K112860
PAGE 1 OF 2

3 510(k) Summary

JUN - 8 2012

510(k) Owner/SUBMITTER	Coloