NOTE: See Table 4 for Device product specifications.

Capture Wire — The Capture Wire has a Nitinol mesh Filter with a Proximal Mouth Indicator and a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter has a heparin coating designed to maintain patency[1]. The Capture Wire is pre-loaded through the Delivery End of the SpiderFX Catheter with the Filter extending from the Catheter distal tip. The SpiderFX Capture Wire and Catheter are provided in a single hoop.

[1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.

TABLE 4 — SpiderFX Embolic Protection Device Specifications*

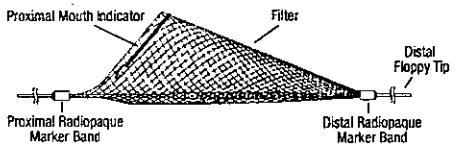
SpiderFX Capture Wire			
Filter Diameter (mm)	5.0	6.0	7.0
Filter Length (mm)**	23	23	24
Capture Wire Length RX (cm)	190	190	190
Capture Wire Length OTW/RX (cm)	320/190	320/190	320/190
Wire Diameter (in./mm)	0.014/0.36	0.014/0.36	0.014/0.36
Distal Wire Tip Coil Length (cm)	1.2	1.2	1.2
SpiderFX Catheter - Delivery End (green)			
Nominal Diameter (in./mm)	0.040/1.02	0.040/1.02	0.040/1.02
Functional Length (cm)	140	140	140
SpiderFX Catheter - Recovery End (blue)			
Diameter (F)	4.2	4.2	4.2
Functional Length (cm)	140	140	140
Total Catheter Length (cm)	180	180	180

*Nominal

**When delivered at maximum recommended vessel size.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

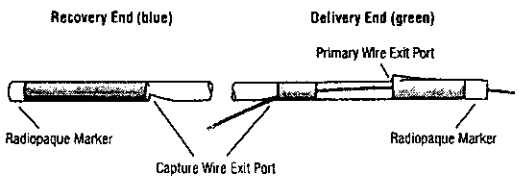
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Capture Wire

CAUTION: *Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.*

SpiderFX Catheter — The SpiderFX Catheter is dual-ended, with a Delivery End (green), and a Recovery End (blue) at the opposite end of the catheter



SpiderFX Catheter

- The **Delivery End** (green) of the SpiderFX Catheter has an embedded radiopaque marker at the distal tip, a primary wire exit port (indicated by a white stripe), a Clear Segment, and a Capture Wire Exit Port. The Capture Wire is pre-loaded into the Delivery End of the Catheter, with the Filter portion extending from the distal tip.
- The center **White Shaft** is used to manipulate the SpiderFX Catheter during delivery and recovery of the SpiderFX Capture Wire.
- The **Recovery End** (blue) of the SpiderFX Catheter has an embedded radiopaque marker at its distal tip, and a Capture Wire Exit Port.

Latex is not a component of the SpiderFX Embolic Protection Device.

INSTRUCTIONS FOR USE – SpiderFX Catheter

NOTE: *If using alternate catheter for delivery/recovery of the SpiderFX Capture Wire refer to instructions starting on page 4.*

Preparing the SpiderFX Embolic Protection Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the anticipated distal tip of interventional device to be used to treat the lesion. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the anticipated distal tip of interventional device, to allow for adequate Filter deployment.

WARNING: Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 2 Sizing Guide).

4. Ensure the guide catheter/sheath size will accommodate the SpiderFX Catheter. (Table 5).

TABLE 5 — Sizing Guide[1]

Target Vessel Size (mm)	Filter Size (mm)	Primary Guidewire Size (in)	Guide Catheter/ Sheath Min I.D.[2] (in)
3.0 - 4.0	5.0	0.014-0.018	0.066
3.5 - 5.0	6.0	0.014-0.018	0.066
4.5 - 6.0	7.0	0.014-0.018	0.066

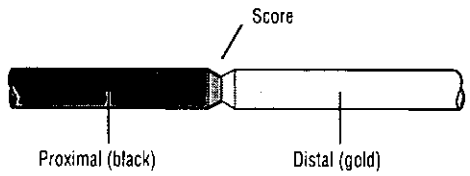
[1] Nominal
[2] Select a guide catheter that provides coaxial alignment and stable backup support.

5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the Catheter near the Primary Wire Exit Port and gently pull to expose the Catheter. The remaining Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the Catheter.

NOTE: *If using the 320/190 cm convertible version of the SpiderFX Device, it may be snapped at any point during the intervention if no over-the-wire devices are intended to be used. To do this, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*

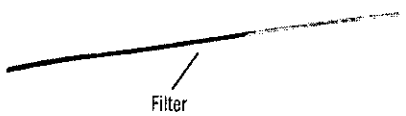


Capture Wire

8. Hold the Catheter at the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the Catheter at the distal white tips of either end. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.

9. Continue holding the Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter portion stops in the proximal end of the Clear Segment of the Catheter.



Filter in Proper Position in Clear Segment

CAUTION: *The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.*

10. Flush through the distal tip with heparinized saline until all air is removed and fluid passes from the Primary Wire Exit Port (22.5 cm proximal to the distal tip of the Catheter). A 23 gauge blunt needle included in the packaging may be used, if desired. Do not apply excessive force to the Capture Wire.
11. Gently apply pressure to the Primary Wire Exit Port. Flush until all air is removed and fluid passes from the Capture Wire Exit Port (40 cm proximal to Catheter distal tip).

WARNING: Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.

Delivery and Deployment

12. Access the vessel being treated using standard technique, and advance the primary guidewire at least 5 cm beyond the anticipated distal end of interventional device used to treat the lesion.
13. Observe the Primary Wire Exit Port indicated by a white stripe on the Catheter, to ensure the Port hole is visible.

NOTE: *When loading the primary guidewire, gently bend the Catheter placing the Primary Wire Exit Port at the apex of the curve*

CAUTION: *Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.*

14. Load the distal tip of the SpiderFX Device Delivery End (green) onto the proximal end of the primary guidewire and advance, so the primary wire exits at the Primary Wire Exit Port.

CAUTION: *DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.*

15. Gently advance the SpiderFX Delivery End carrying the Capture Wire over the primary wire and into the guide catheter/sheath. Continue advancing until the radiopaque marker at the distal tip of the Delivery End is at least 4-5 cm distal to the anticipated distal end of the interventional device used.

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CAUTION: *Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the Catheter.*

WARNING: Maintain the Capture Wire exit port of the SpiderFX Delivery Catheter within Guide Catheter/Sheath. This results in a 38 cm maximum distance from distal tip of Guide Catheter/Sheath to distal tip of Delivery Catheter. Failure to maintain this port within the Guide Catheter/Sheath may result in increased Filter advancement/ deployment forces and vessel and/or device damage.

WARNING: Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.

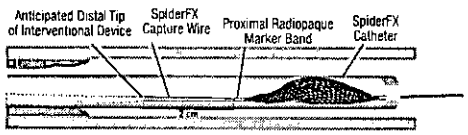
WARNING: Do not apply excessive force to Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

16. Hold the Catheter stationary, and withdraw the primary guidewire, leaving the Delivery Catheter and Capture Wire in place.
17. Hold the Catheter stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.

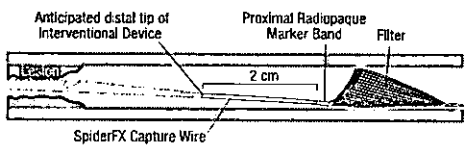
18. Observe and adjust the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the anticipated distal end of the interventional device used to treat the lesion.



Position of SpiderFX Catheter Relative to Interventional Device.

CAUTION: *Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.*

WARNING: Do not deploy the Filter within a previously implanted stent



Position of Filter Relative to Interventional Device

19. Hold the Capture Wire stationary, and gently pull back on the Catheter to expose and deploy the Filter in the vessel. To reposition the Filter (if required),advance the Catheter back over the Filter, adjust the position of the Catheter and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter.

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX (or comparable) Catheter. This may lead to embolization of debris, and vessel and/or device damage.

20. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Delivery Catheter together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
21. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
22. Once the Filter is deployed in the desired location, carefully remove the SpiderFX Catheter from the patient. Keep the Catheter in the sterile field. **DO NOT DISCARD THE CATHETER.** The Recovery End (blue) is required for Capture Wire recovery.
23. Place the SpiderFX Catheter in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter.
24. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/ no-flow. If slow/no flow should occur, the Filter should be recovered (See *Recovery and Removal*).

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use mechanical rotational thrombectomy with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).

WARNING: After recovering the Filter, do not attempt to flush the Filter and/or reintroduce the Filter into the patient. The Filter must be discarded and a new Filter used if embolic protection is still needed.

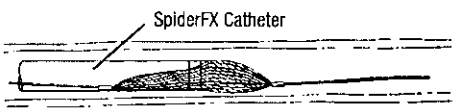
Recovery and Removal

25. After completion of the interventional procedure, wet the distal 20 cm of the Recovery End (blue) of the Catheter with heparinized saline. Flush the distal tip of the Recovery End to remove all air, until fluid passes from the Capture Wire Exit Port (25 cm from the tip).

WARNING: Do not grip the Catheter at the distal white tips of either end. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

26. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.
27. Advance the Catheter under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
28. There are two methods for Filter Recovery:

A — Partial Enclosure Recovery: Gently advance the Recovery End over the Filter, until the proximal portion of the Filter is inside the Catheter, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the radiopaque marker of the Recovery Catheter.



A. Partial Enclosure Recovery

WARNING: Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

B — Full Enclosure Recovery: Gently advance the Recovery End over the Filter until all radiopaque markers on the Filter are within the Catheter, proximal to the Catheter distal marker. The Distal Floppy Tip may remain outside the Catheter.



B. Full Enclosure Recovery

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

29. Carefully remove the Catheter and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the SpiderFX Catheter to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

CAUTION: *Do not re-sterilize or reuse this device.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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INSTRUCTIONS FOR USE – Alternate Catheter of Choice

NOTE: *Commercially available catheters can be used for delivery/recovery of the SpiderFX Capture Wire. Confirm that the Catheter of Choice is 0.035" guidewire compatible and is compatible with the Capture Wire length, guide catheter/sheath, and primary wire prior to use.*

Preparing the SpiderFX Embolic Protection Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the anticipated distal tip of interventional device to be used to treat the lesion. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the anticipated distal tip of interventional device, to allow for adequate Filter deployment.

WARNING: Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 6 Sizing Guide).

TABLE 6 — Filter Sizing Guide

Target Vessel Size (mm)	Filter Size (mm)
3.0 - 4.0	5.0
3.5 - 5.0	6.0
4.5 - 6.0	7.0

NOTE: *Ensure that the length of the Catheter of Choice is such that it accommodates the Capture Wire length.*

4. Ensure the guide catheter/sheath size will accommodate the Catheter of Choice according to its instructions for use.
5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the SpiderFX Catheter near the Primary Wire Exit Port and gently pull to expose the SpiderFX Catheter. The remaining SpiderFX Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the SpiderFX Catheter.
8. Hold the SpiderFX Catheter near the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the SpiderFX Catheter at the distal white tips of either end. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the SpiderFX Catheter.

9. Continue holding the SpiderFX Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter and Distal Floppy Tip are fully contained within the distal tip of the SpiderFX Catheter.

WARNING: Failure to fully contain the Distal Floppy Tip within the distal end of the SpiderFX Catheter Delivery End during loading could result in kinking of the Distal Floppy Tip.

Delivery and Deployment

10. Access the vessel being treated using standard technique, and advance the primary guidewire and/or Catheter of Choice at least 5cm beyond the anticipated distal end of interventional device used to treat the lesion.
11. Hold the Catheter of Choice stationary and withdraw the primary guidewire.
12. Following removal of primary guidewire, flush the Catheter of Choice lumen with sterile heparinized saline.
13. Gently guide the tip of the SpiderFX Device Delivery End (green) into the proximal end of the Catheter of Choice or until the tip of the SpiderFX Catheter aligns with the lumen of the Catheter of Choice.

WARNING: Do not advance the SpiderFX Catheter against resistance. This may result in deformation of the embedded Radiopaque Marker Band contained within the SpiderFX Catheter tip.

14. Hold the SpiderFX Catheter and Catheter of Choice stationary, and gently advance the Capture Wire until the Filter enters the lumen of the Catheter of Choice.

NOTE: *The user should feel a reduction in force when the Filter has exited the SpiderFX Catheter and is fully contained within the Catheter of Choice.*

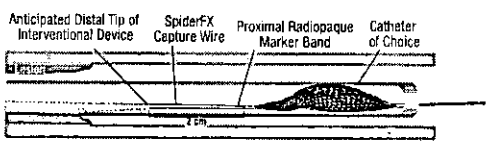
15. Continue to advance the Capture Wire through the SpiderFX Catheter and Catheter of Choice approximately 5 to 7 inches to ensure the Capture Wire's tapered section is fully supported within the Catheter of Choice.

CAUTION: *Failure to support the distal tapered section of the Capture Wire within the Catheter of Choice while advancing the Filter could result in kinking of the Capture Wire.*

16. Hold the Capture Wire stationary, and pull back on the SpiderFX Catheter to offload the SpiderFX Catheter from the Capture Wire. Keep the SpiderFX Catheter in the sterile field. **DO NOT DISCARD THE SPIDERFX CATHETER** in the event that the SpiderFX Catheter Recovery End (blue) may be needed for Filter recovery.
17. Place the SpiderFX Catheter in sterile heparinized saline or sterile field. Do not bend or kink the SpiderFX Catheter.
18. Hold the Catheter of Choice stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter of Choice distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.

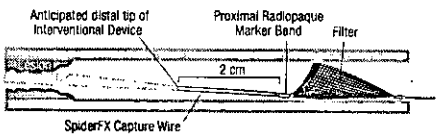
19. Observe and adjust the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the anticipated distal end of the interventional device used to treat the lesion.



Position of Catheter of Choice Relative to Interventional Device.

CAUTION: *Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without coming within 2 cm of the Filter proximal end.*

WARNING: Do not deploy the Filter within a previously implanted stent.



Position of Filter Relative to Interventional Device

20. Hold the Capture Wire stationary, and gently pull back on the Catheter of Choice to expose and deploy the Filter in the vessel. To reposition the Filter (if required), advance the Catheter of Choice back over the Filter, adjust the position of the Catheter of Choice and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter of Choice.

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the Catheter of Choice or SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.

21. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Catheter of Choice together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
22. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
23. Once the Filter is deployed in the desired location, carefully remove the Catheter of Choice from the patient. Keep the Catheter of Choice in the sterile field. DO NOT DISCARD THE CATHETER OF CHOICE. The Catheter of Choice may be used for Capture Wire recovery.
24. Place the Catheter of Choice in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter of Choice.

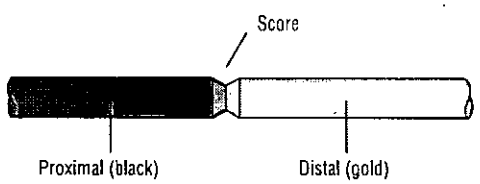
NOTE: *The SpiderFX Catheter Recovery End (blue) may also be used for Capture Wire recovery.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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25. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

NOTE: *If using the 320/190 cm convertible version of the SpiderFX Device, it may be snapped at any point during the intervention if no over-the-wire devices are intended to be used. To do this, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*



Capture Wire

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow. If slow/no flow should occur, the Filter should be recovered (See *Recovery and Removal*).

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use mechanical rotational thrombectomy with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).

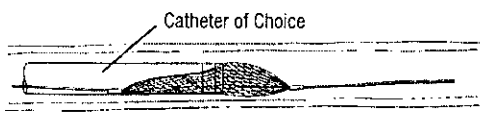
WARNING: After recovering the Filter, do not attempt to flush the Filter and/or reintroduce the Filter into the patient. The Filter must be discarded and a new Filter used if embolic protection is still needed.

Recovery and Removal

26. After completion of the interventional procedure, flush the Catheter of Choice from the proximal end to remove all air, until fluid passes through the distal tip.

NOTE: *The SpiderFX Catheter Recovery End (blue) may also be used for Capture Wire recovery. See instructions for 'Recovery and Removal' with SpiderFX starting on page 4, step 25.*

27. Load the Catheter of Choice onto the Capture Wire and through the guide catheter/sheath.
28. Advance the Catheter of Choice under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
29. Gently advance the Catheter of Choice over the Filter, until the proximal portion of the Filter is inside the Catheter of Choice, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the distal radiopaque marker of the Catheter of Choice.



Recovery of SpiderFX Capture Wire with Catheter of Choice.

WARNING: Exercise caution when withdrawing a full Filter through a deployed stent. If resistance is felt, advance the Filter and Catheter of Choice distally and draw the Filter more fully into the Catheter of Choice before re-attempting withdrawal as illustrated below.



30. Carefully remove the Catheter of Choice and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the Catheter of Choice to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

CAUTION: *Do not re-sterilize or reuse this device.*

STORAGE

- Do not store in direct sunlight
- Keep dry

WARRANTY DISCLAIMER

Although the product has been manufactured under carefully controlled conditions, ev3 Inc. has no control over the conditions under which this product is used. ev3 Inc., therefore disclaims all warranties, both express and implied, with respect to the product including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ev3 Inc. shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind ev3 Inc. to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Tollfree + 800 716 6700
www.ev3.net

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SpiderFX is a trademark of ev3 and may be registered in the U.S. and other countries.
Protected under one or more of the following: US Patent 7,717,934; 7,637,920; 7,556,636; 7,556,635; 7,410,492; 7,404,820; 7,371,250; 7,367,986; 6,979,343; 6,843,798; 6,712,835; 6,325,815. Non-US patents issued & pending.

500769-001 (B) APR/11 US

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

510(k) Summary

SpiderFX® Embolic Protection Device

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1. Submitter Information

Applicant	ev3 Inc. 3033 Campus Drive Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Brenda Johnson Principal Regulatory Affairs Specialist
Date Prepared	October 27, 2011

2. Subject Device

Device Trade Name	SpiderFX® Embolic Protection Device
Device Common Name	Embolic Protection Device
Classification Name	Temporary Carotid Catheter for Embolic Capture 21 CFR 870.1250, Product Code NTE
Classification Panel	Cardiovascular

3. Predicate Devices

Device Trade Name	SpiderFX® Embolic Protection Device; SpideRX® Embolic Protection Device Angioslide eXtra™ PTA Balloon Catheter with Embolic Capture Feature
510(k) Number	K063204; K052659; K090364
510(k) Clearance Date	November 14, 2006; February 17, 2006; March 23, 2010

4. Device Description

The SpiderFX® Embolic Protection Device is a percutaneously delivered distal embolic protection system that can be delivered over any 0.014" or 0.018" guidewire. The SpiderFX Embolic Protection Device contains a Capture Wire composed of a nitinol mesh filter mounted on a 190 cm or a convertible 320/190 cm PTFE-coated 0.014" stainless steel guidewire and a dual-ended SpiderFX Catheter for delivery and recovery. The SpiderFX® Embolic Protection Device uses the following materials: pebax, grilamid, platinum/iridium, nitinol, stainless steel, PTFE coating, gold tungsten, and hydrophilic coating.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

5. Indications for Use

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk, either during standalone procedures or together with PTA and/or stenting, in the treatment of severely calcified lesions in arteries of the lower extremities.

6. Comparison of Technological Characteristics

The SpiderFX® Embolic Protection Device is the identical device as the currently marketed SpiderFX Embolic Protection Device (K063204). The SpiderFX Embolic Protection Device for peripheral use and the predicate SpiderFX Embolic Protection Device for carotid use share the following technological characteristics:

- Intended use
- Fundamental scientific technology and operating principle
- Design & Dimensions
- Materials
- Manufacturing site and methods
- Sterilization site, method, parameters, and sterility assurance level
- Packaging
- Shelf Life

Additionally, the Indications for Use, labeling, and Instructions For Use are similar between the proposed and marketed devices. The differences include a revised sizing matrix for use during interventions in lower extremity vessels, allowing use of the SpiderFX Device with atherectomy interventional devices, and allowing use of commercially available catheters, that are minimally 0.035" guide wire compatible, for delivery and/or recovery of the SpiderFX Capture Wire. Bench and animal testing was performed to demonstrate the proposed use of the device met pre-determined acceptance criteria.

7. Biocompatibility Testing

Device materials in the proposed SpiderFX® Embolic Protection Device are identical to the materials in the commercially available SpiderFX® and SpideRX® Embolic Protection Devices. Biocompatibility testing was leveraged from the predicate SpiderFX® and SpideRX® Embolic Protection Device submissions and included cytotoxicity, sensitization, intracutaneous injection, systemic injection, hemolysis, pyrogen, complement activation, and thrombogenicity. The SpideRX Catheter and Capture Wire from the predicate SpideRX Device (K052659) meet the requirements for biocompatibility testing outlined in ISO 10993-1 Part 1: 2003 "Biological Evaluation of Medical Devices".

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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8. Performance Testing Summary

To demonstrate substantial equivalence of the subject SpiderFX® Embolic Protection Device to the predicate device, the technological characteristics and performance criteria were evaluated. Using FDA Guidance Documents on non-clinical testing of medical devices and internal Risk Analysis procedures, the following tests were performed:

- Stent Compatibility
- Filter Efficiency
- Radial Outward Force
- Simulated Use
- Deployment/Retrieval Forces
- *In Vivo* Animal Studies

The following testing was leveraged from the predicate SpiderFX® and SpideRX® Embolic Protection Device submissions. Test results met the specified acceptance criteria and were included in K063204 or K052659:

- Embolic Capture Efficiency and Retrieval Ability
- Simulated Use
- Deployment/Retrieval Forces
- Filter Capacity
- Resistance to Filter Rupture During Removal of a Fully Loaded Filter
- Flow Characteristics
- Tip Flexibility
- Tensile Strength
- Torque Strength
- Torque Response
- Kink Resistance
- Dimensional Verification
- Package Integrity
- Sterilization
- Shelf Life

The results from these tests demonstrate that the technological characteristics and performance criteria of the SpiderFX® Embolic Protection Device are comparable to the predicate device and that the SpiderFX® Embolic Protection Device performs in a manner equivalent to the predicate device currently on the market for the same intended use.

9. Clinical Summary

DEFINITIVE Ca^{++} was a prospective, multi-center, non-randomized, single-arm study to compare the SilverHawk TurboHawk and the SpiderFX to performance goals derived from an observational multi-center registry (TALON) of subjects with lower extremity PAD who underwent revascularization with catheter-based plaque excision. The purpose of this study was to evaluate the safety and effectiveness of the SilverHawk/TurboHawk and the SpiderFX for the treatment of moderate to severely calcified peripheral arterial disease (PAD) in the superficial femoral and/or the popliteal arteries.

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The primary safety endpoint of the DEFINITIVE Ca^{++} study was freedom from major adverse event (MAE) rate. MAE was defined as a serious adverse event that results in death, acute myocardial infarction, dissection (grade C or greater), clinical perforation, pseudo-aneurysm, thrombosis, distal embolism (clinically relevant), amputation, or clinically-driven TVR, through 30 days post-procedure, as adjudicated by the clinical events committee (CEC). The 30-day freedom from MAE rate was 93.1% (122/131). The 95% lower confidence limit was 88.3% (as calculated by the Exact method), greater than the performance goal of 85.5%. Therefore, the primary safety endpoint was met.

10. Conclusions

Based on the intended use, technological characteristics, safety and performance testing included in this submission, ev3 considers the proposed SpiderFX® Embolic Protection Device to be substantially equivalent to its predicates.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

From:	Steven S. Brooks Medical Officer, ODE PVDB
To:	Todd Courtney Scientific Reviewer, ODE PVDB
Cc:	Kenneth Cavanaugh Division Chief, ODE PVDB
Subject:	K111010/S001 SpiderFX Embolic Protection Device, Peripheral Indication ev3 Endovascular Inc.
Date:	October 14, 2011

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

(b)(4) Q&A with sponosr and FDA

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

(b)(4) Q&A with sponosr and FDA

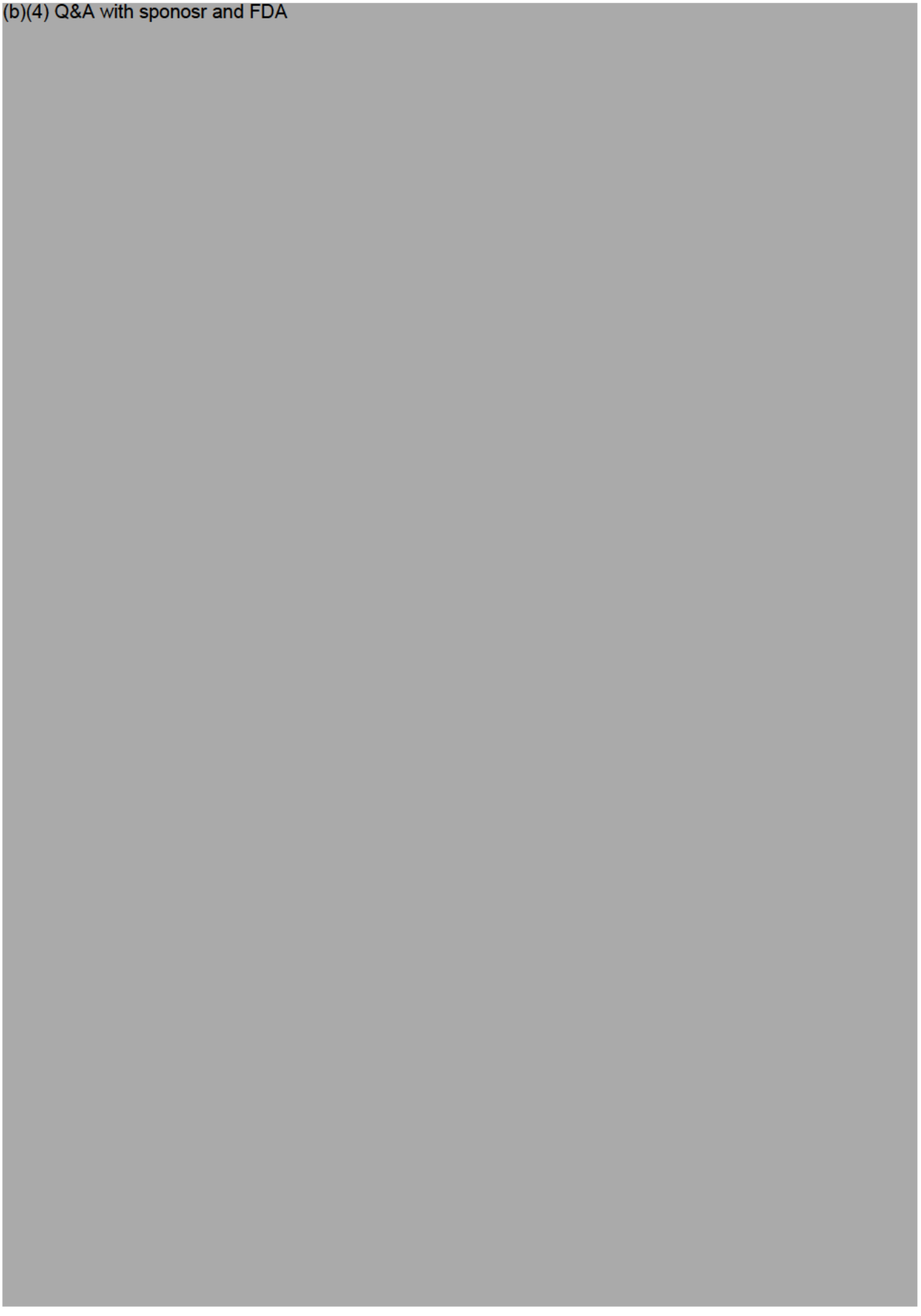
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

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Records processed under FOIA request 2017-9992; Released on 1/29/2019

FDA U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Veterinary Consultation Memorandum

Date: October 14, 2011

From: Victoria Hampshire, VMD

To: Todd Courtney

Recommendation: SE

Subject: K111010 S001

EV3 Spider FX

48

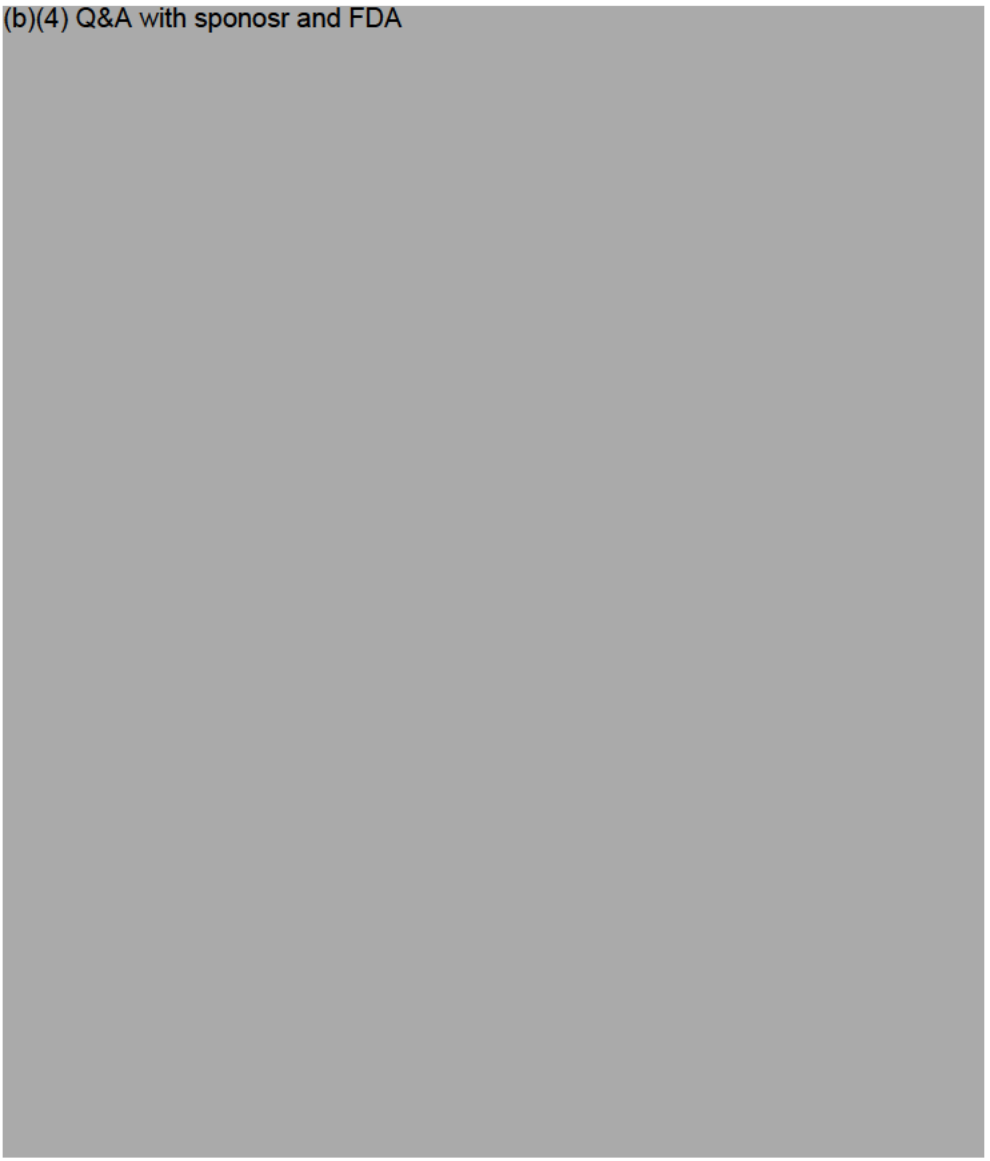
K110315 S001

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

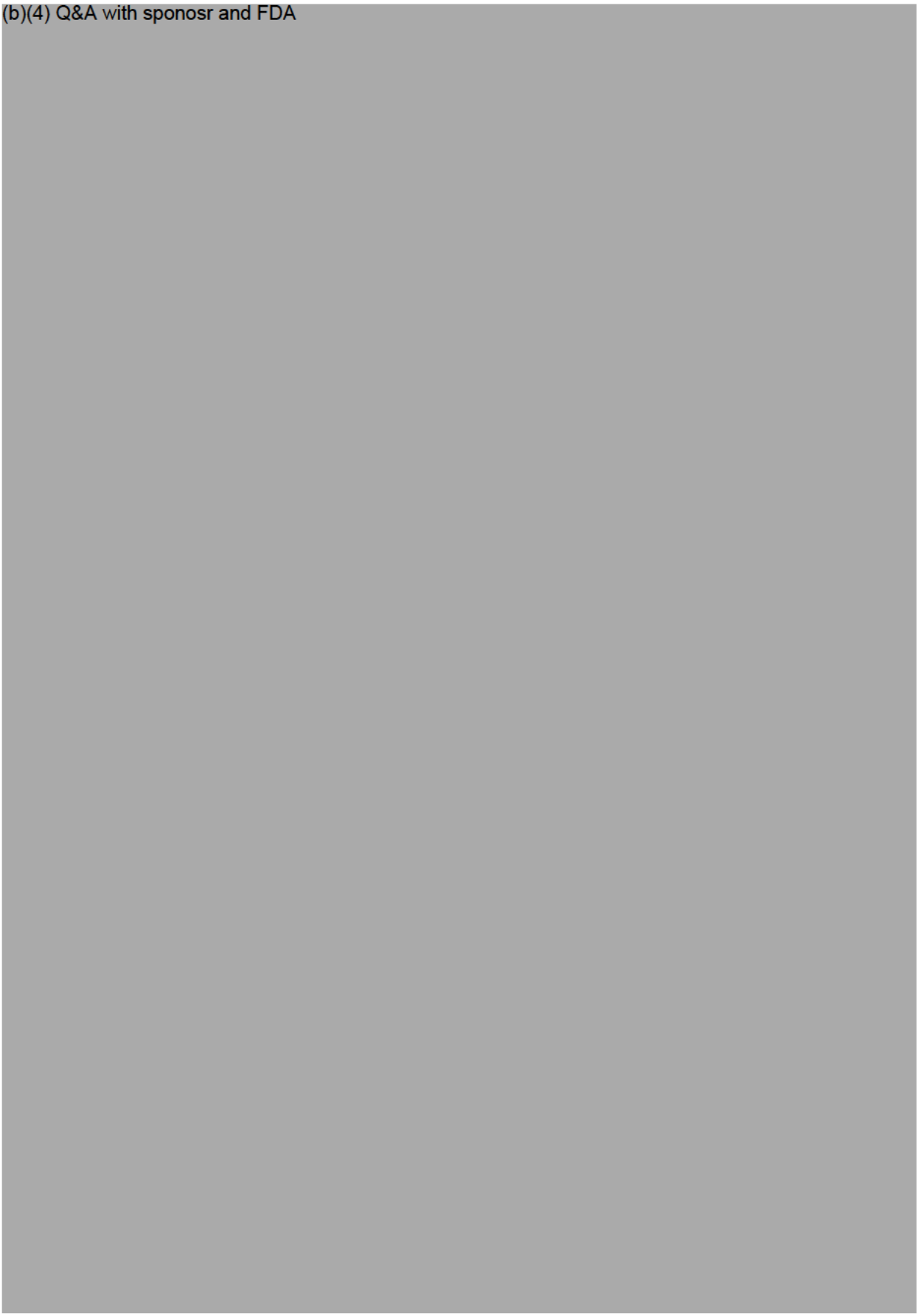
Animal Studies

(b)(4) Q&A with sponosr and FDA



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

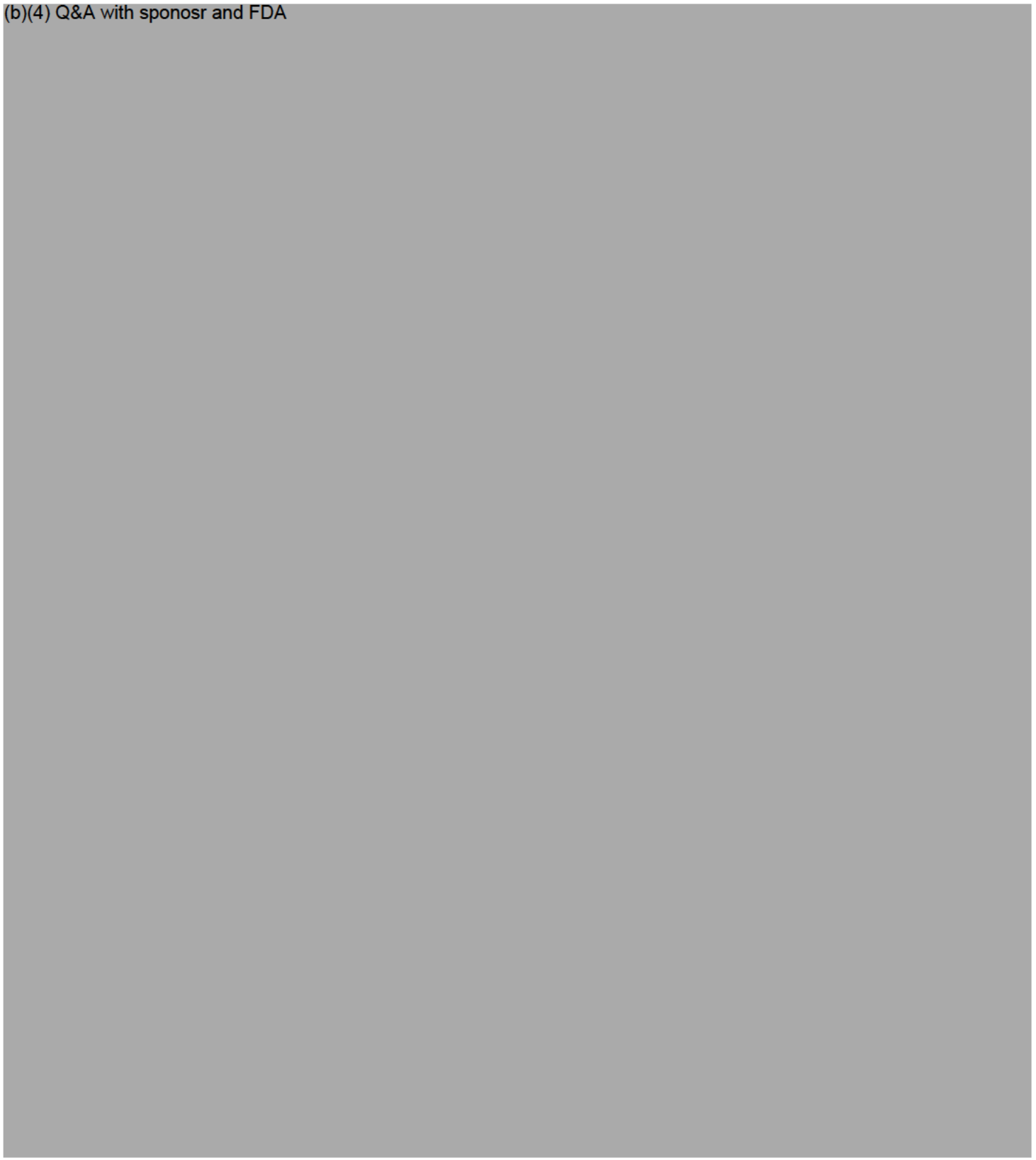
Records processed under FOIA request 2017-9992; Released on 1/29/2019



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

(b)(4) Q&A with sponosr and FDA



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b)(4) Q&A with sponosr and FDA



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Fife, Elizabeth *

From: Microsoft Exchange
To: 'brenda.johnson@ev3.net'
Sent: Tuesday, October 04, 2011 11:45 AM
ubject: Relayed: K111010 Additional Information Received

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'brenda.johnson@ev3.net'

Subject: K111010 Additional Information Received

Sent by Microsoft Exchange Server 2007

53

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Nichols, Karl *

From: Microsoft Exchange
To: 'brenda.johnson@ev3.net'
Sent: Wednesday, September 14, 2011 3:31 PM
Subject: Relayed: K111010- Extension Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'brenda.johnson@ev3.net'

Subject: K111010- Extension Letter

Sent by Microsoft Exchange Server 2007

55

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Fife, Elizabeth *

From: Microsoft Exchange
To: 'bjohnson@ev3.net'
Sent: Thursday, August 18, 2011 11:16 AM
ıbject: Relayed: K111010 Holding

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'bjohnson@ev3.net'

Subject: K111010 Holding

Sent by Microsoft Exchange Server 2007

59

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Todd Courtney

Subject: 510(k) Number K111010

To: The Record

Please list CTS decision code AJ

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)

☒ Hold (Additional Information or Telephone Hold).

☐ Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	*Attach IFU*		
510(k) Summary /510(k) Statement	*Attach Summary*		
Truthful and Accurate Statement.	*Must be present for a Final Decision*		
Is the device Class III? If yes, does firm include Class III Summary?	*Must be present for a Final Decision*		
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)			
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, *Certification with Requirements of ClinicalTrials.gov Data Bank*? (If not, then applicant must be contacted to obtain completed form.)			
Does this device include an Animal Tissue Source?			
All Pediatric Patients age<=21			
Neonate/Newborn (Birth to 28 days)			
Infant (29 days -< 2 years old)			
Child (2 years -< 12 years old)			
Adolescent (12 years -< 18 years old)			
Transitional Adolescent A (18 - <21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Transitional Adolescent B (18 -<= 21, No special considerations compared to adults => 21 years old)

Nanotechnology

Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html) | Contact OC

Regulation Number	Class*	Product Code
870.1250	II	NTE

(*If unclassified, see 510(k) Staff)

Additional Product Codes: _____

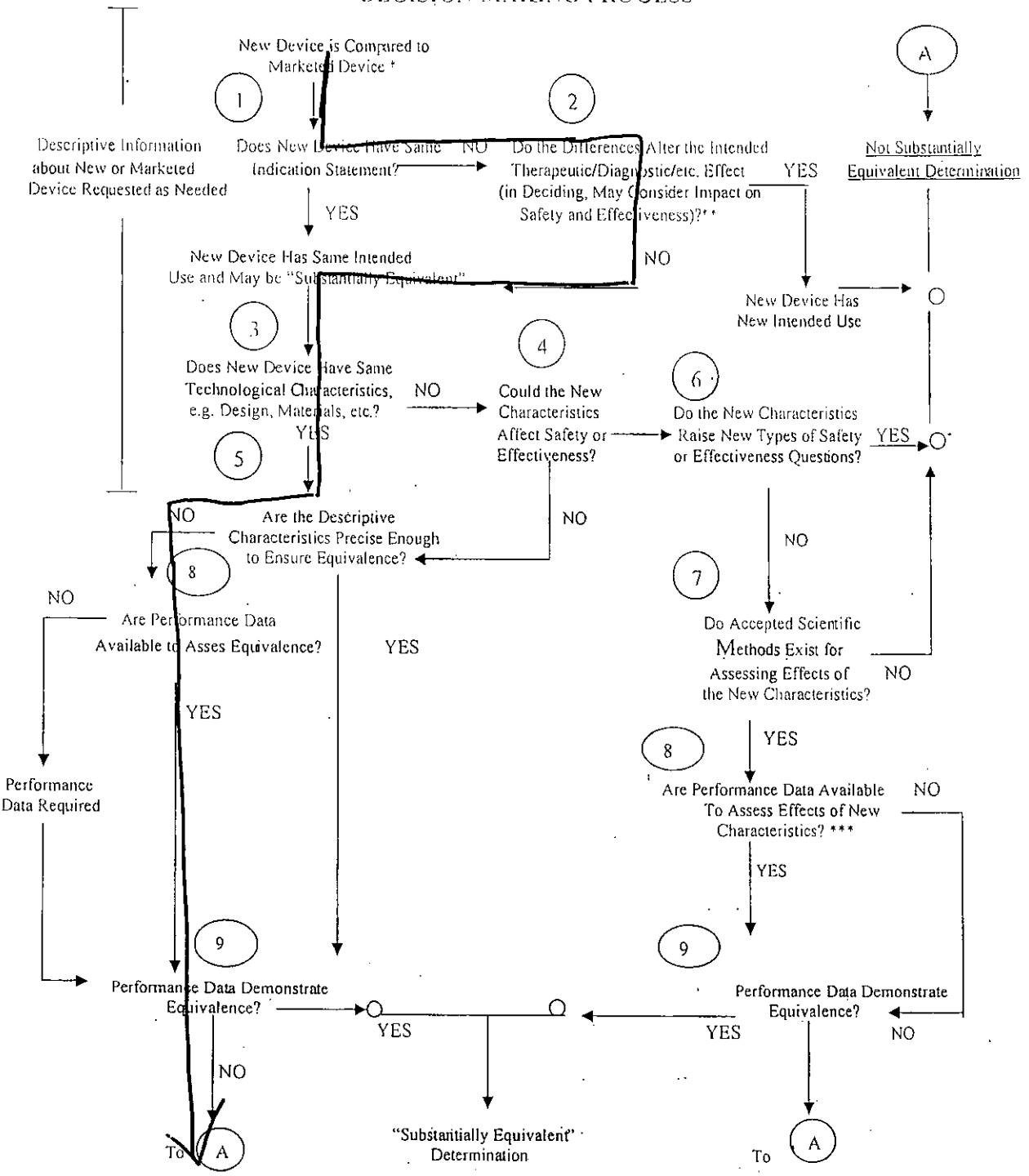
Review: _____ (Branch Chief) PVDB (Branch Code) 8/17/4 (Date)

Final Review: _____ (Division Director) (Date)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional/Abbreviated

K111010

Date: 06/01/2011
To: The Record
From: Todd Courtney

Office: ODE
Division: DCD

510(k) Holder: ev3
Device Name: SpiderFX Embolic Protection Device
Contact: Brenda Johnson
Phone: 763-398-7238
Fax: 763-591-3248
Email: bjohnson@ev3.net

I. Purpose and Submission Summary

ev3 would like to introduce the SpiderFX Embolic Protection Device into interstate commerce. The SpiderFX Embolic Protection Device is a percutaneously-delivered distal embolic protection device, designed to capture and remove dislodged debris during peripheral interventional procedures. The device is identical to the device that is marketed in the US for carotid (K063204) and saphenous vein graft (K063785) indications. Thus the sponsor leveraged pre-clinical testing from those submissions to support clearance of the device for the proposed indication. The sponsor also conducted a clinical study with the SpiderFX and TurboHawk atherectomy device. The sponsor is seeking an indication for embolic protection in the lower peripheral vasculature with any device. Since the study was specific to calcific lesions with the TurboHawk, the SpiderFX will be limited to use in those situations.

AI is the recommendation, as there are several deficiencies that need to be addressed.

II. Administrative Requirements

	Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	X		
Truthful and Accuracy Statement	X		
510(k) Summary or 510(k) Statement	X		
Standards Form	X		

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		X	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

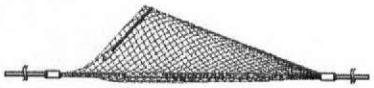
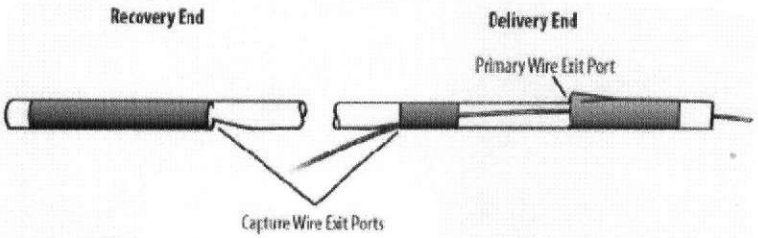
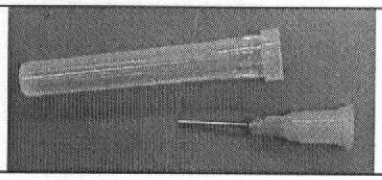
	Yes	No	N/A
Is the device an implant (implanted longer than 30 days)?		X	
Does the device design use software?		X	
Is the device sterile?	X		
Is the device reusable (not reprocessed single use)?		X	
Are "cleaning" instructions included for the end user?			X

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 12 - 3: SpiderFX System Components and Accessory

Component	Diagram
SpiderFX Capture Wire	
SpiderFX Catheter	
Blunt tip flushing needle accessory	

IV. Indications for Use

The SpiderFX has the following indications for use.

> The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material during revascularization procedures of arteries in the lower extremities. The diameter of the artery at the site of filter basket placement should be between 3.0 mm and 6.0 mm.

The SpiderFX device was investigated along with the TurboHawk atherectomy device in moderate or severely calcified lesions. The indications for use should state that the SpiderFX device is indicated for use alongside the TurboHawk in patients with moderate to severely calcified lesions.

V. Predicate Device Comparison

The predicate device has the following indications for use.

Indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0 mm and 7.0 mm.

Device Name	SpiderFX – K111010	SpiderFX – K063204	SpiderFX – K052659
Indication	Lower extremities	Carotid	Carotid
Indications for Use	The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material during revascularization procedures of arteries in the lower extremities. The diameter of the artery at the site of filter basket placement should be between 3.0 mm and 6.0 mm.	Indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0 mm and 7.0 mm.	

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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<table>
<tr><td>Device Name</td><td>SpiderFX – K111010</td><td colspan="2">SpiderFX – K063204</td><td>SpiderFX – K052659</td></tr>
<tr><td>Indicated Vessel Diameters</td><td>3.0 – 6.0 mm</td><td colspan="3">3.0 – 7.0 mm</td></tr>
<tr><td>System Components</td><td>SpiderFX Catheter
Capture Wire
Flushing Needle</td><td colspan="3">SpiderRX Catheter
Capture Wire</td></tr>
<tr><td>Guide (Sheath) Compatibility</td><td colspan="4">6F (5F) – min 0.066"</td></tr>
<tr><td>Guidewire Compatibility</td><td colspan="4">0.014" or 0.018"</td></tr>
<tr><td>Wire Exit Location</td><td colspan="4">22.5 cm (Primary Guidewire)
40 cm (Capture Guidewire)</td></tr>
<tr><td>Catheter Configuration</td><td colspan="4">Dual-ended Rapid Exchange
(Delivery End and Recovery End)</td></tr>
<tr><td>Catheter Delivery End Nominal Diameter</td><td colspan="4">(b) (4)</td></tr>
<tr><td>Catheter Recovery End Nominal Diameter</td><td colspan="4"></td></tr>
<tr><td>Catheter Materials</td><td colspan="4"></td></tr>
<tr><td>Capture Wire Lengths</td><td colspan="3">190 cm; 320 cm convertible to 190 cm</td><td>320 cm convertible to 190 cm</td></tr>
<tr><td>Filter Size</td><td colspan="2">5, 6, 7 mm</td><td colspan="2">3, 4, 5, 6, 7 mm</td></tr>
<tr><td>Recommended Vessel Size</td><td colspan="2"><table><tr><th>Filter Size (mm)</th><th>Target Vessel Size (mm)</th></tr><tr><td>5.0</td><td>3.0 – 4.0</td></tr><tr><td>6.0</td><td>3.5 – 5.0</td></tr><tr><td>7.0</td><td>4.5 – 6.0</td></tr></table></td><td colspan="2"><table><tr><th>Filter Size (mm)</th><th>Target Vessel Size (mm)</th></tr><tr><td>3.0</td><td>3.0</td></tr><tr><td>4.0</td><td>3.1 – 4.0</td></tr><tr><td>5.0</td><td>4.1 – 5.0</td></tr><tr><td>6.0</td><td>4.5 – 6.0</td></tr><tr><td>7.0</td><td>5.5 – 7.0</td></tr></table></td></tr>
<tr><td>Filter Materials</td><td colspan="4">(b) (4)</td></tr>
<tr><td>Filter Design</td><td colspan="4">Eccentric</td></tr>
<tr><td>Recommended Distance between Lesion and Filter</td><td colspan="3">2.0 cm</td><td>1.5 cm</td></tr>
</table>

VI. Labeling

The sponsor provided a copy of the proposed and predicate labeling. The warnings and contraindications are appropriate and consistent with those found in the predicate labeling.

With the exception of the issue with the indications for use detailed above, I have no concerns with the labeling.

VII. Sterilization/Shelf Life/Reuse

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The SpiderFX Device is provided to the user sterile and labeled for single use only. The device is not intended for sterilization or reprocessing by the user. The SpiderFX Device is sterilized using the identical ethylene oxide sterilization cycles as the currently marketed SpiderFX Device (K063204) and SpideRX Device (K052659).

The SpiderFX Device is ethylene oxide (EO) sterilized in a fixed chamber at Steris-Isomedix and meets a sterility assurance level (SAL) of 10^{-6}. Sterilization validation and associated revalidation activities are performed based on ISO 11135 Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization, using Method C: Half-cycle Method. Ethylene oxide sterilization residue levels post-aeration are in compliance with the ISO 10993-7:2008 standard. The sterility assurance level (SAL) is 10^{-6}.

The packaging for the proposed device is identical to the packaging from the previously cleared version of the same device and the test data of the predicate devices is applicable to this version of SpiderFX.

The SpiderFX Device has the identical two-year shelf life as its predicate devices, SpiderFX (K063204, K063785) and SpideRX (K052659, K053195). No further shelf life testing was needed to support the peripheral indication.

As the device is identical to an already marketed device and the sterilization, packaging and shelf-life have not changed, I have no concerns with the sterilization, packaging, or shelf-life.

VIII. Biocompatibility

The device materials in the proposed SpiderFX Device are identical to the materials in the commercially available SpideRX Device (K052659) and SpiderFX Device (K063204). Therefore, no new biocompatibility testing was performed.

I have no concerns with the lack of additional biocompatibility testing.

IX. Software

Not applicable

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable

XI. Performance Testing – Bench

(b) (4)

[redacted]

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In section 11 of the submission, the sponsor provided a summary of the bench testing that was leveraged to support clearance of this device. This testing is shown below and can be found in the following submissions: G080017, G080025, G030115, G020248, K052659, K053195, K063204, K063786, and K070540 (NSE'd). All of the data shown below was reviewed in either K052659 or K063204.

The sponsor conducted the following tests on the device:

(b) (4)

The following testing was leveraged from the predicate SpiderFX® and SpideRX® Embolic Protection Device submissions. Test results met the specified acceptance criteria and were included in K063204 or K052659:

(b) (4)

References to Previous FDA reviews: Testing Recommended in FDA Guidance Document - Use with PTA Catheters and Stents

Test	Submission where Data Reviewed
Embolic Capture Efficiency and Retrieval Ability	K063204
Stent Compatibility	K063204
Simulated Use	K063204
Deployment/ Retrieval Forces	K063204
Filter Capacity	K052659
Resistance to Filter Rupture During Removal of a Fully-Loaded Filter	K063204
Flow Characteristics	K052659
Radial Outward Force	K063204
Tip Flexibility- Catheter	K052659
Tip Flexibility- Wire	K052659
Tensile Strength – Catheter	K052659
Torque Strength - Catheter	K052659

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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References to Previous FDA reviews: Testing Recommended in FDA Guidance Document - Use with PTA Catheters and Stents

Test	Submission where Data Reviewed
Torque Strength - Wire	K063204
Torque Response - Catheter	K052659
Torque Response - Wire	K063204
Kin Resistance - Catheter	K052659
Dimensional Verification	K063204
Packaging Visual Inspection	K063204
Heparin Coating Durability	K052659
Heparin Activity	K063204
Wire Bias	K063204

Testing to Support the Revised Sizing Matrix and Interventions with Atherectomy, Laser, and Thrombectomy Devices

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA request 2017-9992; Released on 1/29/2019

Testing to Support the Revised Sizing Matrix and Interventions with Atherectomy, Laser, and Thrombectomy Devices

Test Name/Qty:	Acceptance Criteria:	Test Results:
(b) (4)		

I have no concerns with the sponsor leveraging testing from previous clearances of the device for the carotid and saphenous vein graft indications. I also have no concerns with the testing conducted to support the revised sizing matrix and interventions with atherectomy, laser, and thrombectomy devices.

XII. Performance Testing – Animal

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

[redacted]

XIII. Performance Testing – Clinical

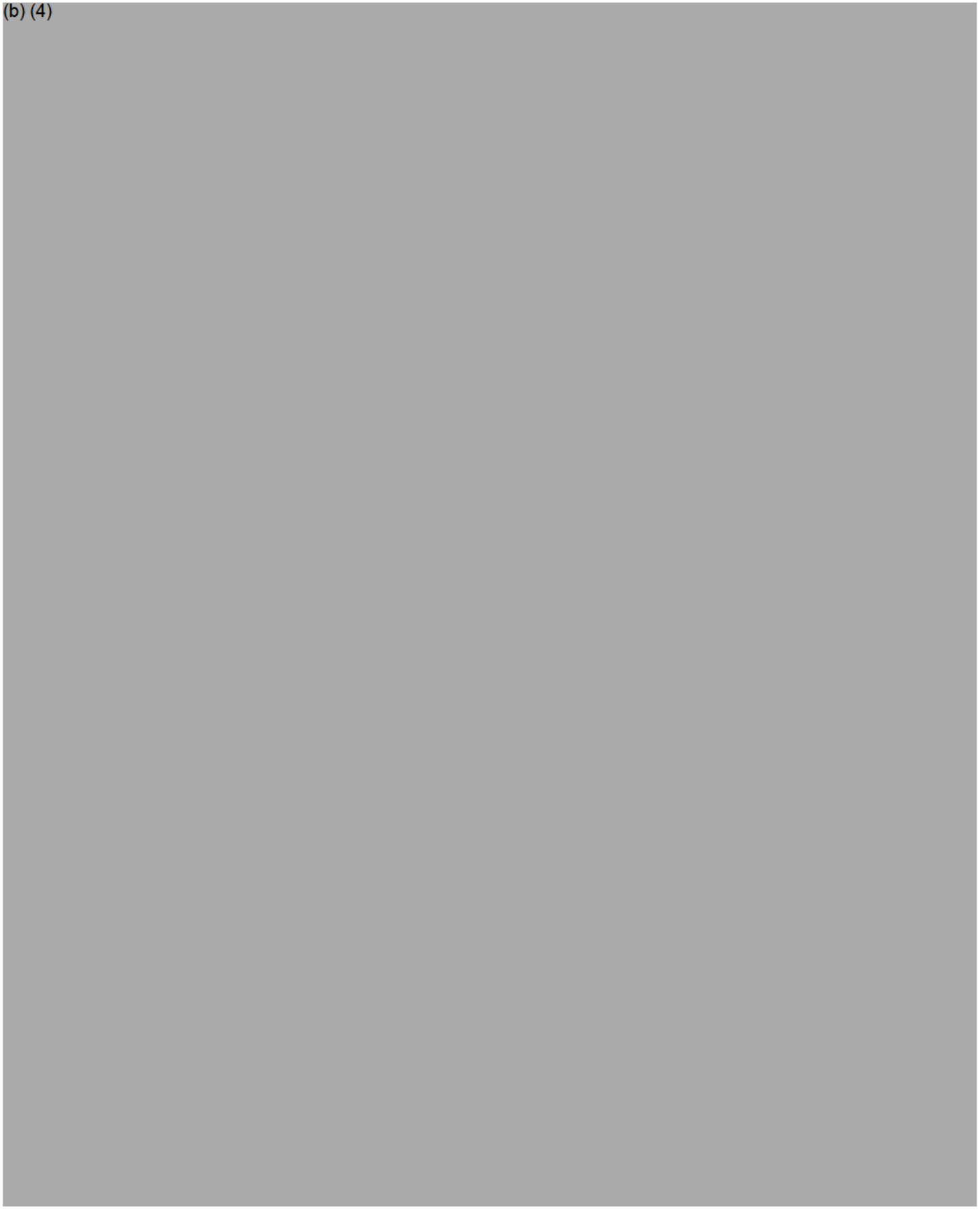
(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)



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(b) (4)



XIV. Substantial Equivalence Discussion

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	Yes	No	
1. Same Indication Statement?		N	If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		N	If **YES** = Stop **NSE**
3. Same Technological Characteristics?	Y		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		N	If **NO** = Go To 8 If **YES** = Stop **SE**
6. New Types Of Safety Or Effectiveness Questions?			If **YES** = Stop **NSE**
7. Accepted Scientific Methods Exist?			If **NO** = Stop **NSE**
8. Performance Data Available?	Y		If **NO** = Request Data
9. Data Demonstrate Equivalence?		N	Final Decision: AI

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1) Explain how the new indication differs from the predicate device's indication:

   The sponsor is proposing expanding the indications for use to the peripheral vasculature.

2) Explain why there is or is not a new effect or safety or effectiveness issue:

   The SpiderFx is the same device, only being used in the peripheral vasculature. The risks associated with use in the peripherals are less than the risks of use in the carotids, which the device is indicated for currently.

3) Describe the new technological characteristics:

4) Explain how new characteristics could or could not affect safety or effectiveness:

5) Explain how descriptive characteristics are not precise enough:

   The sponsor provided a limited device description. Performance and clinical data are needed to demonstrate substantial equivalence.

6) Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:

7) Explain why existing scientific methods can not be used:

8) Explain what performance data is needed:

9) Explain how the performance data demonstrates that the device is or is not substantially equivalent:

   There are deficiencies remaining that need to be addressed. See below.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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XV. Deficiencies

(b) (4)

Animal Studies

(b) (4)

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(b) (4)

Labeling

(b) (4)

XVI. Contact History

None

XVII. Recommendation

Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: NTE

Recommendation: AI

Reviewer

8-17-2011
Date

Branch Chief

17 AUG 11.
Date

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Animal Study Review Memo

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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FDA U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Veterinary Consultation Memorandum

From: Victoria Hampshire, VMD

To: Todd Courtney

Date: 5-19-2011

Subject: K110010 Spider FX with Silver Hawk or PTA

Recommendation: AI

Summary rationale:

- ☐ **The testing for capture efficiency is not persuasively SE for the reasons cited in the deficiency 3 below.**
- ☐ **It is not clear that acceptance criteria for filter damage included inspection of the actual filter or that the lack of simulated use of the clinically relevant device with cutters in use is a reasonable test of device damage by the Silver Hawk**
- ☐ **It is not clear that the methods of pathological assessment included a review of vascular damage along the path between the filter and the fully retracted Silver Hawk**
- ☐ **There is no mention of whether the animals on the chronic study were reasonably assessed in life for pain or gait abnormalities. There is no contributing veterinary scientist report.**

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

[redacted]

Veterinary Review

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Clinical Review Memo

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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From:	Steven S. Brooks Medical Officer, ODE PVDB
To:	Todd Courtney Scientific Reviewer, ODE PVDB
Cc:	Kenneth Cavanaugh Division Chief, ODE PVDB
Subject:	K111010 SpiderFX Embolic Protection Device, Peripheral Indication ev3 Endovascular Inc.
Date:	May 27, 2011

Recommendation:
I recommend an Additional Information letter.

Background:
The basis for this submission is a modified indication for a legally marketed device. The legally marketed predicate devices are the SpiderFX Embolic Protection Device (K063204) and the SpideRX Embolic Protection Device (K052659).

(b) (4)

[redacted]

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(b) (4)

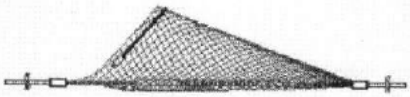
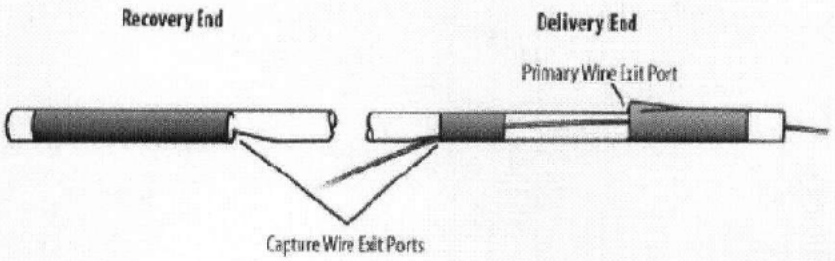
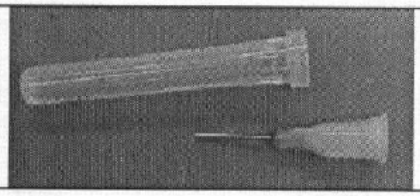


Device Description:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 12 - 3: SpiderFX System Components and Accessory

Component	Diagram
SpiderFX Capture Wire	
SpiderFX Catheter	
Blunt tip flushing needle accessory	

The proposed SpiderFX Device uses the identical design as the currently marketed SpiderFX Device (K063204). There are no design changes for this device.

Indications For Use:

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material during revascularization procedures of arteries in the lower extremities. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 6.0mm.

(b) (4)

[redacted]

Intended Use:

Percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The device Capture Wire is used as the 0.014" wire for interventional device delivery.

Revised Sizing Matrix and Compatibility with Atherectomy, Thrombectomy, and Laser Devices:

To support the addition of atherectomy, thrombectomy, and laser devices and the revised sizing matrix, testing was completed to evaluate whether the SpiderFX Device performed as intended when used with worst-case atherectomy devices in

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peripheral vessels with the revised sizing matrix. A Design/Interface FMECA was completed to identify the bench and animal testing that was necessary to demonstrate compatibility between the worst-case atherectomy devices and the SpiderFX Device. Several of the identified bench tests required development of new testing models.

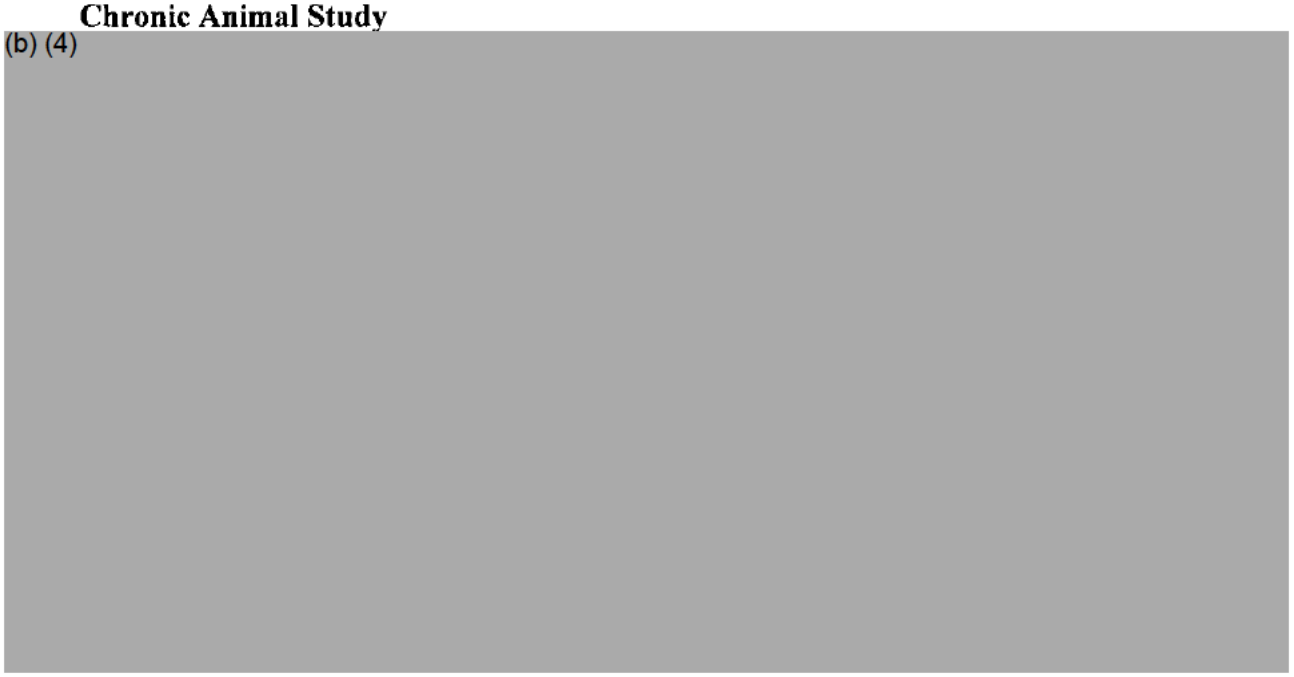
Acute Animal Study

(b) (4)



Chronic Animal Study

(b) (4)



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(b) (4)



Performance Testing - Clinical

(b) (4)



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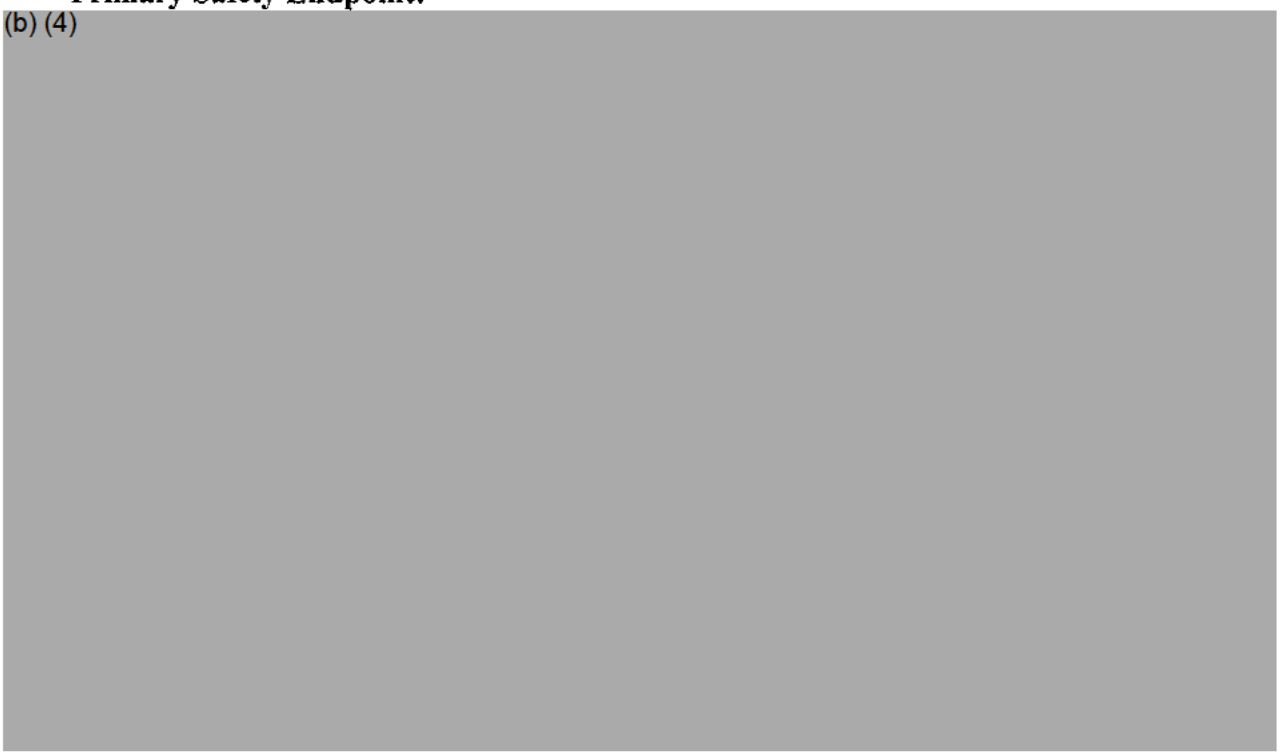
Records processed under FOIA request 2017-9992; Released on 1/29/2019

(b) (4)



Primary Safety Endpoint:

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

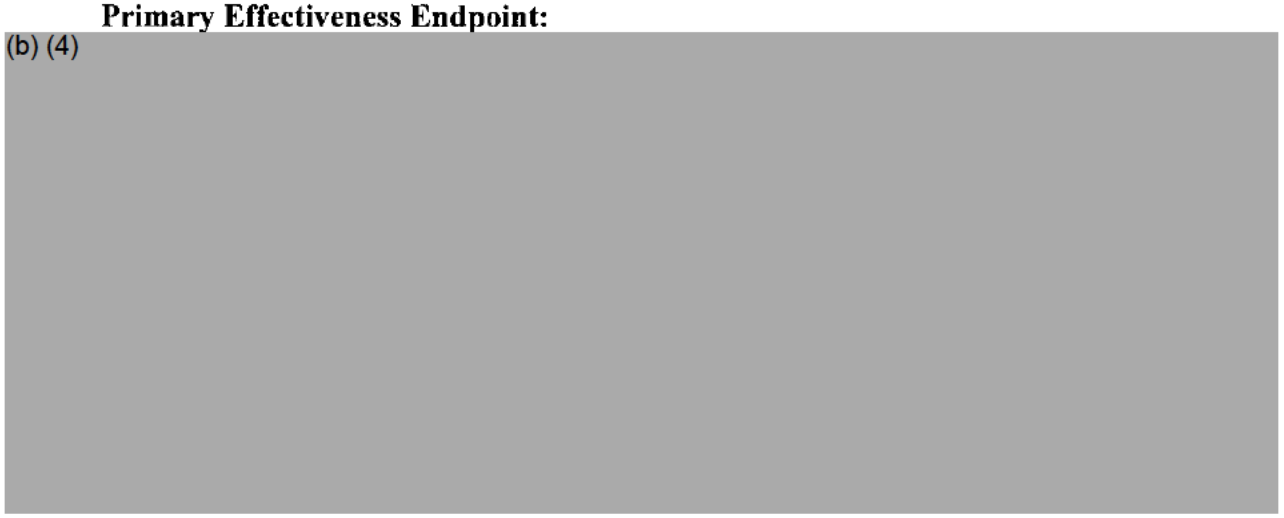
Records processed under FOIA request 2017-9992; Released on 1/29/2019

(b) (4)



Primary Effectiveness Endpoint:

(b) (4)



Secondary Endpoints:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

[redacted]

Inclusion Criteria

(b) (4)

[redacted]

Exclusion Criteria

(b) (4)

[redacted]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)



Follow-up:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 2: Study Assessments

(b) (4)

Results:

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

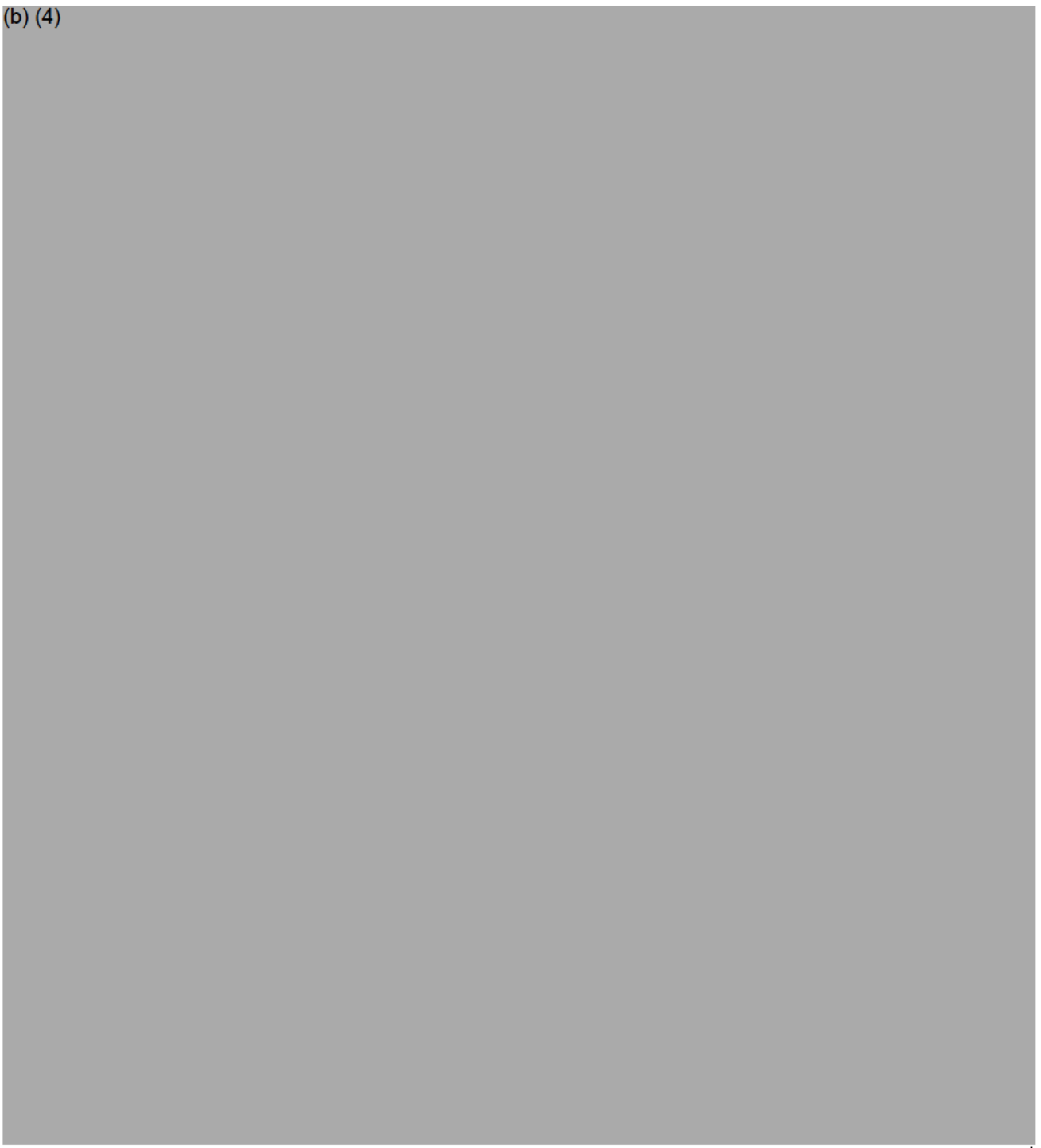
Demographics:

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)



Compliance:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 4: 30-Day Follow-Up Compliance

(b) (4)

[redacted]

Findings:

(b) (4)

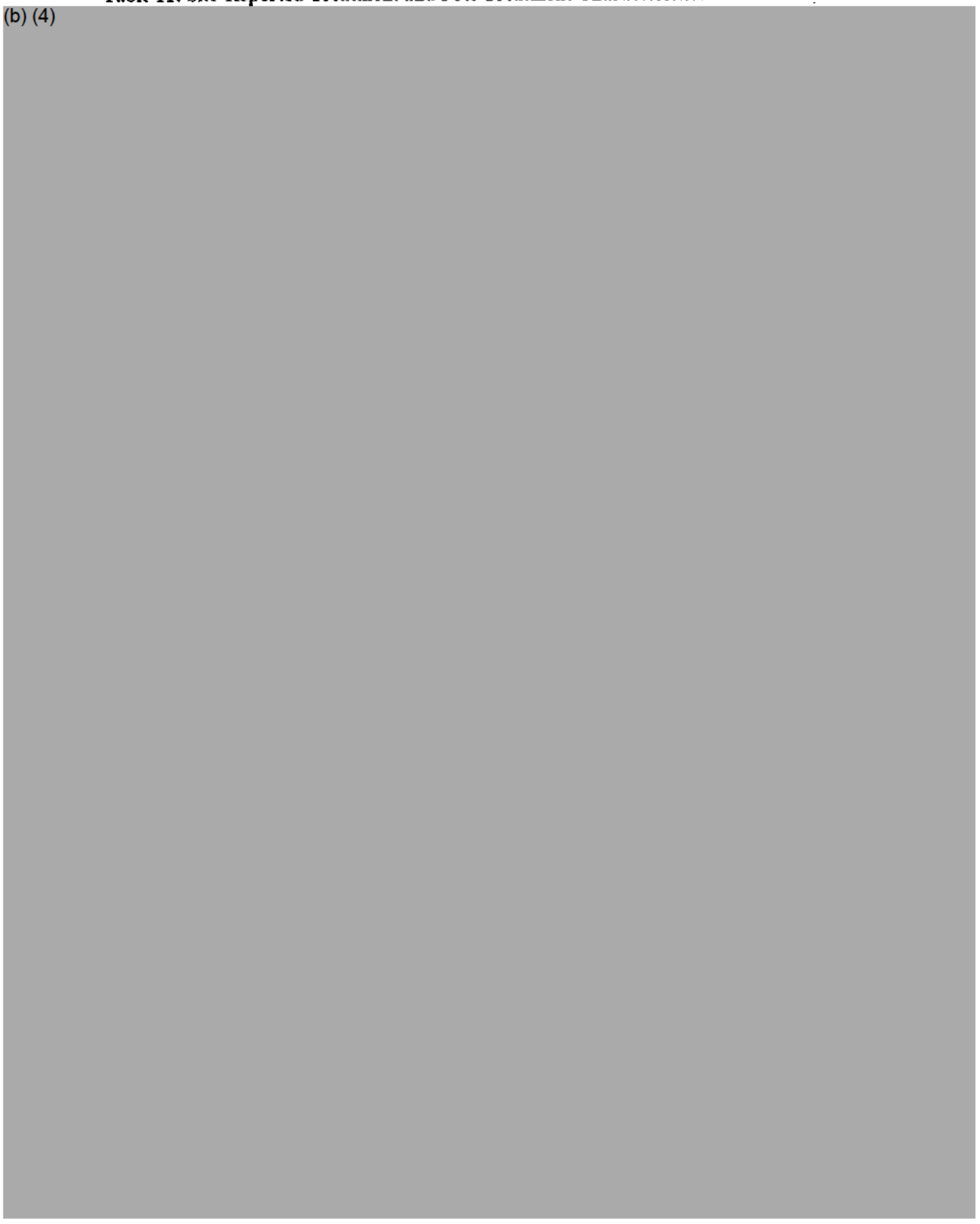
[redacted]

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Table 11: Site-Reported Treatment and Post-Treatment Characteristics

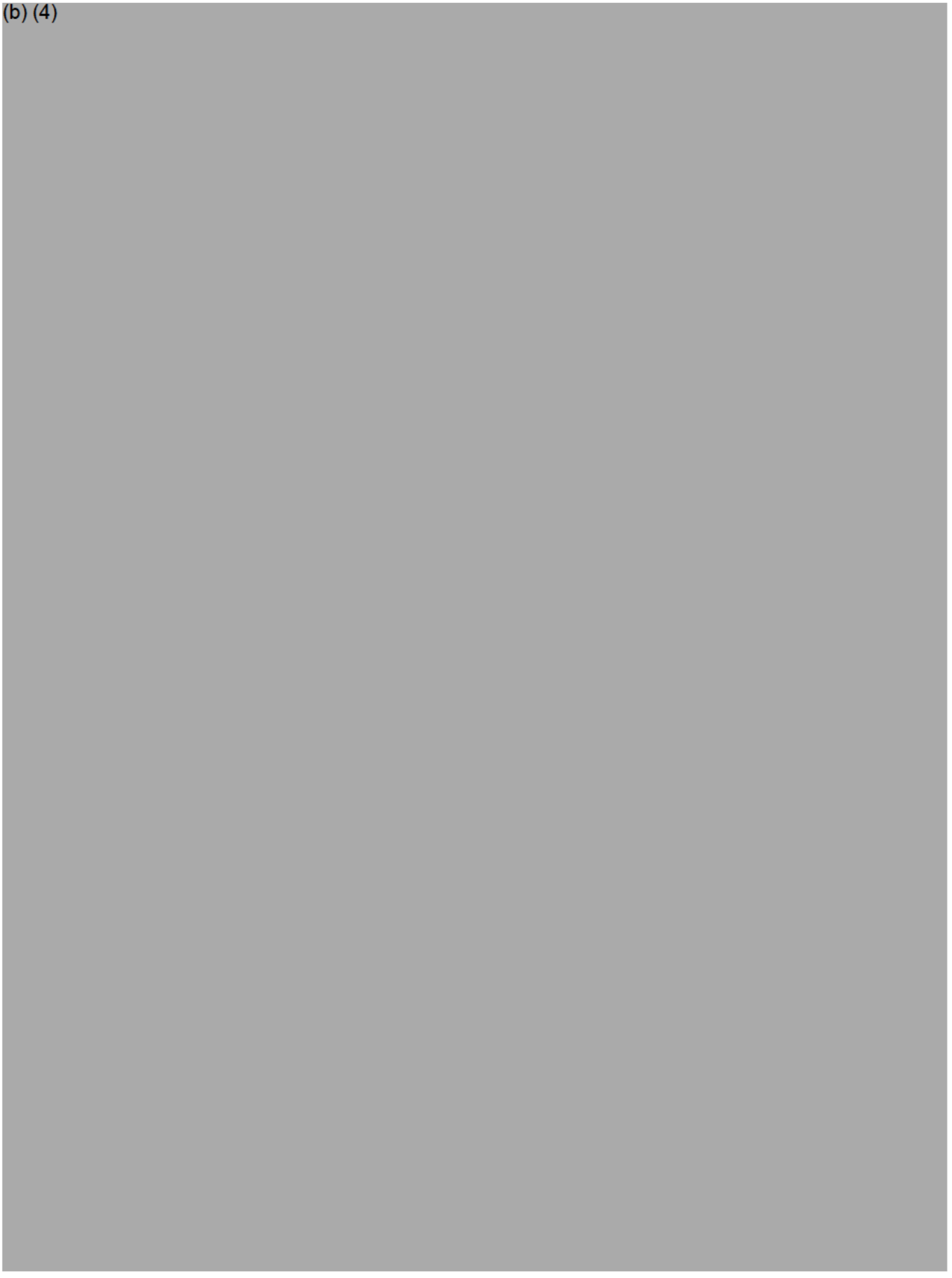
(b) (4)



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(b) (4)



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Table 14: Pre-Procedure and Post-Procedure Run-Off

(b) (4)

Primary Safety Endpoint

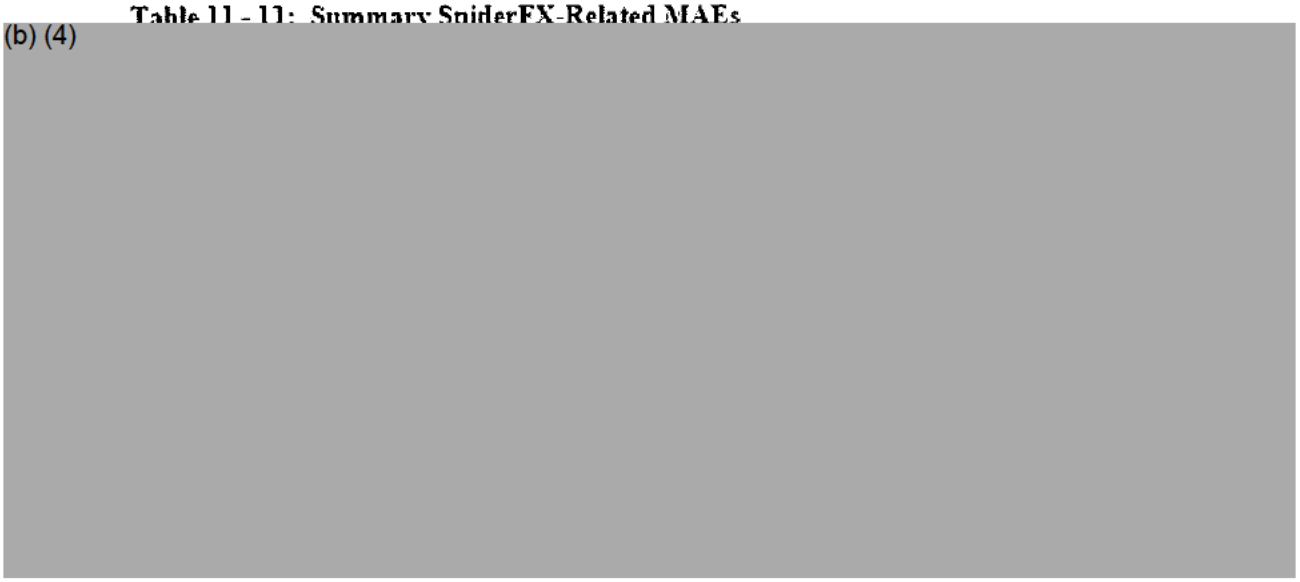
(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 11 - 11: Summary SpiderFX-Related MAEs

(b) (4)



Primary Effectiveness Endpoint

(b) (4)



Secondary Endpoints

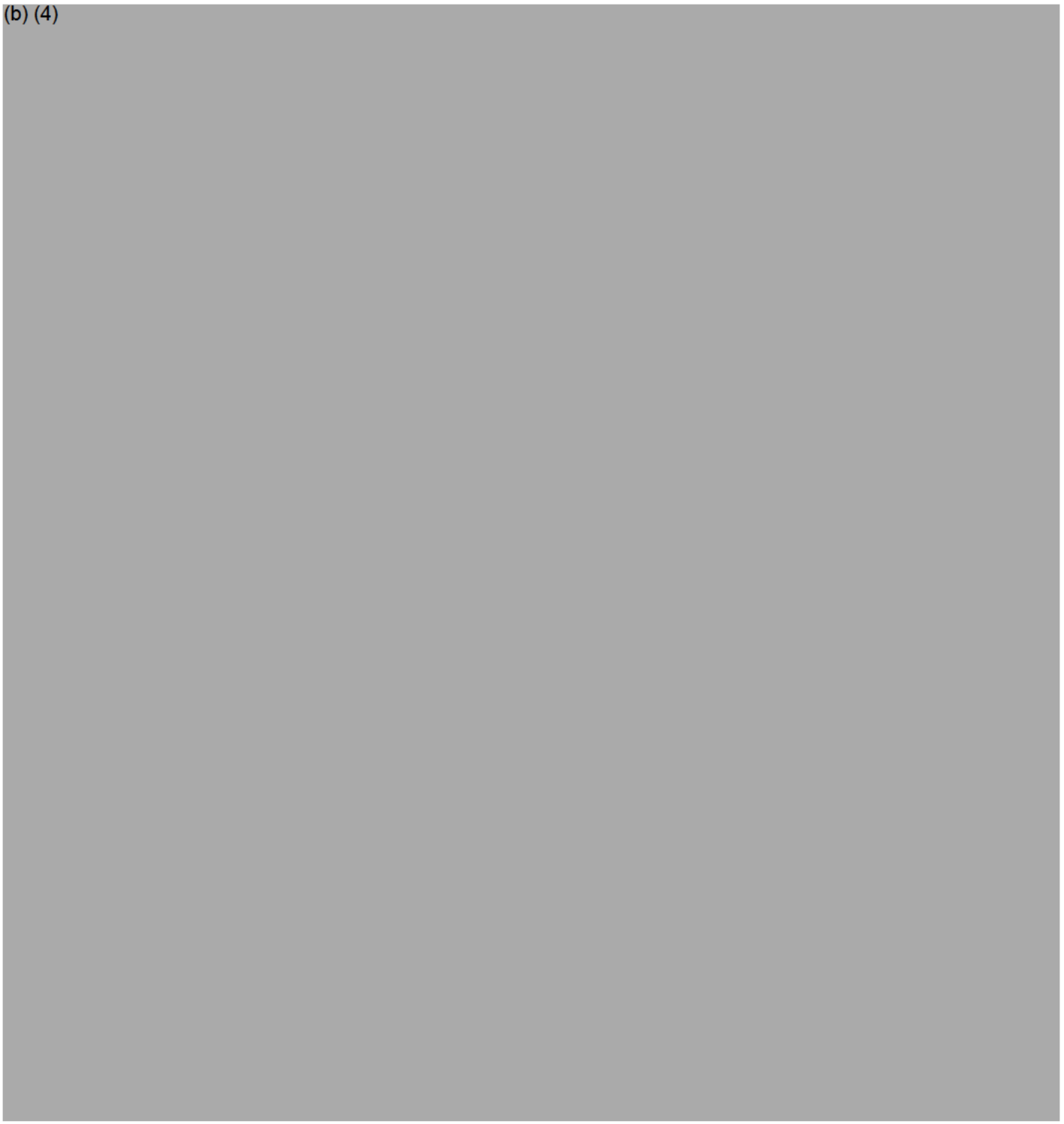
(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)



Adverse Events:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Table 22: Summary of Device and Procedure-Related Adverse Events

(b) (4)

Supplemental Statistical Analyses:

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

Discussion: (b) (4)

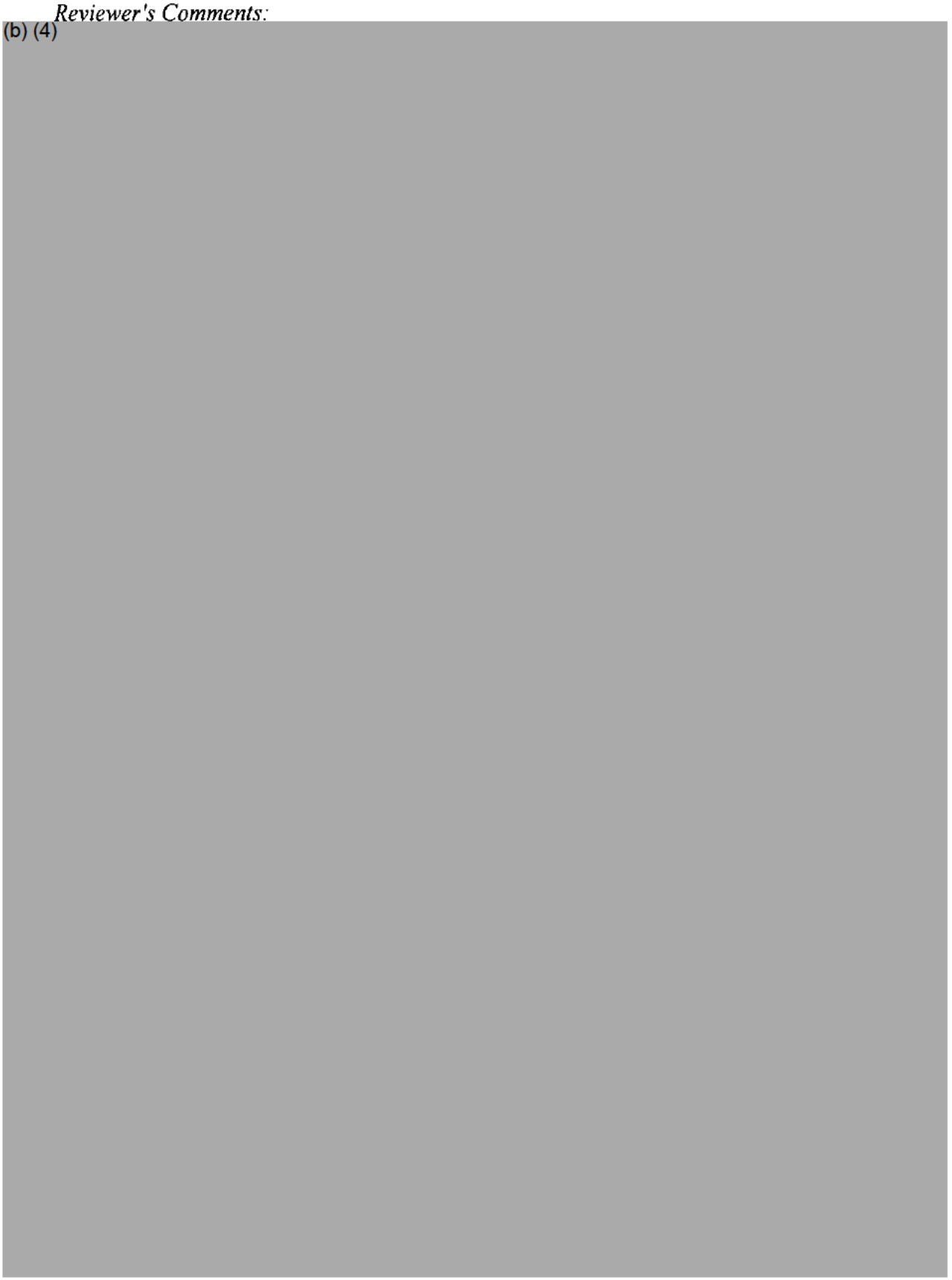
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Reviewer's Comments:

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

Substantial Equivalence:

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)

Reviewer's Comments:

(b) (4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)



Labeling:

(b) (4)



510k Summary:

(b) (4)

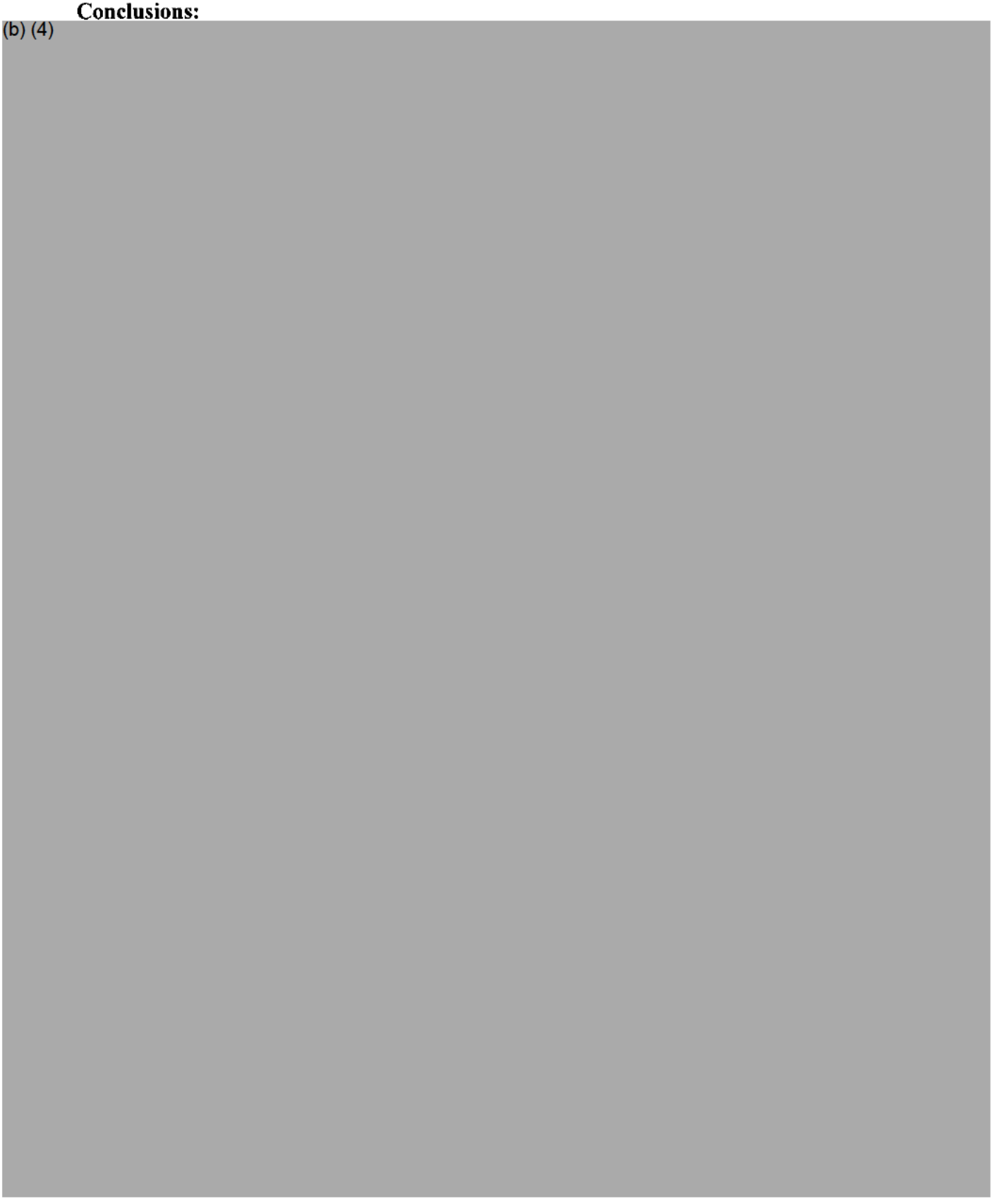


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Conclusions:

(b) (4)



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(b) (4)

Deficiencies:

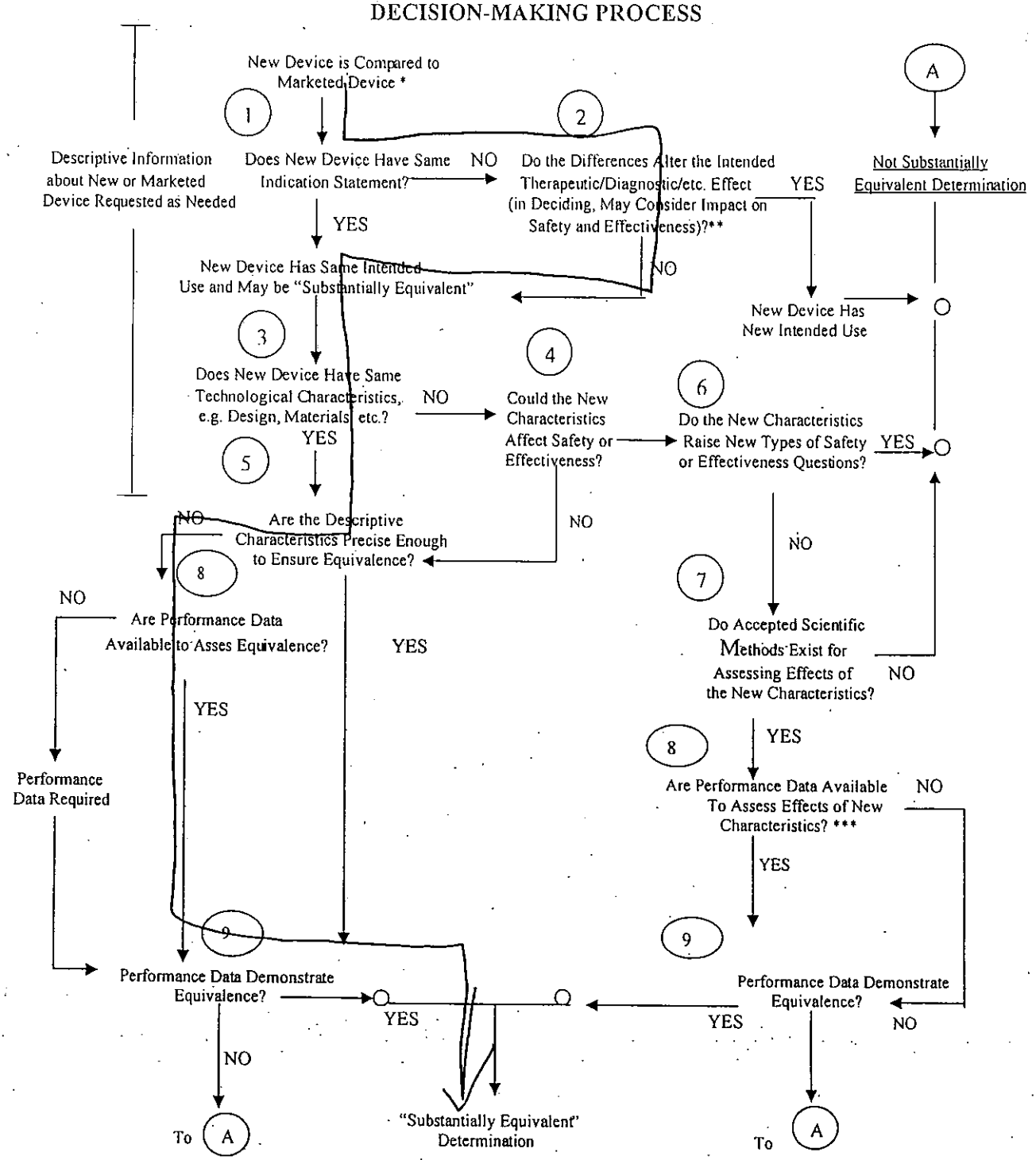
(b) (4)

Steven S. Brooks, MD
Medical Officer ODE DCD

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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K111010/S1
CV/DCD

ev3 Your endovascular company.

FDA CDRH DMC
OCT 3 2011
K55

September 30, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Contents: One paper copy
One eCopy – exact duplicate of paper copy

RE: K111010, SpiderFX Embolic Protection Device
Response to Deficiencies

To Whom It May Concern:

ev3 is supplying the enclosed information as a supplement to **K111010**. This supplement is provided in response to questions received in a letter from FDA dated August 17, 2011. A copy of the letter from FDA is provided in **Attachment A**. The following pages include the FDA questions, followed by the ev3 response.

This submission contains trade secret and confidential commercial information that should be protected in accordance with 21CFR Part 20 and 807.95. If additional information is required, please contact me. My contact information is provided below.

Sincerely,

Brenda Johnson
Principal Regulatory Affairs Specialist
E-mail: brenda.johnson@ev3.net
Phone: 763-398-7238
Fax: 763-591-3248

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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September 30, 2011

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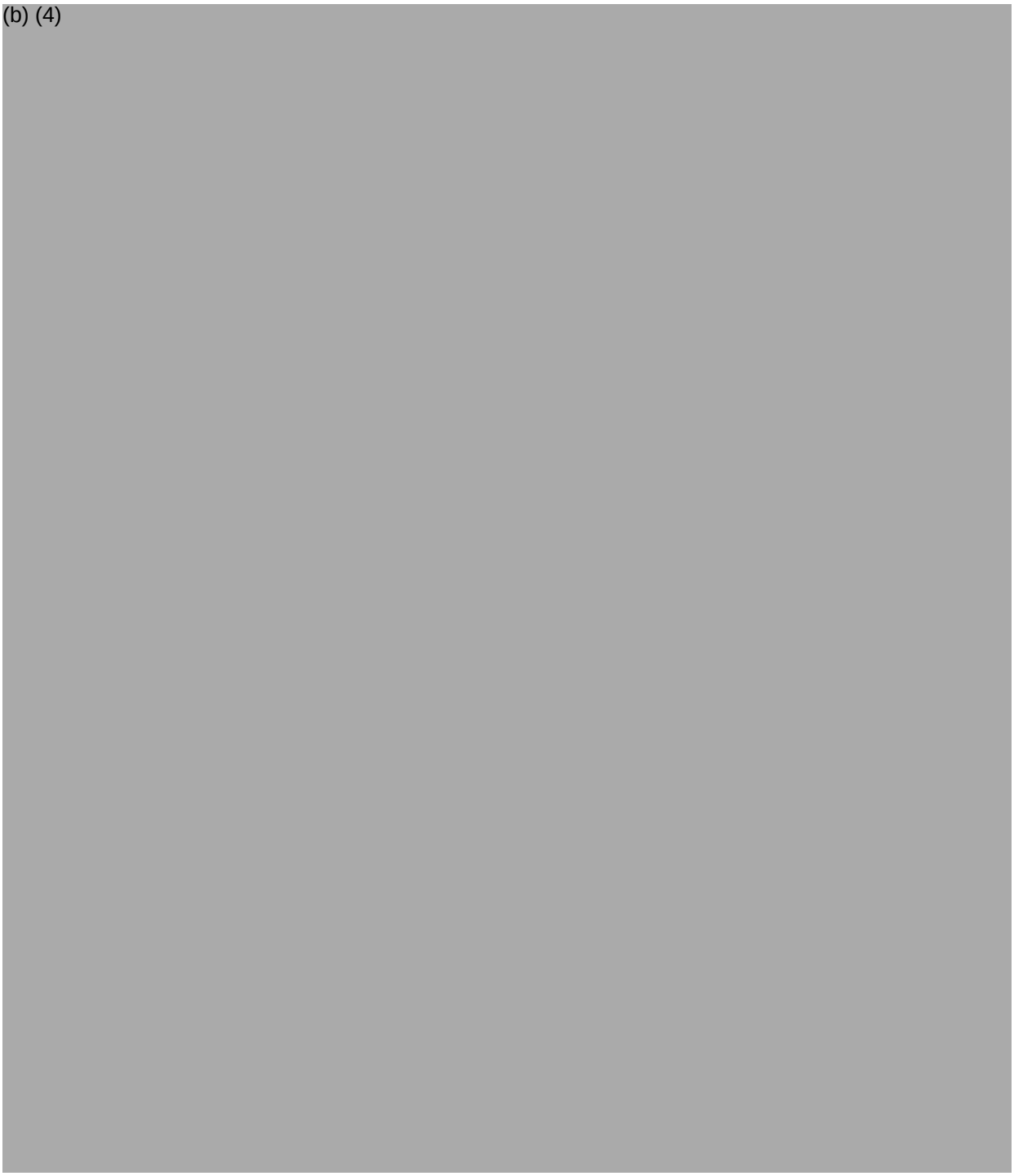
Brenda Johnson
Principal Regulatory Affairs Specialist
E-mail: brenda.johnson@ev3.net
Phone: 763-398-7238
Fax: 763-591-3248

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Animal Studies

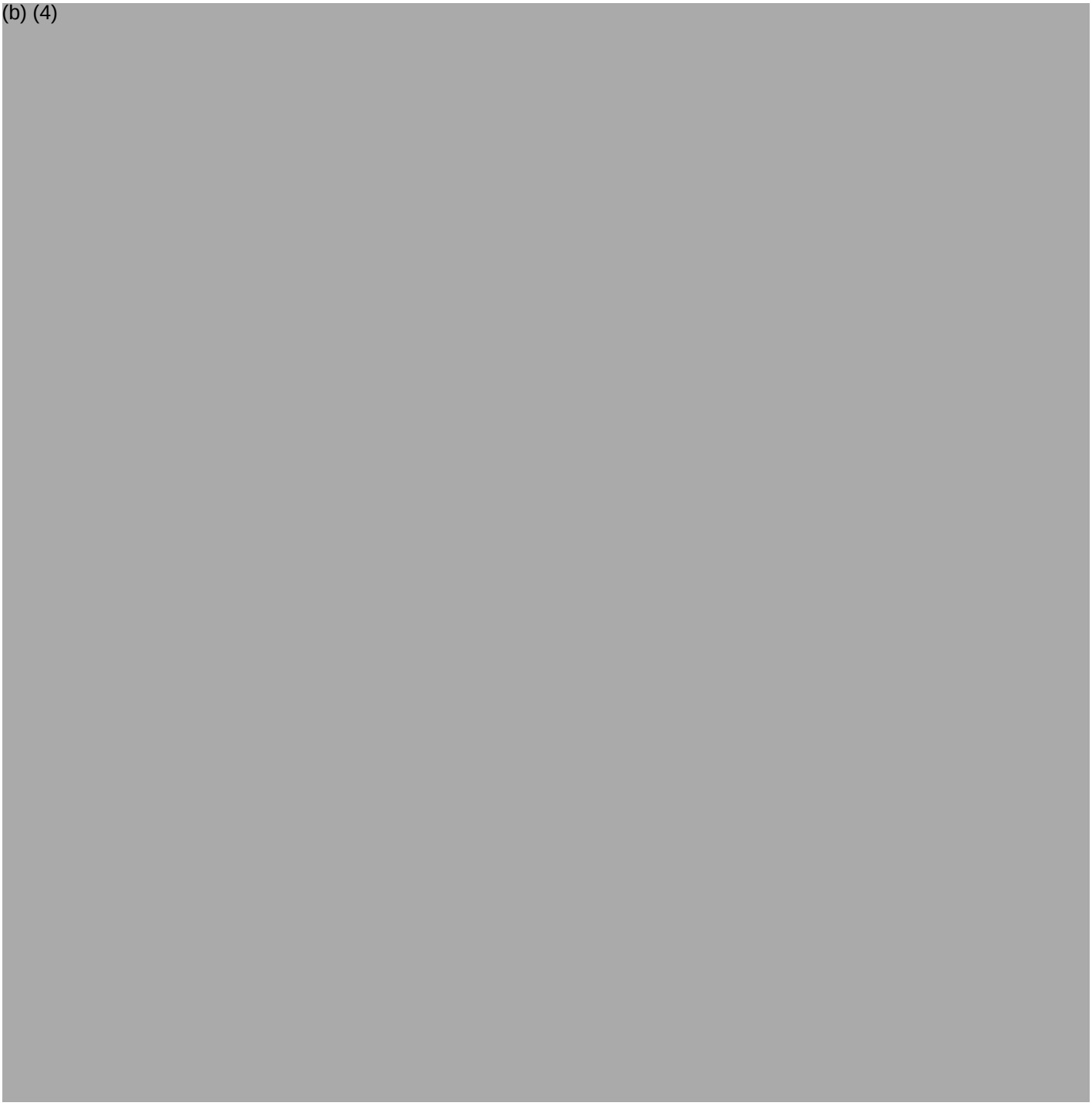
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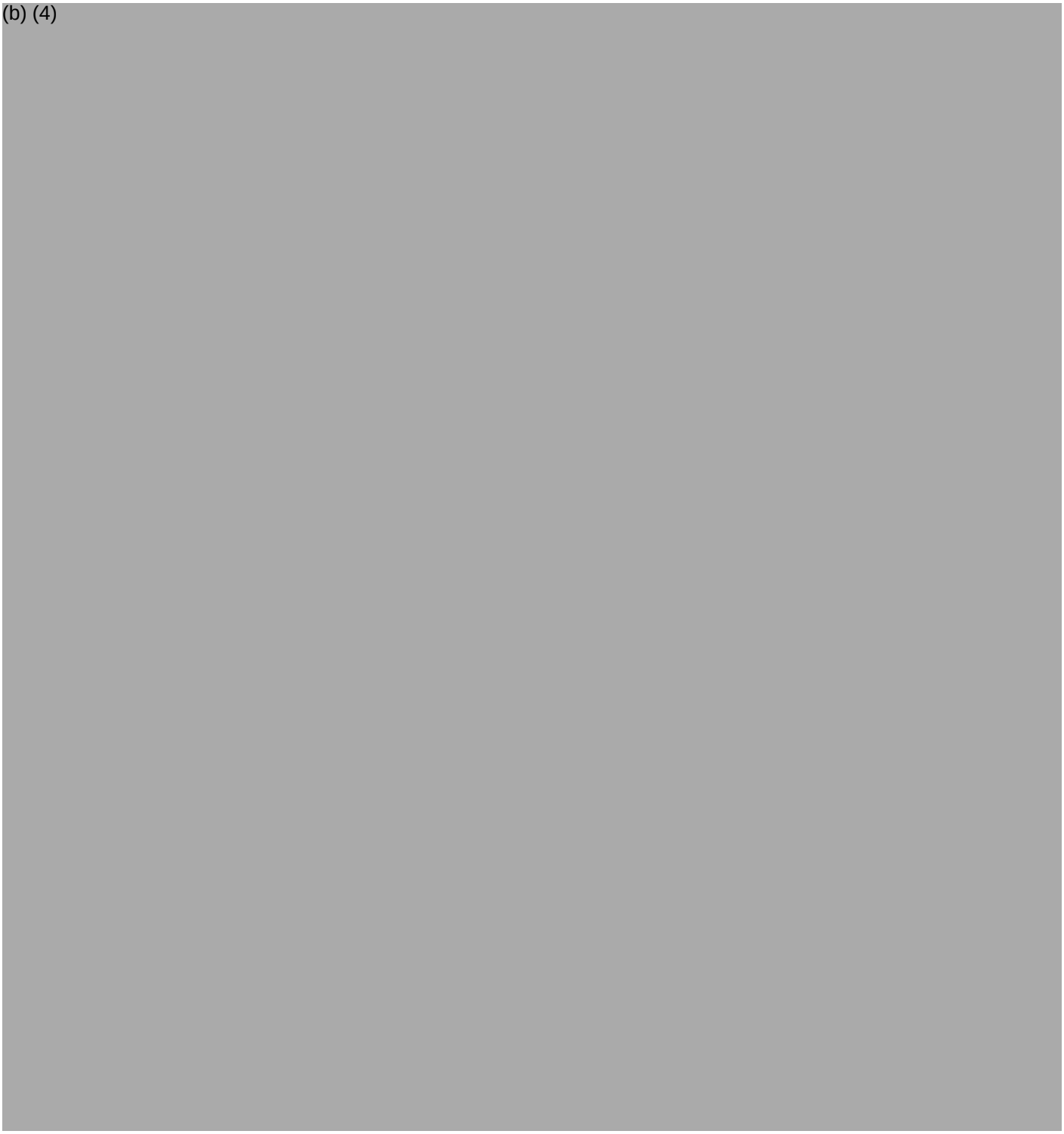
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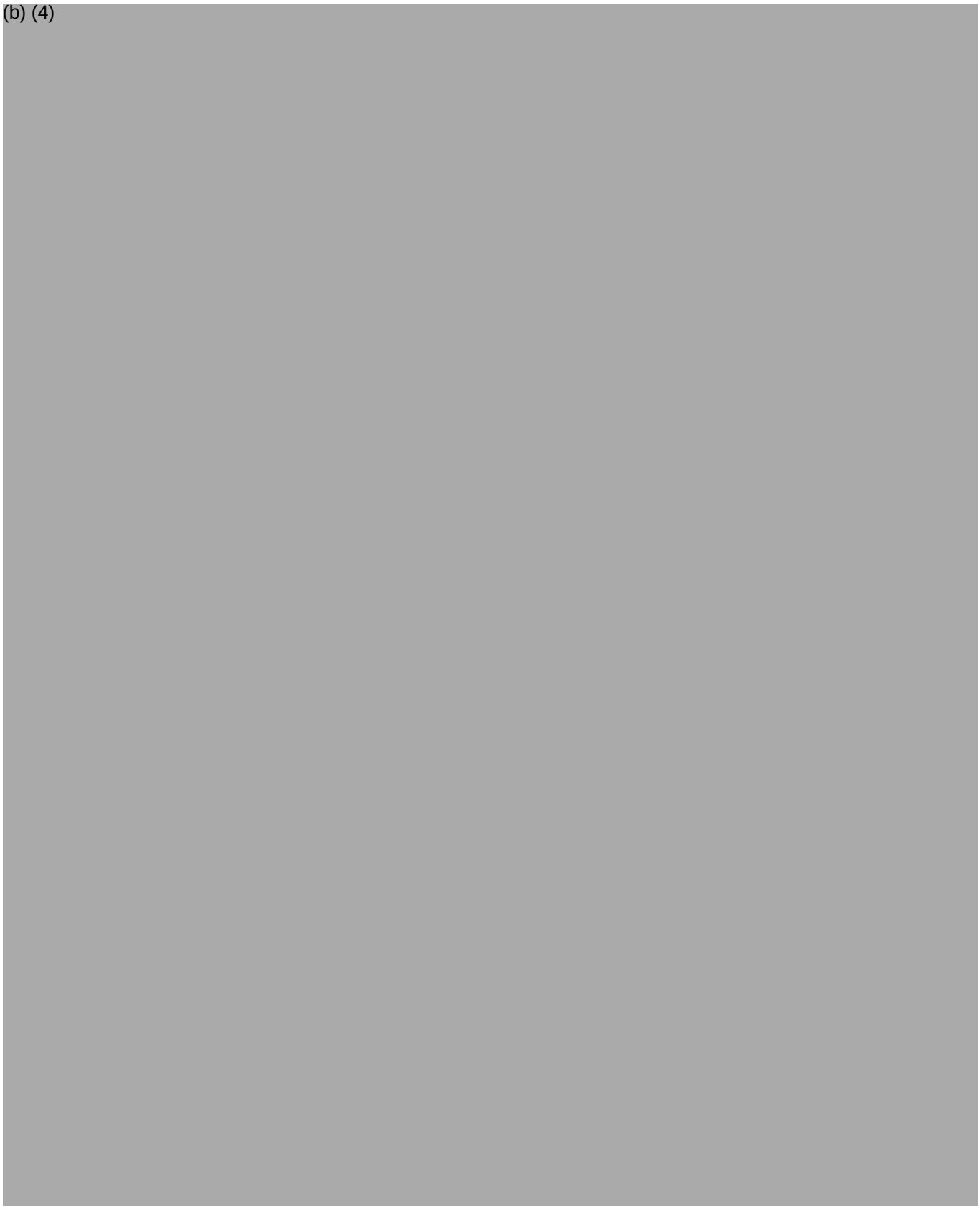
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(b) (4)



Labeling

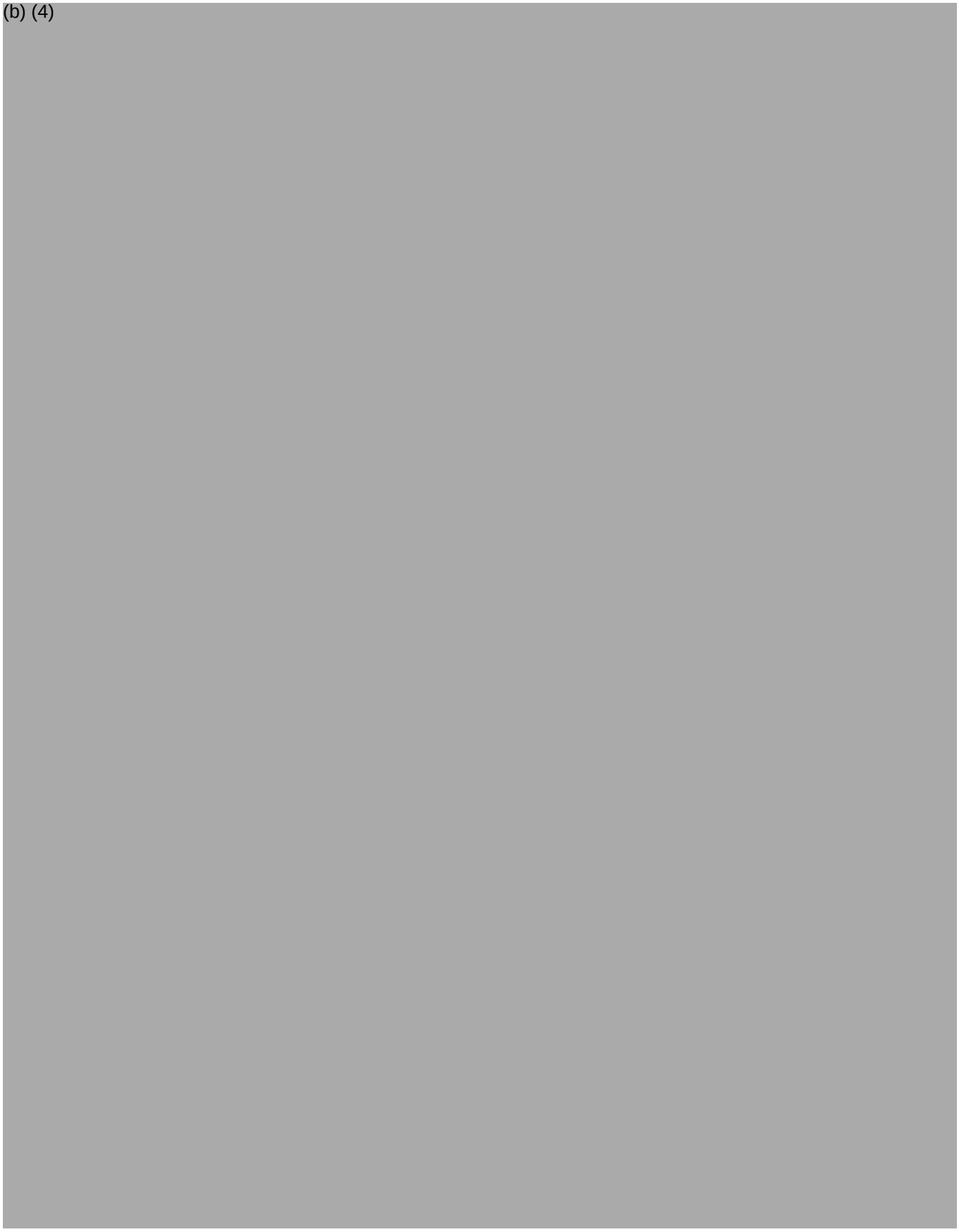
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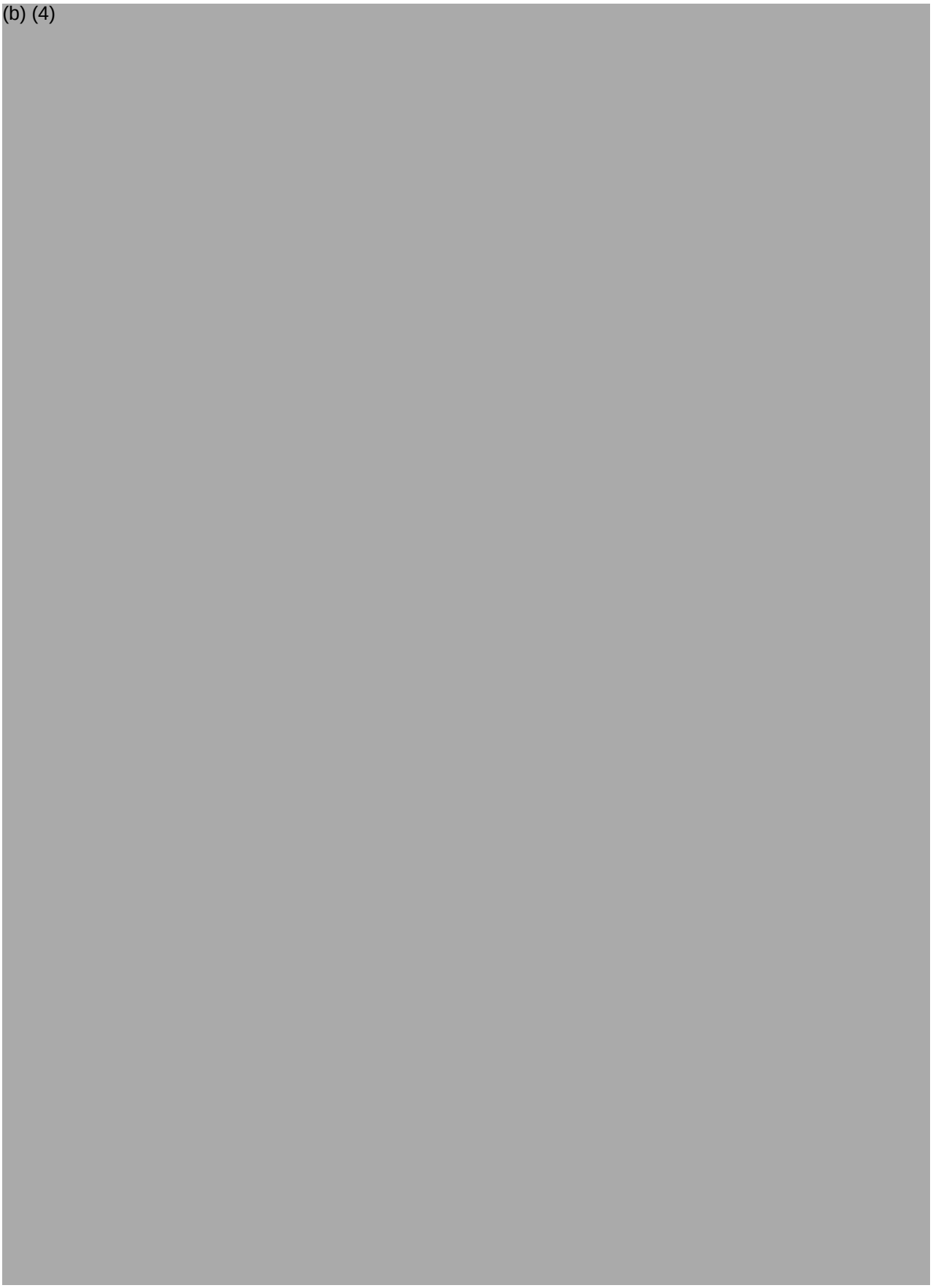
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(b) (4)

Risk/Benefit Analysis

(b) (4)

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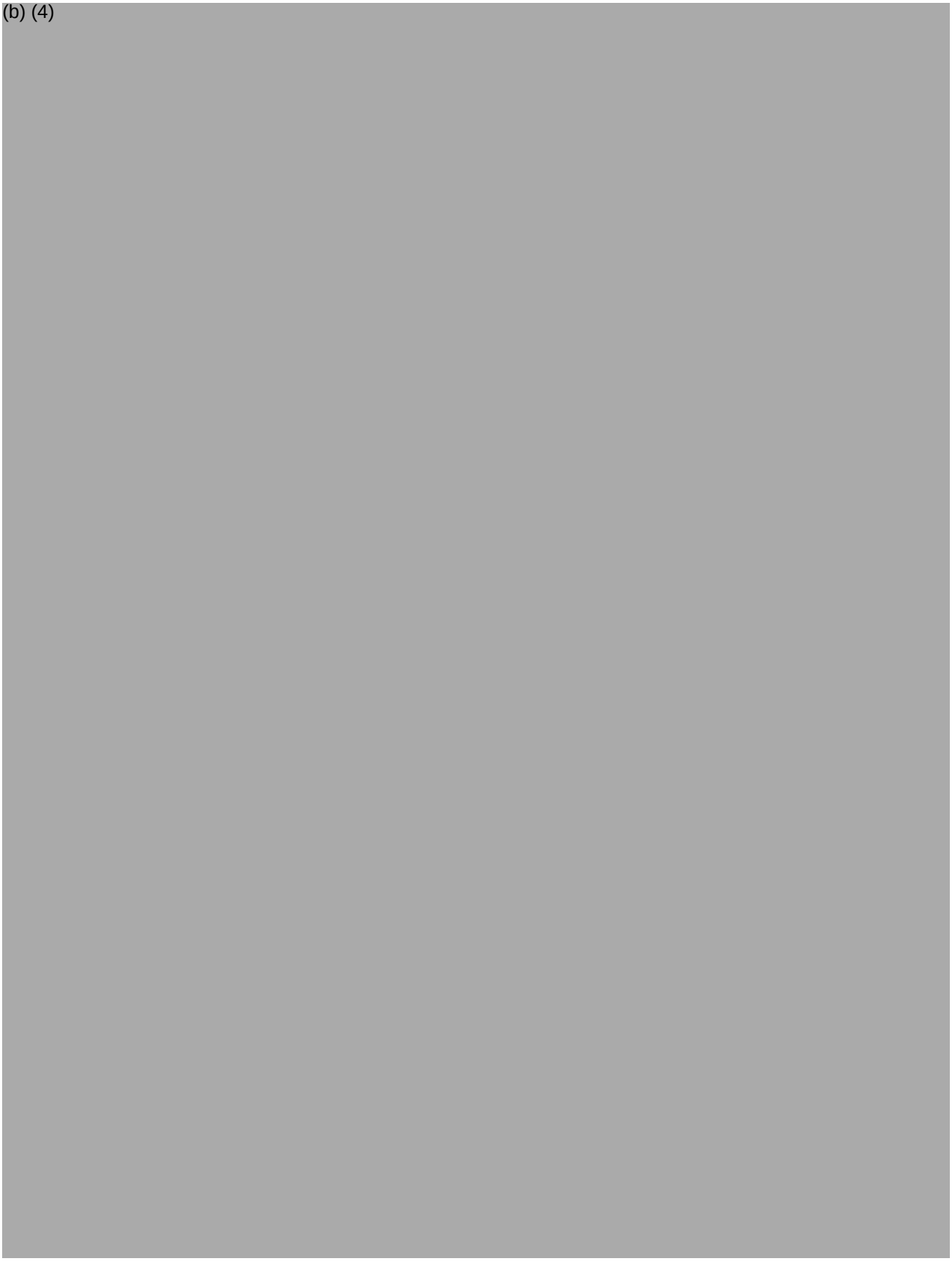
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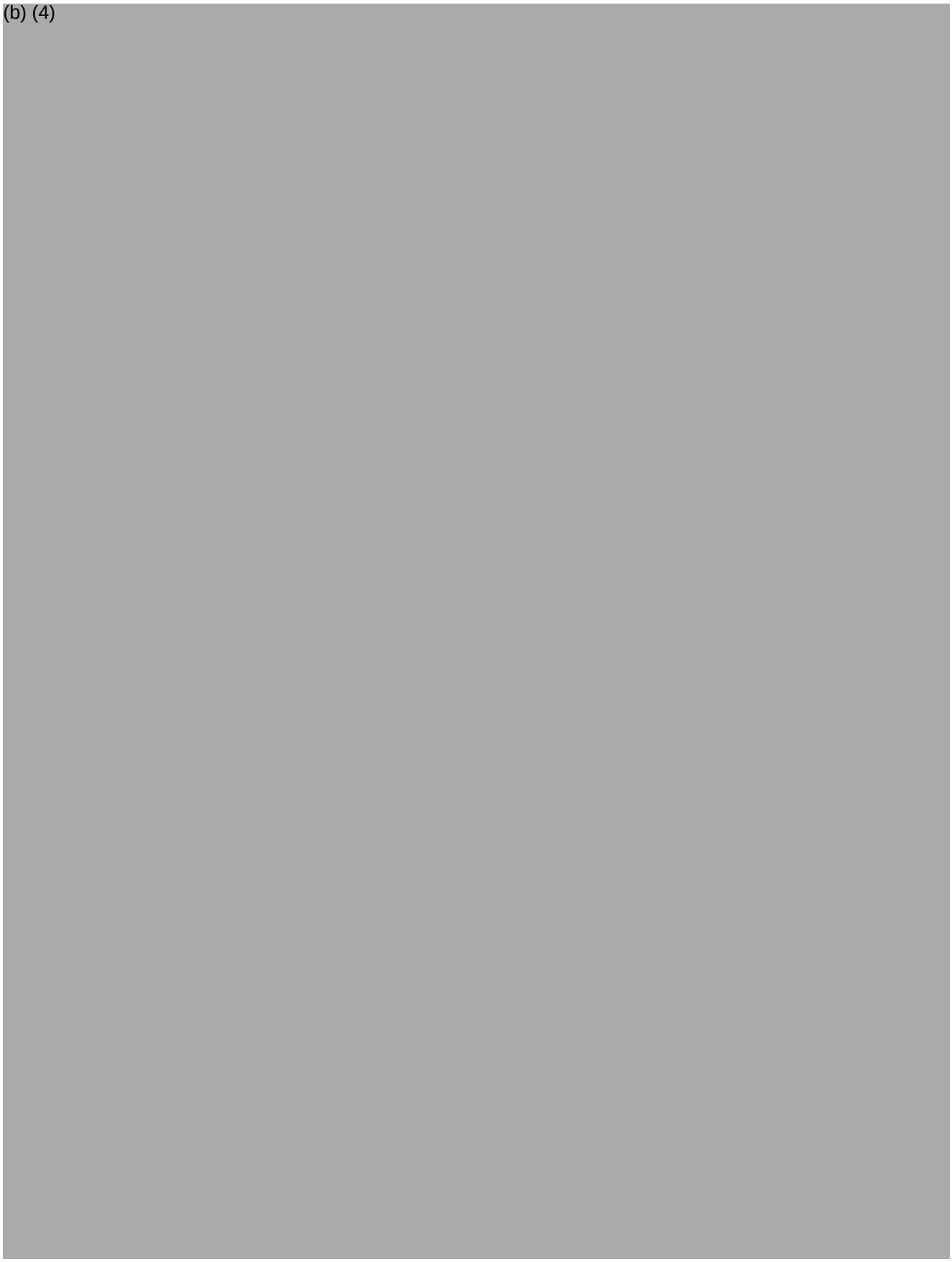
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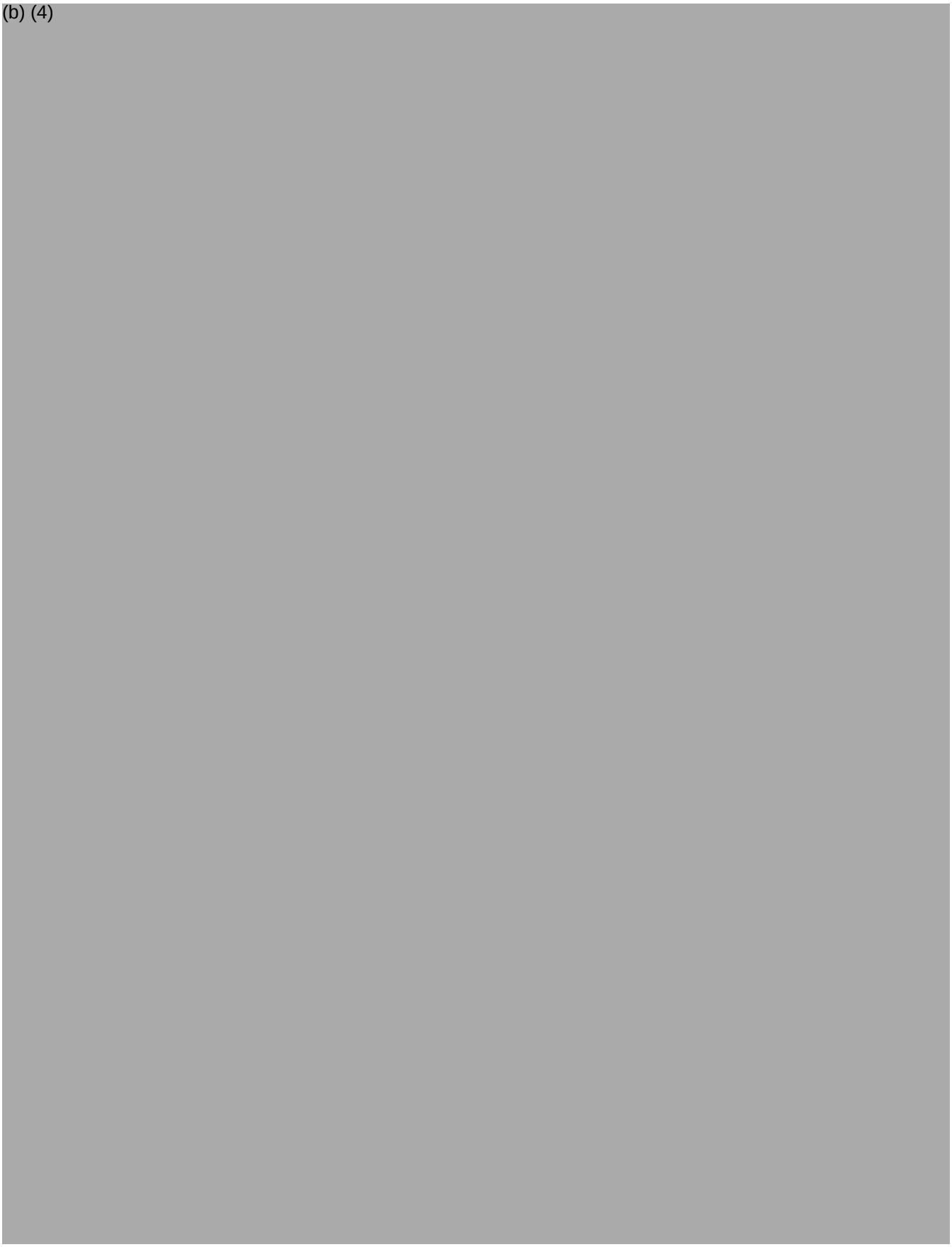
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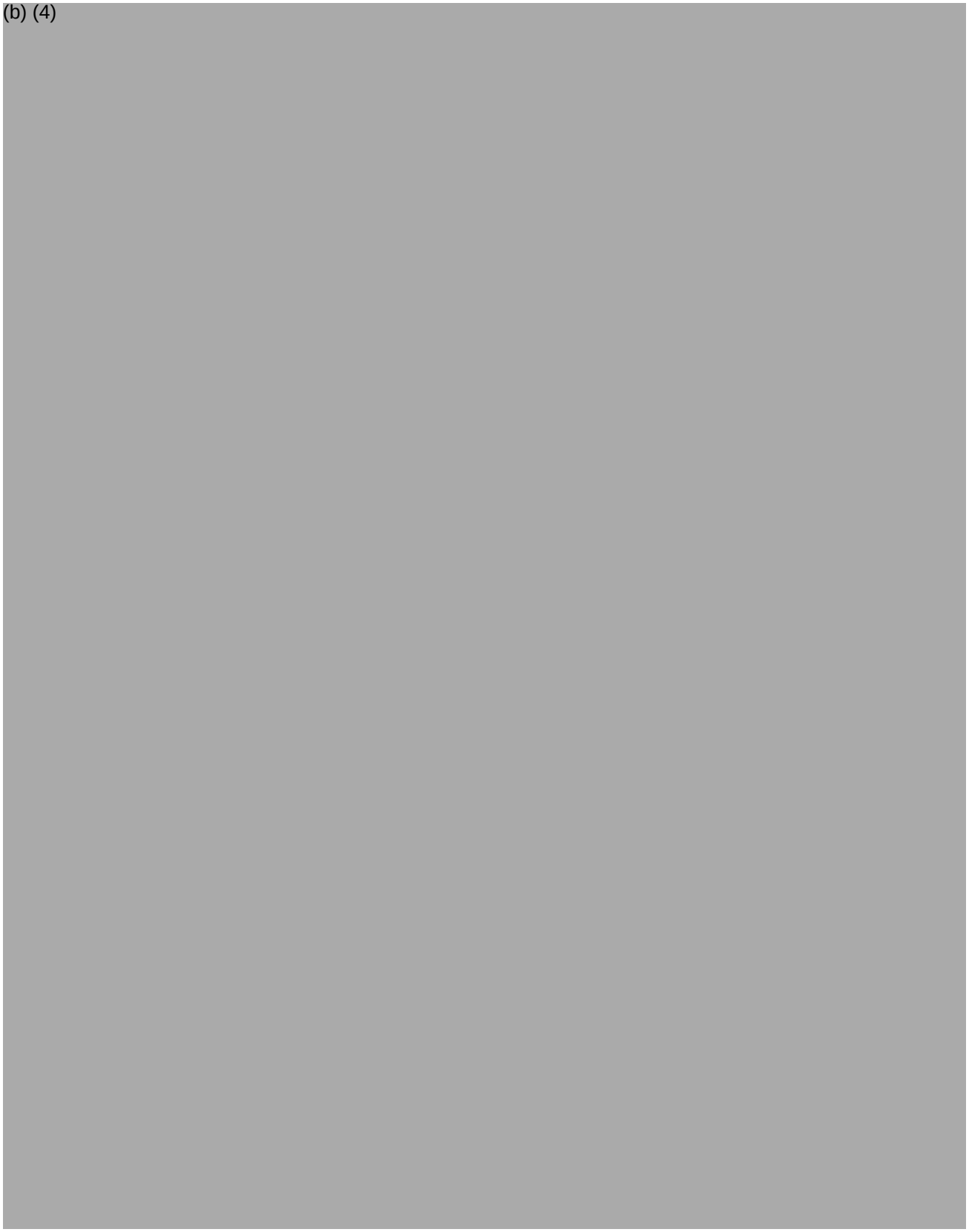
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(b) (4)

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(b) (4)

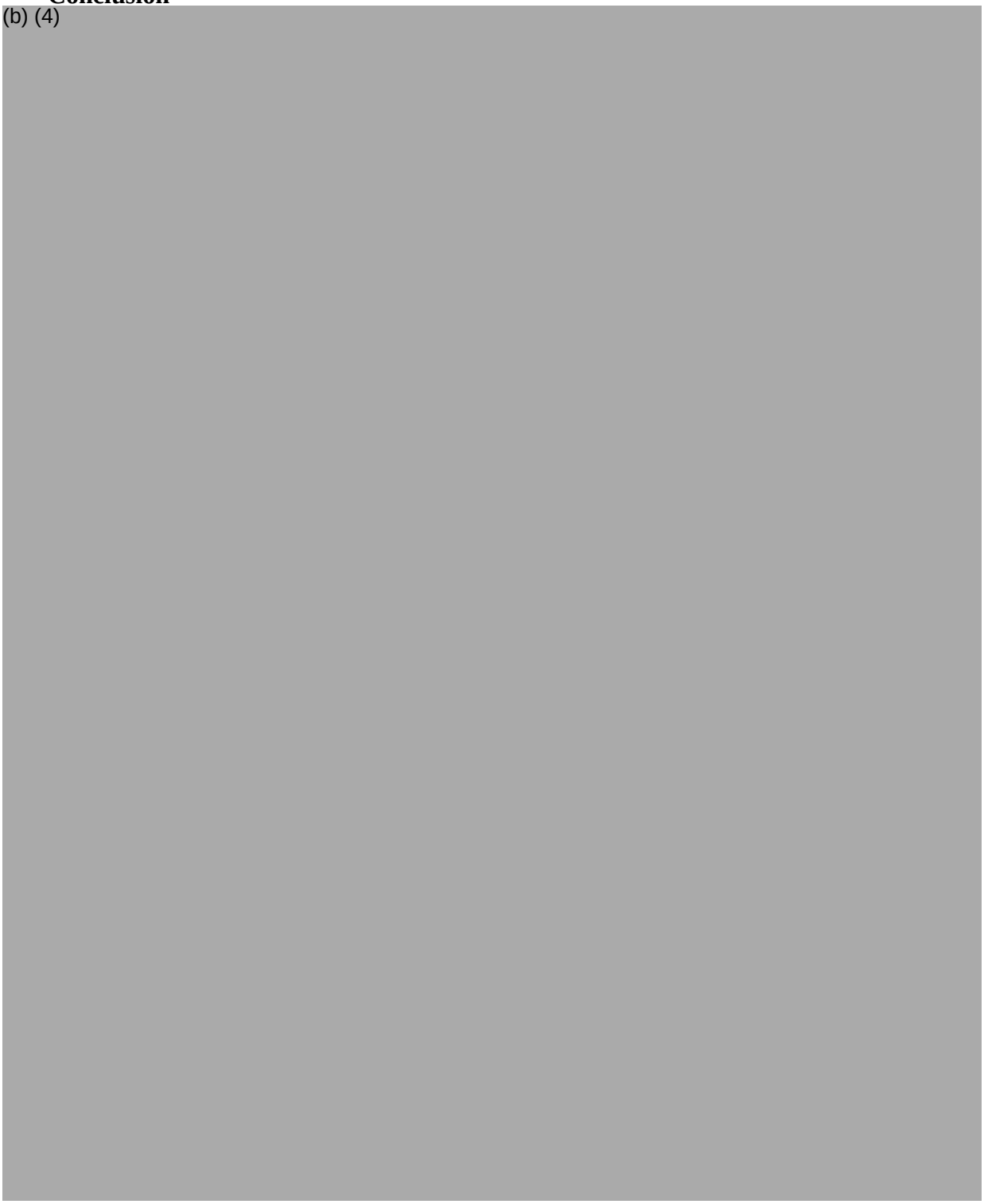


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Conclusion

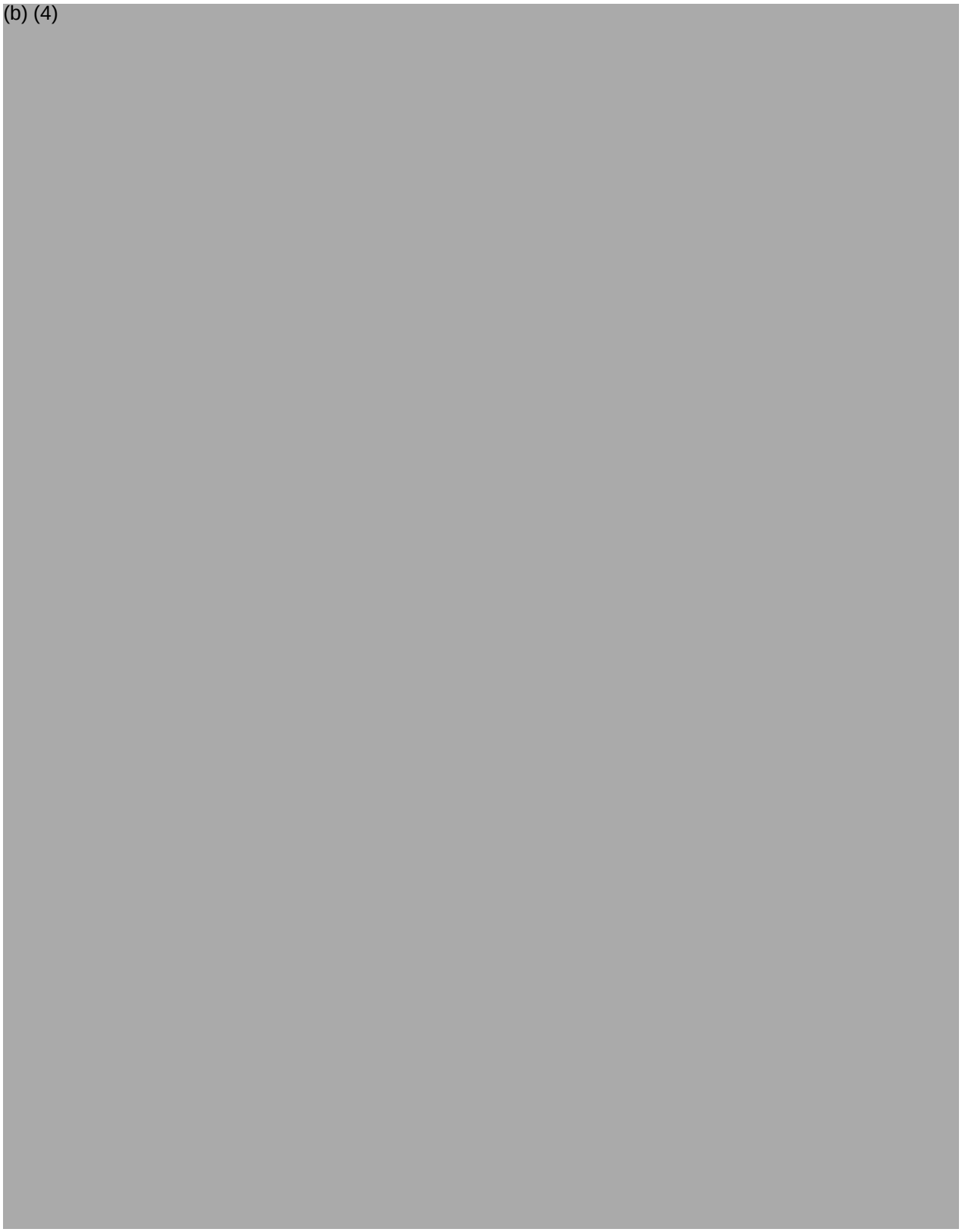
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 17 2011

ev3, Inc.
c/o Brenda Johnson
Principal Regulatory Affairs Specialist
3033 Campus Drive
Plymouth, MN 55441

Re: K111010
Trade Name: SpiderFX Embolic Protection Device
Dated: April 8, 2011
Received: April 11, 2011

Dear Ms. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information you provided. To complete the review of your submission, we require that you address the following deficiencies.

Animal Studies

(b) (4)



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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(b) (4)



Labeling

(b) (4)



The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act (Act) for determining substantial equivalence of your device.

You may not market this device until you have provided adequate information described above and required by 21 CFR 807.87(l), and you have received a letter from FDA allowing you to do so. If you market the device without conforming to these requirements, you will be in violation of the Act. You may, however, distribute this device for investigational purposes to obtain clinical data if needed to establish substantial equivalence. Clinical investigations of this device must be conducted in accordance with the investigational device exemption (IDE) regulations (21 CFR 812).

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. For guidance on 510(k) actions, please see our guidance document entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf

If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act.

The requested information, or a request for an extension of time, should reference your above 510(k) number and should be submitted in duplicate to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning the contents of the letter, please contact Todd Courtney at (301) 796-6371. If you need information or assistance concerning the IDE regulations, please

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100, or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Gina Morrison
for

Lisa M. Lim, PhD
Acting Chief
Peripheral Vascular Devices Branch
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Test Record Cover Page

Test Record Type:
Plan ☐.....Test Record # Pl-
Protocol ☒.....Test Record # (b) (4)
Report ☐.....Test Record # Re-

Date: 01-Jun-07

Revision: A
(if applicable)

Test Record Title: Acute GLP Study to Evaluate Compatability between SpiderFX DEPS and SilverHawk Plaque Excision System

Product: SpiderFX

Project Number: 10093
(if applicable)

Written By: Sara Bakker (author) 01 JUN 07 R&D Engineer (title)

Approved by: (see approval matrix in SOP 1518 for required signatures), and date

01-Jun-07
(Chris Quinn - R&D Project Lead)

01-Jun-07
(Brenda Johnson – Regulatory Affairs)

(b) (4)

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(b)(4) Third Party Study Protocol
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b)(4) Third Party Study Protocol
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ev3®

SpiderFX™

Embolic Protection Device

Instructions for Use

PRODUCT DESCRIPTION

The SpiderFX™ Embolic Protection Device is a percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The SpiderFX Device Capture Wire is used as the 0.014 in. wire for interventional device delivery. The SpiderFX Device can be delivered over any 0.014 in. or 0.018 in. primary wire used to gain access to the lesion site.

The SpiderFX Embolic Protection Device package contains the following components:

- One **Capture Wire** composed of a nitinol mesh Filter with a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter features a heparin-coating designed to maintain patency during Filter deployment[1]. This Capture Wire acts as the primary guidewire for other interventional devices compatible with a 0.014 in. wire. The convertible 320/190 cm Capture Wire is scored, allowing the wire to be snapped to a 190 cm usable length for use with rapid exchange systems, if desired. The distal portion of the Capture Wire for rapid exchange use is gold. The proximal portion for standard over-the-wire use is black.

  [1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.

- One dual-ended **SpiderFX Catheter** used to exchange the primary access guidewire with the Capture Wire, deploy the Capture Wire at the desired location, and recover the Capture Wire at the end of the procedure.
- One 23 gauge Blunt Needle for attachment to a syringe with Luer connector for priming and flushing the Catheter.

Components are delivered sterile, for use within a single vessel only. Do not re-sterilize or reuse.

NOTE: *Commercially available catheters may also be used for delivery/recovery of the SpiderFX Capture Wire. Confirm that the Catheter of Choice is 0.035" guidewire compatible and is compatible with the Capture Wire length, guide catheter/sheath, and primary guidewire prior to use.*

INDICATIONS FOR USE

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk in the treatment of severely calcified lesions in arteries of the lower extremities.

SpiderFX also is indicated as a guidewire and embolic protection system to contain and remove embolic material during percutaneous transluminal angioplasty (PTA) and stent procedures of severely calcified lesions in superficial femoral and popliteal arteries. The vessel diameter at the filter basket placement site should be between 3.0mm and 6.0mm.

CONTRAINDICATIONS

Use of the SpiderFX Embolic Protection Device is contraindicated under these circumstances:

- Do not use with patients in whom anticoagulant and antiplatelet therapy is contraindicated
- Do not use in vessels with excessive tortuosity
- Do not use in patients with uncorrected bleeding disorders
- Do not use in the renal arteries

WARNINGS

The SpiderFX Embolic Protection Device should be used only by physicians who are trained in the proper use of the device.

- This device is supplied STERILE for single use only. Do not reprocess or re-sterilize. Reprocessing and re-sterilizing could increase the risk of patient infection and risk of compromised device performance.
- Refer to the instructions supplied with all interventional devices to be used in conjunction with the SpiderFX Embolic Protection Device for their intended uses, contraindications and potential complications.
- The safety and effectiveness of this device as an embolic protection system have not been established in the renal or iliac arteries.
- The appropriate antiplatelet and anticoagulation therapy should be administered pre- and post-procedure in accordance with standard medical practice.
- Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 2 Sizing Guide).
- Do not grip the Catheter at the distal white tips of either end. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.
- Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.
- Maintain the Capture Wire exit port of the SpiderFX Delivery Catheter within Guide Catheter/Sheath. This results in a 38 cm maximum distance from distal tip of Guide Catheter/Sheath to distal tip of Delivery Catheter. Failure to maintain this port within the Guide Catheter/Sheath may result in increased Filter advancement/deployment forces and vessel and/or device damage.
- Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.
- Do not apply excessive force to the Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.
- Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.
- Do not place the SpiderFX Capture Wire tip in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.
- Do not deploy the Filter within a previously implanted stent.
- Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX (or comparable) Catheter. This may lead to embolization of debris, and vessel and/or device damage.
- Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow. If slow/no flow should occur, the Filter should be recovered (See *Recovery and Removal*).
- Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.
- Do not use mechanical rotational thrombectomy with the Capture Wire.
- Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow flow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).
- After recovering the Filter, do not attempt to flush the Filter and/or reintroduce the Filter into the patient. The Filter must be discarded and a new Filter used if embolic protection is still needed.
- Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the SpiderFX (or comparable) Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

PRECAUTIONS

- Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.
- Do not use the product if the packaging sterile barriers have been damaged or compromised.
- If using the SpiderFX Delivery Catheter for filter delivery, the Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.
- Improper bending of the SpiderFX Catheter at the Primary Wire Exit Port could result in damage to the Catheter.
- If using the SpiderFX Catheter for filter delivery, DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.
- Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the catheter.
- Do not advance the Filter while the primary wire is still within the catheter lumen.
- Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without coming within 2 cm of the Filter proximal end.

Summary of DEFINTIVE Ca++ Study

DEFINITIVE Ca++ was a prospective, multi-center, non-randomized, single-arm study to compare the SilverHawk TurboHawk and the SpiderFX to performance goals derived from an observational multi-center registry (TALON) of subjects with lower extremity PAD who underwent revascularization with catheter-based plaque excision. The purpose of this study was to evaluate the safety and effectiveness of the SilverHawk/TurboHawk and the SpiderFX for the treatment of moderate to severely calcified peripheral arterial disease (PAD) in the superficial femoral and/or the popliteal arteries.

A total of 133 subjects were enrolled. Subject demographics are provided in Table1.

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Table 1: Subject Demographics and Baseline Clinical Characteristics

Subject Characteristics	N=133
Age (yrs.)	
Mean ± SD (N)	69.7 ± 9.8 (133)
Range (min, max)	(41.0, 95.0)
Male	71.4% (95/133)
Diabetes	47.4% (63/133)
History of hypertension requiring medication	91.7% (122/133)
History of MI	30.8% (41/133)
Hyperlipidemia	88.0% (117/133)
History of CABG or PCI	52.6% (70/133)
History of major amputation	0.8% (1/133)
Family history of CAD	49.6% (66/133)
History of peripheral intervention	57.1% (76/133)
History of smoking	78.9% (105/133)
CVA/TIA	15.8% (21/133)
Renal insufficiency	24.8% (33/133)
Rutherford clinical category score	
2	31.6% (42/133)
3	52.6% (70/133)
4	15.8% (21/133)

MI- myocardial infarction, CABG- coronary artery bypass graft, PCI- percutaneous coronary intervention, CAD- coronary artery disease, CVA- cerebrovascular accident, TIA - transient ischemic attack

The primary safety endpoint of the DEFINITIVE Ca++ study was freedom from major adverse event (MAE) rate. MAE was defined as a serious adverse event that results in death, acute myocardial infarction, dissection (grade C or greater), clinical perforation, pseudo-aneurysm, thrombosis, distal embolism (clinically relevant), amputation, or clinically-driven TVR, through 30 days post-procedure, as adjudicated by the clinical events committee (CEC). The 30-day freedom from MAE rate was 93.1% (122/131). The 95% lower confidence limit was 88.3% (as calculated by the Exact method), greater than the performance goal of 85.5%. Therefore, the primary safety endpoint was met. A summary of the MAEs is provided in Table 2.

Table 2: Summary of Major Adverse Events

Major Adverse Event	
Total	6.8% (9/133) [9]
Death	0.0% (0/133) [0]
Acute myocardial infarction	0.8% (1/133) [1]
Dissection, target vessel (C)	0.0% (0/133) [0]
Dissection, target vessel (grade D or greater)	0.8% (1/133) [1]
Vessel clinical perforation, target vessel	2.3% (3/133) [3]
Pseudoaneurysm, target vessel	0.0% (0/133) [0]
Thrombosis, target vessel	0.8% (1/133) [1]
Distal embolism	2.3% (3/133) [3]
Amputation, above metatarsal line	0.0% (0/133) [0]
Clinically Driven TVR	0.0% (0/133) [0]

Presence of debris in the SilverHawk/TurboHawk and SpiderFX by visual inspection at time of procedure was assessed. Debris (excised plaque) was present in the nosecone of the SilverHawk/ TurboHawk devices in 97.0% (129/133) of cases. Debris was present in 88.4% (122/138) of deployed SpiderFX filters upon recovery. Preservation of run-off distal to SpiderFX was determined by angiography of run-off vessels at the end of the procedure, as adjudicated by the angiographic core laboratory. Preservation of run-off was verified by the angiographic core laboratory in 98.3% (113/115) of subjects with available data. The proportion of asymptomatic subjects increased from 0% at baseline to 52.3% at the 30-day follow-up visit. Likewise, the proportion of subjects with severe claudication decreased from 52.6% at baseline to 6.2% at 30 days

Adverse Events

A summary of device- and procedure-related adverse events is provided in Table 3. There were no Unanticipated Adverse Device Effects or deaths.

Table 3: Summary of Device and Procedure-Related Adverse Events and Serious Adverse Events

Adverse Event	Procedure-Related	Study Requirement-Related	SilverHawk-Related	TurboHawk-Related	SpiderFX-Related	% of subjects [# of events]
All Related Events	38.3% (51/133) [64]	1.5% (2/133) [2]	18.4% (14/76) [14]	19.3% (11/57) [11]	3.8% (5/133) [5]	39.8% (53/133) [66]
Access site adverse event	6.0% (8/133) [9]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	6.0% (8/133) [9]
AV fistula, target vessel	0.8% (1/133) [1]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	0.8% (1/133) [1]
Dissection, grade A or B; non-target vessel	0.8% (1/133) [1]	0.0% (0/133)	0.0% (0/76)	0.0% (0/57)	0.0% (0/133)	0.8% (1/133) [1]
Dissection, grade A or B; target vessel	19.5% (26/133) [26]	0.0% (0/133)	13.2% (10/76) [10]	10.5% (6/57) [6]	0.0% (0/133)	19.5% (26/133) [26]
Dissection, grade D or greater; target vessel	1.5% (2/133) [2]	0.0% (0/133)	13.2% (10/76) [10]	3.5% (2/57) [2]	0.0% (0/133)	1.5% (2/133) [2]
Distal embolism; plaque, thrombus (blood clot) or debris distal to the filter, clinically relevant	2.3% (3/133) [3]	0.0% (0/133)	2.6% (2/76) [2]	1.8% (1/57) [1]	2.3% (3/133) [3]	2.3% (3/133) [3]
GI bleeding due to anticoagulation	0.0% (0/133)	0.8% (1/133) [1]	2.6% (2/76) [2]	1.8% (1/57) [1]	2.3% (3/133) [3]	0.8% (1/133) [1]
Hypotension or hypertension	1.5% (2/133) [2]	0.8% (1/133) [1]	2.6% (2/76) [2]	1.8% (1/57) [1]	2.3% (3/133) [3]	2.3% (3/133) [3]
Myocardial infarction, acute	0.8% (1/133) [1]	0.8% (1/133) [1]	2.6% (2/76) [2]	1.8% (1/57) [1]	2.3% (3/133) [3]	0.8% (1/133) [1]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-811

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Table 3: Summary of Device and Procedure-Related Adverse Events and Serious Adverse Events

Adverse Event	Procedure-Related	Study Requirement-Related	SilverHawk-Related	TurboHawk-Related	SpiderFX-Related	% of subjects [# of events]
Pseudoaneurysm, non-target vessel	0.8% (1/133) [1]	0.0% (0/133)	0.0% (0/076)	0.0% (0/057)	0.0% (0/133)	0.8% (1/133) [1]
Renal insufficiency	1.5% (2/133) [2]	0.0% (0/133)	0.0% (0/076)	0.0% (0/057)	0.0% (0/133)	1.5% (2/133) [2]
Thrombosis (acute and subacute); target vessel	0.8% (1/133) [1]	0.0% (0/133)	1.3% (1/76) [1]	0.0% (0/057)	0.0% (0/133)	0.8% (1/133) [1]
Vasospasm	1.5% (2/133) [2]	0.0% (0/133)	1.3% (1/76) [1]	0.0% (0/057)	1.5% (2/133) [2]	1.5% (2/133) [2]
Vessel clinical perforation, target vessel	2.3% (3/133) [3]	0.0% (0/133)	1.3% (1/76) [1]	3.5% (2/57) [2]	1.5% (2/133) [2]	2.3% (3/133) [3]
Other, respiratory	0.8% (1/133) [1]	0.0% (0/133)	1.3% (1/76) [1]	3.5% (2/57) [2]	1.5% (2/133) [2]	0.8% (1/133) [1]
Other	5.3% (7/133) [9]	0.0% (0/133)	1.3% (1/76) [1]	3.5% (2/57) [2]	1.5% (2/133) [2]	5.3% (7/133) [9]

The results of the DEFINITIVE Ca++ study demonstrate that the SilverHawk/TurboHawk device is safe and effective in the endovascular treatment of moderate to severely calcified lesions in the superficial femoral and/or popliteal arteries when used with the SpiderFX embolic protection device. The data also showed that utilizing the SpiderFX embolic protection device resulted in preservation of run-off in 98.3% of subjects, further supporting that the use of the SpiderFX device is a safe and effective means of embolic protection in subjects undergoing endovascular treatment for peripheral arterial disease.

POTENTIAL COMPLICATIONS

Complications associated with the use of the SpiderFX Embolic Protection Device may include, but are not limited to:

- Access site adverse event (e.g., av fistula, hematoma, hemorrhage, pseudoaneurysm, puncture site infection)
- Adjunct device entanglement
- Adverse reaction to antiplatelet/anticoagulation agents or contrast media
- Allergic reaction to device materials
- Amputation
- Aneurysm
- Arterial dissection
- Death
- Device(s) deformation, collapse, fracture, or rupture
- Device(s) thrombosis (acute and subacute)
- Dissection
- Embolization of air, debris, plaque or thrombus (evidenced by slow or no-flow) from mechanical disruption by the intervention
- Embolization or migration of the interventional device(s)
- Emergency surgery
- GI bleeding due to anticoagulation
- Hemodynamic compromise (e.g., prolonged hypotension requiring treatment with intravenous medications)
- Hypotension or hypertension
- Infection
- Ischemia
- Myocardial infarction
- Renal insufficiency
- Renal failure requiring dialysis
- Repeat intervention to treatment site
- Sepsis
- Significant cardiac arrhythmia requiring treatment with medications and/or transvenous pacing
- Stent entanglement
- Stroke
- Thrombosis (acute and subacute)
- Transient Ischemia Attack (TIA)
- Vasospasm
- Vessel dissection, perforation, rupture or intimal flap
- Vessel/filter occlusion

DEVICE COMPONENTS

The SpiderFX Embolic Protection Device package contains one each of the following components:

NOTE: *See Table 4 for Device product specifications.*

Capture Wire — The Capture Wire has a Nitinol mesh Filter with a Proximal Mouth Indicator and a Distal Floppy Tip, mounted on a 190 cm or convertible 320/190 cm PTFE-coated 0.014 in. stainless steel wire. The Filter has a heparin coating designed to maintain patency[1]. The Capture Wire is pre-loaded through the Delivery End of the SpiderFX Catheter with the Filter extending from the Catheter distal tip. The SpiderFX Capture Wire and Catheter are provided in a single hoop.

[1] The heparin coating is intended to maintain Filter patency, and should not have a systemic effect in the patient.

TABLE 4 — SpiderFX Embolic Protection Device Specifications*

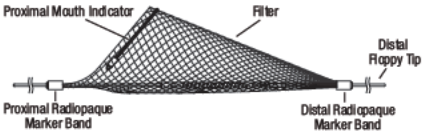
SpiderFX Capture Wire			
Filter Diameter (mm)	5.0	6.0	7.0
Filter Length (mm)**	23	23	24
Capture Wire Length RX (cm)	190	190	190
Capture Wire Length OTW/RX (cm)	320/190	320/190	320/190
Wire Diameter (in /mm)	0.014/0.36	0.014/0.36	0.014/0.36
Distal Wire Tip Coil Length (cm)	1.2	1.2	1.2
SpiderFX Catheter - Delivery End (green)			
Nominal Diameter (in./mm)	0.040/1.02	0.040/1.02	0.040/1.02
Functional Length (cm)	140	140	140
SpiderFX Catheter - Recovery End (blue)			
Diameter (F)	4.2	4.2	4.2
Functional Length (cm)	140	140	140
Total Catheter Length (cm)	180	180	180

*Nominal

**When delivered at maximum recommended vessel size.

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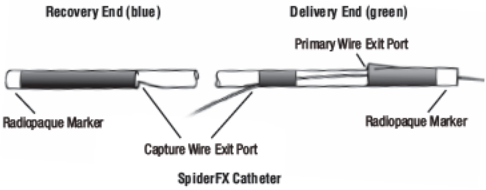
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Capture Wire

CAUTION: *Do not bend or shape the Distal Floppy Tip of the Capture Wire. This may cause device damage. The Capture Wire is not intended for use as a steerable guidewire.*

SpiderFX Catheter — The SpiderFX Catheter is dual-ended, with a Delivery End (green), and a Recovery End (blue) at the opposite end of the catheter



SpiderFX Catheter

- The **Delivery End** (green) of the SpiderFX Catheter has an embedded radiopaque marker at the distal tip, a primary wire exit port (indicated by a white stripe), a Clear Segment, and a Capture Wire Exit Port. The Capture Wire is pre-loaded into the Delivery End of the Catheter, with the Filter portion extending from the distal tip.
- The center **White Shaft** is used to manipulate the SpiderFX Catheter during delivery and recovery of the SpiderFX Capture Wire.
- The **Recovery End** (blue) of the SpiderFX Catheter has an embedded radiopaque marker at its distal tip, and a Capture Wire Exit Port.

Latex is not a component of the SpiderFX Embolic Protection Device.

INSTRUCTIONS FOR USE – SpiderFX Catheter

NOTE: *If using alternate catheter for delivery/recovery of the SpiderFX Capture Wire refer to instructions starting on page 4.*

Preparing the SpiderFX Embolic Protection Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the anticipated distal tip of interventional device to be used to treat the lesion. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the anticipated distal tip of interventional device, to allow for adequate Filter deployment.

WARNING: Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 2 Sizing Guide).

4. Ensure the guide catheter/sheath size will accommodate the SpiderFX Catheter. (Table 5).

TABLE 5 — Sizing Guide[1]

Target Vessel Size (mm)	Filter Size (mm)	Primary Guidewire Size (in)	Guide Catheter/ Sheath Min I.D.[2] (in)
3 0 - 4.0	5 0	0.014-0.018	0 066
3 5 - 5.0	6 0	0.014-0.018	0 066
4 5 - 6.0	7 0	0.014-0.018	0 066

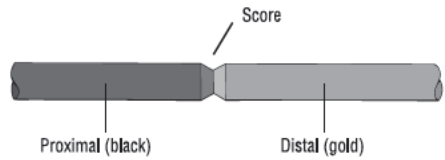
[1] Nominal
[2] Select a guide catheter that provides coaxial alignment and stable backup support.

5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the Catheter near the Primary Wire Exit Port and gently pull to expose the Catheter. The remaining Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the Catheter.

NOTE: *If using the 320/190 cm convertible version of the SpiderFX Device, it may be snapped at any point during the intervention if no over-the-wire devices are intended to be used. To do this, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*

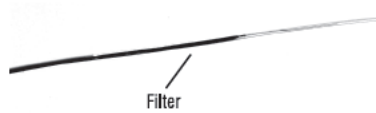


Capture Wire

8. Hold the Catheter at the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the Catheter at the distal white tips of either end. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the Catheter.

9. Continue holding the Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter portion stops in the proximal end of the Clear Segment of the Catheter.



Filter in Proper Position in Clear Segment

CAUTION: *The Filter and Distal Floppy Tip should be visible within the Clear Segment of the Catheter.*

10. Flush through the distal tip with heparinized saline until all air is removed and fluid passes from the Primary Wire Exit Port (22.5 cm proximal to the distal tip of the Catheter). A 23 gauge blunt needle included in the packaging may be used, if desired. Do not apply excessive force to the Capture Wire.
11. Gently apply pressure to the Primary Wire Exit Port. Flush until all air is removed and fluid passes from the Capture Wire Exit Port (40 cm proximal to Catheter distal tip).

WARNING: Failure to adequately close off the Primary Wire Exit Port during flushing of the Delivery End of the SpiderFX Catheter may result in air embolism.

Delivery and Deployment

12. Access the vessel being treated using standard technique, and advance the primary guidewire at least 5 cm beyond the anticipated distal end of interventional device used to treat the lesion.
13. Observe the Primary Wire Exit Port indicated by a white stripe on the Catheter, to ensure the Port hole is visible.

NOTE: *When loading the primary guidewire, gently bend the Catheter placing the Primary Wire Exit Port at the apex of the curve*

CAUTION: *Improper bending of the Catheter at the Primary Wire Exit Port could result in damage to the Catheter.*

14. Load the distal tip of the SpiderFX Device Delivery End (green) onto the proximal end of the primary guidewire and advance, so the primary wire exits at the Primary Wire Exit Port.

CAUTION: *DO NOT allow the primary wire to advance proximally past the Primary Wire Exit Port. Contact with the Distal Floppy Tip or Filter could result in damage to the device.*

15. Gently advance the SpiderFX Delivery End carrying the Capture Wire over the primary wire and into the guide catheter/sheath. Continue advancing until the radiopaque marker at the distal tip of the Delivery End is at least 4-5 cm distal to the anticipated distal end of the interventional device used.

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***CAUTION**: Clearly identify the Capture Wire and primary guidewire while advancing. Do not completely rotate the SpiderFX Catheter, which can cause the wires to wrap around the Catheter.*

WARNING: Maintain the Capture Wire exit port of the SpiderFX Delivery Catheter within Guide Catheter/Sheath. This results in a 38 cm maximum distance from distal tip of Guide Catheter/Sheath to distal tip of Delivery Catheter. Failure to maintain this port within the Guide Catheter/Sheath may result in increased Filter advancement/deployment forces and vessel and/or device damage.

WARNING: Minimize torque of the Capture Wire after it has been introduced into the patient. Torqueing the Capture Wire is likely to result in wire whipping.

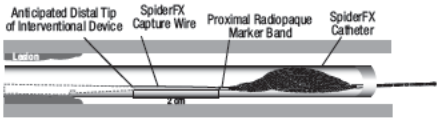
WARNING: Do not apply excessive force to Capture Wire. This may lead to distal embolization of debris, and vessel and/or device damage.

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

16. Hold the Catheter stationary, and withdraw the primary guidewire, leaving the Delivery Catheter and Capture Wire in place.
17. Hold the Catheter stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.

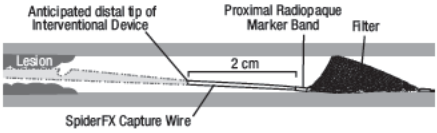
18. Observe and adjust the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the anticipated distal end of the interventional device used to treat the lesion.



Position of SpiderFX Catheter Relative to Interventional Device.

***CAUTION**: Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without contacting the Filter proximal end.*

WARNING: Do not deploy the Filter within a previously implanted stent



Position of Filter Relative to Interventional Device

19. Hold the Capture Wire stationary, and gently pull back on the Catheter to expose and deploy the Filter in the vessel. To reposition the Filter (if required),advance the Catheter back over the Filter, adjust the position of the Catheter and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter.

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the SpiderFX (or comparable) Catheter. This may lead to embolization of debris, and vessel and/or device damage.

20. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Delivery Catheter together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
21. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
22. Once the Filter is deployed in the desired location, carefully remove the SpiderFX Catheter from the patient. Keep the Catheter in the sterile field. **DO NOT DISCARD THE CATHETER.** The Recovery End (blue) is required for Capture Wire recovery.
23. Place the SpiderFX Catheter in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter.
24. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow. If slow/no flow should occur, the Filter should be recovered (See *Recovery and Removal*).

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use mechanical rotational thrombectomy with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).

WARNING: After recovering the Filter, do not attempt to flush the Filter and/or reintroduce the Filter into the patient. The Filter must be discarded and a new Filter used if embolic protection is still needed.

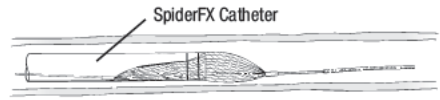
Recovery and Removal

25. After completion of the interventional procedure, wet the distal 20 cm of the Recovery End (blue) of the Catheter with heparinized saline. Flush the distal tip of the Recovery End to remove all air, until fluid passes from the Capture Wire Exit Port (25 cm from the tip).

WARNING: Do not grip the Catheter at the distal white tips of either end. This may result in deformation of the embedded Radiopaque Marker Bands and/or inner lumen of the Catheter.

26. Load the Recovery End (blue) of the Catheter onto the Capture Wire and through the guide catheter/sheath.
27. Advance the Catheter under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
28. There are two methods for Filter Recovery:

A — Partial Enclosure Recovery: Gently advance the Recovery End over the Filter, until the proximal portion of the Filter is inside the Catheter, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the radiopaque marker of the Recovery Catheter.



A. Partial Enclosure Recovery

WARNING: Exercise caution when using the partial recovery method to withdraw a full Filter through a deployed stent. If resistance is felt, advance the Filter and Recovery End of the Catheter distally and draw the Filter more fully into the Catheter before re-attempting withdrawal.

B — Full Enclosure Recovery: Gently advance the Recovery End over the Filter until all radiopaque markers on the Filter are within the Catheter, proximal to the Catheter distal marker. The Distal Floppy Tip may remain outside the Catheter.



B. Full Enclosure Recovery

WARNING: Never withdraw or move an intravascular device against any resistance until the cause is determined. Advancing with such resistance may lead to embolization of debris, and vessel and/or device damage.

29. Carefully remove the Catheter and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the SpiderFX Catheter to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

***CAUTION**: Do not re-sterilize or reuse this device.*

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-811

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INSTRUCTIONS FOR USE –
Alternate Catheter of Choice

NOTE: *Commercially available catheters can be used for delivery/recovery of the SpiderFX Capture Wire. Confirm that the Catheter of Choice is 0.035" guidewire compatible and is compatible with the Capture Wire length, guide catheter/sheath, and primary wire prior to use.*

Preparing the SpiderFX Embolic Protection Device for Use

1. Administer anticoagulation medications and monitor activated clotting time per standard institutional guidelines. Use of antiplatelet medications in conjunction with intralumenal interventions using this device is recommended.
2. Perform angiography.
3. Identify the location within the vessel where the Filter of the SpiderFX Device will be deployed, approximately 3 cm distal to the anticipated distal tip of interventional device to be used to treat the lesion. Measure the vessel diameter at this location in millimeters, and select the appropriate Filter diameter size. Also confirm that 4-5 cm vessel length exists distal to the anticipated distal tip of interventional device, to allow for adequate Filter deployment.

WARNING: Do not undersize or oversize the Filter in relation to the selected vessel diameter. This may result in inadequate vessel wall apposition or incomplete deployment of the Filter. Undersizing or oversizing could cause slow/no-flow, and/or embolization of debris. (Refer to Table 6 Sizing Guide).

TABLE 6 — Filter Sizing Guide

Target Vessel Size (mm)	Filter Size (mm)
3.0 - 4.0	5.0
3.5 - 5.0	6.0
4.5 - 6.0	7.0

NOTE: *Ensure that the length of the Catheter of Choice is such that it accommodates the Capture Wire length.*

4. Ensure the guide catheter/sheath size will accommodate the Catheter of Choice according to its instructions for use.
5. Using sterile technique, remove the SpiderFX Device components with the hoop from the packaging, and place in a sterile work area.

CAUTION: *Do not use the product if the packaging sterile barriers have been damaged or compromised.*

6. Remove the colored portion of the hoop to expose the Filter and the Delivery End (green) of the SpiderFX Catheter.
7. Grasp the SpiderFX Catheter near the Primary Wire Exit Port and gently pull to expose the SpiderFX Catheter. The remaining SpiderFX Catheter may remain in the hoop, or be removed from the hoop to expose the Recovery End (blue) of the SpiderFX Catheter.
8. Hold the SpiderFX Catheter near the distal tip and submerge only the Filter in heparinized saline to wet and remove air.

WARNING: Do not grip the SpiderFX Catheter at the distal white tips of either end. This may result in deformation of the embedded radiopaque marker band and/or inner lumen of the SpiderFX Catheter.

9. Continue holding the SpiderFX Catheter near the distal tip to provide support to the catheter shaft. If the hydrophilic coating has become wet and is slippery, gauze may be needed to avoid pinching the distal end of the catheter. Pull the Capture Wire proximally until the Filter and Distal Floppy Tip are fully contained within the distal tip of the SpiderFX Catheter.

WARNING: Failure to fully contain the Distal Floppy Tip within the distal end of the SpiderFX Catheter Delivery End during loading could result in kinking of the Distal Floppy Tip.

Delivery and Deployment

10. Access the vessel being treated using standard technique, and advance the primary guidewire and/or Catheter of Choice at least 5cm beyond the anticipated distal end of interventional device used to treat the lesion.
11. Hold the Catheter of Choice stationary and withdraw the primary guidewire.
12. Following removal of primary guidewire, flush the Catheter of Choice lumen with sterile heparinized saline.
13. Gently guide the tip of the SpiderFX Device Delivery End (green) into the proximal end of the Catheter of Choice or until the tip of the SpiderFX Catheter aligns with the lumen of the Catheter of Choice.

WARNING: Do not advance the SpiderFX Catheter against resistance. This may result in deformation of the embedded Radiopaque Marker Band contained within the SpiderFX Catheter tip.

14. Hold the SpiderFX Catheter and Catheter of Choice stationary, and gently advance the Capture Wire until the Filter enters the lumen of the Catheter of Choice.

NOTE: *The user should feel a reduction in force when the Filter has exited the SpiderFX Catheter and is fully contained within the Catheter of Choice.*

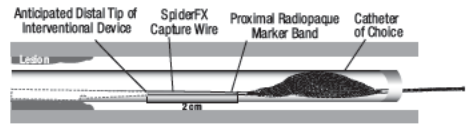
15. Continue to advance the Capture Wire through the SpiderFX Catheter and Catheter of Choice approximately 5 to 7 inches to ensure the Capture Wire's tapered section is fully supported within the Catheter of Choice.

CAUTION: *Failure to support the distal tapered section of the Capture Wire within the Catheter of Choice while advancing the Filter could result in kinking of the Capture Wire.*

16. Hold the Capture Wire stationary, and pull back on the SpiderFX Catheter to offload the SpiderFX Catheter from the Capture Wire. Keep the SpiderFX Catheter in the sterile field. **DO NOT DISCARD THE SPIDERFX CATHETER** in the event that the SpiderFX Catheter Recovery End (blue) may be needed for Filter recovery.
17. Place the SpiderFX Catheter in sterile heparinized saline or sterile field. Do not bend or kink the SpiderFX Catheter.
18. Hold the Catheter of Choice stationary, and gently advance the Capture Wire until the radiopaque distal marker on the Filter aligns with the radiopaque marker on the Catheter of Choice distal tip.

WARNING: Do not place the SpiderFX Capture Wire in a vessel that does not allow for wire movement. This may lead to embolization of debris, and vessel and/or device damage.

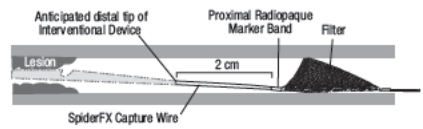
19. Observe and adjust the position of the Filter under fluoroscopy to ensure the Proximal Radiopaque Marker Band is at least 2 cm distal to the anticipated distal end of the interventional device used to treat the lesion.



Position of Catheter of Choice Relative to Interventional Device.

CAUTION: *Proper Filter position should be sufficiently distal to the lesion so the interventional device may be properly advanced without coming within 2 cm of the Filter proximal end.*

WARNING: Do not deploy the Filter within a previously implanted stent.



Position of Filter Relative to Interventional Device

20. Hold the Capture Wire stationary, and gently pull back on the Catheter of Choice to expose and deploy the Filter in the vessel. To reposition the Filter (if required), advance the Catheter of Choice back over the Filter, adjust the position of the Catheter of Choice and Capture Wire together, and redeploy. NEVER attempt to move the Filter outside of the Catheter of Choice.

WARNING: Do not attempt to reposition or remove the Capture Wire without the use of the Catheter of Choice or SpiderFX Catheter. This may lead to embolization of debris, and vessel and/or device damage.

21. A gold radiopaque Proximal Mouth Indicator will be seen when the Filter is properly opened. If this is not seen, attempt to either redeploy the Filter or remove both the Filter/Capture Wire and the Catheter of Choice together. Once the Capture Wire is removed from the patient, it may not be reintroduced or reused.
22. Confirm the Filter and the Proximal Radiopaque Marker Band are in apposition to the vessel wall by including a side view shown above.
23. Once the Filter is deployed in the desired location, carefully remove the Catheter of Choice from the patient. Keep the Catheter of Choice in the sterile field. DO NOT DISCARD THE CATHETER OF CHOICE. The Catheter of Choice may be used for Capture Wire recovery.
24. Place the Catheter of Choice in sterile heparinized saline or sterile field, and save for recovery of the SpiderFX Capture Wire. Do not bend or kink the Catheter of Choice.

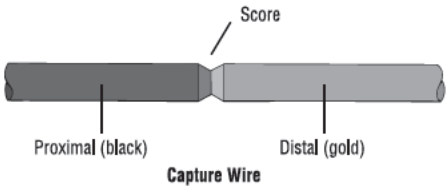
NOTE: *The SpiderFX Catheter Recovery End (blue) may also be used for Capture Wire recovery.*

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25. Use the 0.014 in. Capture Wire as the primary guidewire for other interventional devices. Perform the procedure. Keep the Capture Wire stationary during use.

NOTE: *If using the 320/190 cm convertible version of the SpiderFX Device, it may be snapped at any point during the intervention if no over-the-wire devices are intended to be used. To do this, firmly grasp the Capture Wire on each side of the score of the wire (gold and black) and snap the wire. Leave the black portion of the wire in the hoop or discard.*



Capture Wire

WARNING: Dwell time for the SpiderFX Capture Wire is not to exceed 60 minutes. Occlusion could occur, resulting in slow/no-flow. If slow/no flow should occur, the Filter should be recovered (See *Recovery and Removal*).

WARNING: Minimize movement of the Capture Wire after initial placement. Excessive movement of the Capture Wire may lead to embolization of debris, and vessel and/or device damage.

WARNING: Do not use mechanical rotational thrombectomy with the Capture Wire.

WARNING: Frequently observe the SpiderFX Capture Wire under fluoroscopy and monitor the patient to verify the Filter has not become occluded with debris resulting in slow/no-flow. The Filter should be recovered if it becomes occluded or if flow is compromised (See *Recovery and Removal*).

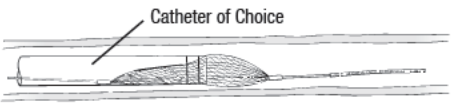
WARNING: After recovering the Filter, do not attempt to flush the Filter and/or reintroduce the Filter into the patient. The Filter must be discarded and a new Filter used if embolic protection is still needed.

Recovery and Removal

26. After completion of the interventional procedure, flush the Catheter of Choice from the proximal end to remove all air, until fluid passes through the distal tip.

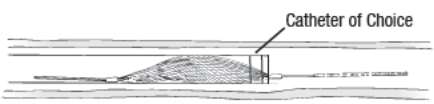
NOTE: *The SpiderFX Catheter Recovery End (blue) may also be used for Capture Wire recovery. See instructions for 'Recovery and Removal' with SpiderFX starting on page 4, step 25.*

27. Load the Catheter of Choice onto the Capture Wire and through the guide catheter/sheath.
28. Advance the Catheter of Choice under fluoroscopy until the distal tip radiopaque marker aligns with the Proximal Radiopaque Marker Band on the Filter.
29. Gently advance the Catheter of Choice over the Filter, until the proximal portion of the Filter is inside the Catheter of Choice, as indicated by the gold radiopaque Proximal Mouth Indicator of the Filter being fully compressed against the Capture Wire and proximal to the distal radiopaque marker of the Catheter of Choice.



Recovery of SpiderFX Capture Wire with Catheter of Choice.

WARNING: Exercise caution when withdrawing a full Filter through a deployed stent. If resistance is felt, advance the Filter and Catheter of Choice distally and draw the Filter more fully into the Catheter of Choice before re-attempting withdrawal as illustrated below.



30. Carefully remove the Catheter of Choice and Capture Wire together as a unit. Open the hemostasis valve on the guide catheter/sheath to allow the Catheter of Choice to exit without resistance. Use care to avoid interaction with the site of the intervention. Discard after removal from the patient.

CAUTION: *Do not re-sterilize or reuse this device.*

STORAGE

- Do not store in direct sunlight
- Keep dry

WARRANTY DISCLAIMER

Although the product has been manufactured under carefully controlled conditions, ev3 Inc. has no control over the conditions under which this product is used. ev3 Inc., therefore disclaims all warranties, both express and implied, with respect to the product including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. ev3 Inc. shall not be liable to any person or entity for any medical expenses or any direct, incidental or consequential damages caused by any use, defect, failure or malfunction of the product, whether a claim for such damages is based upon warranty, contract, tort or otherwise. No person has any authority to bind ev3 Inc. to any representation or warranty with respect to the product. The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Disclaimer of Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of this Disclaimer of Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Disclaimer of Warranty did not contain the particular part or term held to be invalid.

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Protected under one or more of the following: US Patent 7,717,934; 7,637,920; 7,556,636; 7,556,635; 7,410,492; 7,404,820; 7,371,250; 7,367,986; 6,979,343; 6,843,798; 6,712,835; 6,325,815. Non-US patents issued & pending.

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Revised Substantial Equivalence

	Proposed Device	Predicate Devices		
Device Name	**SpiderFX**	**SpiderFX**	**SpideRX**	**Angioslide eXtra**
Indication	**Lower Extremities**	**Carotid Use**	**Carotid Use**	**Lower Extremities**
510(k) Number	K111010 (pending)	K063204	K052659	K090364
Intended Use				
Indications For Use	The SpiderFX Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk in the treatment of severely calcified lesions in arteries of the lower extremities. The vessel diameter at the filter basket placement site should be between 3.0mm and 6.0mm. SpiderFX also is indicated as a guidewire and embolic protection system to contain and remove embolic material during percutaneous transluminal angioplasty (PTA) and stent procedures of severely calcified lesions in the superficial femoral and popliteal arteries. The vessel diameter at the filter basket placement site should be between 3.0mm and 6.0mm.	Indicated for use as a guidewire and embolic protection system to contain and remove embolic material (thrombus/debris) while performing angioplasty and stenting procedures in carotid arteries. The diameter of the artery at the site of filter basket placement should be between 3.0mm and 7.0mm.		Indicated for PTA and for capture and containment of embolic material during angioplasty, for the femoral, iliac, ilio-femoral, popliteal, tibial, peroneal, and profunda arteries.

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Revised Substantial Equivalence

	Proposed Device	Predicate Devices		
Device Name	**SpiderFX**	**SpiderFX**	**SpideRX**	**Angioslide eXtra**
Indication	**Lower Extremities**	**Carotid Use**	**Carotid Use**	**Lower Extremities**
Intended Use	Percutaneously delivered distal embolic protection device, designed to capture and remove dislodged debris during interventional procedures. The device Capture Wire is used as the 0.014" wire for interventional device delivery.			Containment and removal of embolic material is achieved by proximal vessel occlusion, by means of an inflatable balloon, and subsequent aspiration of embolic material.
Indicated Vessel Diameters	3.0 – 6.0 mm	3.0 – 7.0 mm		Balloon sizes are 4, 5, 6 mm
Technological Characteristics				
Method of Embolic Capture	Distal filter			Proximal vessel occlusion followed by aspiration of embolic material
System Components	SpiderFX Catheter Capture Wire Flushing Needle		SpideRX Catheter Capture Wire	Co-axial dual lumen catheter with a foldable balloon near distal tip
Guide (Sheath) Compatibility	6F (5F) – min. 0.066"			6-7F
Primary Wire Compatibility	0.014" or 0.018"			0.035"
Wire Exit Location	22.5 cm (Primary guidewire) 40 cm (Capture Wire)			N/A, Over-the-wire
Catheter Configuration	Dual-ended Rapid Exchange (Delivery End and Recovery End)			Co-axial dual lumen
Catheter Delivery End Nominal Diameter	(b) (4)			Unknown
Catheter Recovery End Nominal Diameter	(b) (4)			N/A

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Revised Substantial Equivalence

<table>
<tr><th></th><th>Proposed Device</th><th colspan="2">Predicate Devices</th><th></th></tr>
<tr><th>Device Name</th><th>SpiderFX</th><th>SpiderFX</th><th>SpideRX</th><th>Angioslide eXtra</th></tr>
<tr><th>Indication</th><th>Lower Extremities</th><th>Carotid Use</th><th>Carotid Use</th><th>Lower Extremities</th></tr>
<tr><td>Catheter Materials</td><td colspan="3">• (b) (4)
• (b) (4)
• (b) (4)
• (b) (4)</td><td>Materials unknown for: Balloon, Radiopaque markers, Inner shaft, Outer shaft, Handle enclosure, Cylinder, T-connector, Inflation port, Pulling rod with guidewire port, Pulling rod locks</td></tr>
<tr><td>Capture Wire Lengths</td><td colspan="2">(b) (4)</td><td>(b) (4)</td><td>N/A; use standard guidewire</td></tr>
<tr><td>Device Sizes</td><td>5, 6, 7 mm</td><td colspan="2">3, 4, 5, 6, 7 mm</td><td>4, 5, 6 mm</td></tr>
<tr><td>Recommended Vessel Sizing</td><td><table><tr><th>Filter Size (mm)</th><th>Target Vessel Size (mm)</th></tr><tr><td>5.0</td><td>3.0 – 4.0</td></tr><tr><td>6.0</td><td>3.5 – 5.0</td></tr><tr><td>7.0</td><td>4.5 – 6.0</td></tr></table></td><td colspan="2"><table><tr><th>Filter Size (mm)</th><th>Target Vessel Size (mm)</th></tr><tr><td>3.0</td><td>3.0</td></tr><tr><td>4.0</td><td>3.1 – 4.0</td></tr><tr><td>5.0</td><td>4.1 – 5.0</td></tr><tr><td>6.0</td><td>4.5 – 6.0</td></tr><tr><td>7.0</td><td>5.5 – 7.0</td></tr></table></td><td>Device sizes are 4, 5, 6 mm</td></tr>
<tr><td>Filter Materials</td><td colspan="3">• (b) (4)
• (b) (4)
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• (b) (4)
• (b) (4)
• (b) (4)</td><td>N/A</td></tr>
<tr><td>Filter Design</td><td colspan="3">Eccentric</td><td>N/A</td></tr>
<tr><td>Recommended Distance Between Lesion and Filter</td><td>2.0 cm</td><td colspan="2">1.5 cm</td><td>N/A</td></tr>
</table>

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Indications for Use Statement

510(k) Number (if known): K111010

Device Name: SpiderFX® Embolic Protection Device

Indications for Use:

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk in the treatment of severely calcified lesions in arteries of the lower extremities.

SpiderFX also is indicated as a guidewire and embolic protection system to contain and remove embolic material during percutaneous transluminal angioplasty (PTA) and stent procedures of severely calcified lesions in superficial femoral and popliteal arteries. The vessel diameter at the filter basket placement site should be between 3.0mm and 6.0mm.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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510(k) Summary

SpiderFX® Embolic Protection Device

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R § 807.92.

1. Submitter Information

Applicant	ev3 Inc. 3033 Campus Drive Plymouth, MN 55441-2651 Tel: 763-398-7000 Fax: 763-591-3248
Contact Person	Brenda Johnson Principal Regulatory Affairs Specialist
Date Prepared	September 30, 2011

2. Subject Device

Device Trade Name	SpiderFX® Embolic Protection Device
Device Common Name	Embolic Protection Device
Classification Name	Temporary Carotid Catheter for Embolic Capture 21 CFR 870.1250, Product Code NTE
Classification Panel	Cardiovascular

3. Predicate Devices

Device Trade Name	SpiderFX® Embolic Protection Device; SpideRX® Embolic Protection Device Angioslide eXtra™ PTA Balloon Catheter with Embolic Capture Feature
510(k) Number	K063204; K052659; K090364
510(k) Clearance Date	November 14, 2006; February 17, 2006; March 23, 2010

4. Device Description

The SpiderFX® Embolic Protection Device is a percutaneously delivered distal embolic protection system that can be delivered over any 0.014" or 0.018" guidewire. The SpiderFX Embolic Protection Device contains a Capture Wire composed of a nitinol mesh filter mounted on a 190 cm or a convertible 320/190 cm PTFE-coated 0.014" stainless steel guidewire and a dual-ended SpiderFX Catheter for delivery and recovery. The SpiderFX® Embolic Protection Device uses the following materials: pebax, grilamid, platinum/iridium, nitinol, stainless steel, PTFE coating, gold tungsten, and hydrophilic coating.

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5. Indications for Use

The SpiderFX® Embolic Protection Device is indicated for use as a guidewire and embolic protection system to contain and remove embolic material in conjunction with the TurboHawk in the treatment of severely calcified lesions in arteries of the lower extremities.

SpiderFX also is indicated as a guidewire and embolic protection system to contain and remove embolic material during percutaneous transluminal angioplasty (PTA) and stent procedures of severely calcified lesions in superficial femoral and popliteal arteries. The vessel diameter at the filter basket placement site should be between 3.0mm and 6.0mm.

6. Comparison of Technological Characteristics

The SpiderFX® Embolic Protection Device is the identical device as the currently marketed SpiderFX Embolic Protection Device (K063204). The SpiderFX Embolic Protection Device for peripheral use and the predicate SpiderFX Embolic Protection Device for carotid use share the following technological characteristics:

- Intended use
- Fundamental scientific technology and operating principle
- Design & Dimensions
- Materials
- Manufacturing site and methods
- Sterilization site, method, parameters, and sterility assurance level
- Packaging
- Shelf Life

Additionally, the Indications for Use, labeling, and Instructions For Use are similar between the proposed and marketed devices. The differences include a revised sizing matrix for use during interventions in lower extremity vessels, allowing use of the SpiderFX Device with atherectomy interventional devices, and allowing use of commercially available catheters, that are minimally 0.035" guide wire compatible, for delivery and/or recovery of the SpiderFX Capture Wire. Bench and animal testing was performed to demonstrate the proposed use of the device met pre-determined acceptance criteria.

7. Biocompatibility Testing

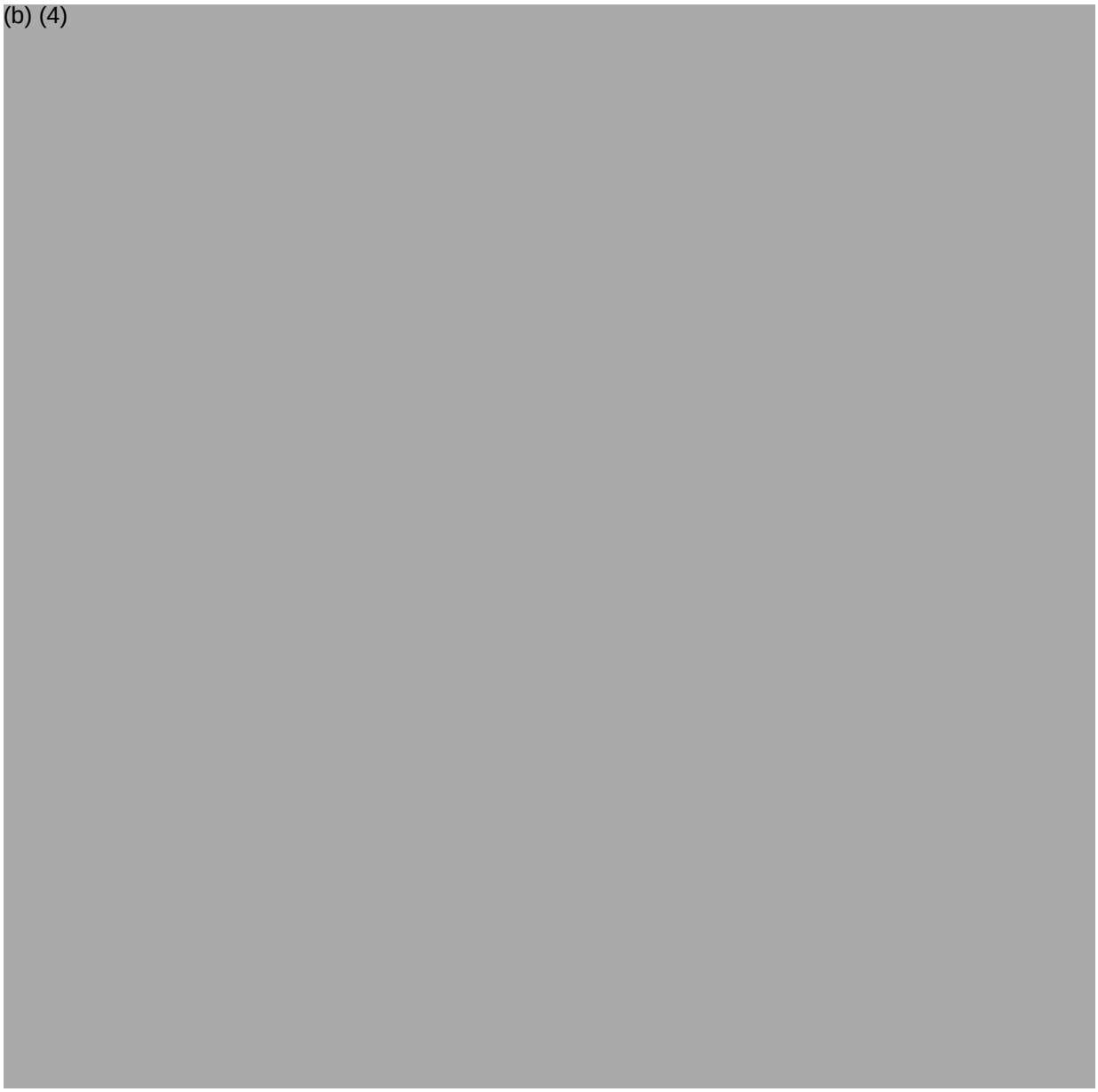
Device materials in the proposed SpiderFX® Embolic Protection Device are identical to the materials in the commercially available SpiderFX® and SpideRX® Embolic Protection Devices. Biocompatibility testing was leveraged from the predicate SpiderFX® and SpideRX® Embolic Protection Device submissions and included cytotoxicity, sensitization, intracutaneous injection, systemic injection, hemolysis, pyrogen, complement activation, and thrombogenicity. The SpideRX Catheter and Capture Wire from the predicate SpideRX Device (K052659) meet the requirements for biocompatibility testing outlined in ISO 10993-1 Part 1: 2003 "Biological Evaluation of Medical Devices".

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8. Performance Testing Summary

(b) (4)



9. Clinical Summary

(b) (4)



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(b) (4)

[redacted]

10. Conclusions

Based on the intended use, technological characteristics, safety and performance testing included in this submission, ev3 considers the proposed SpiderFX® Embolic Protection Device to be substantially equivalent to its predicates.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118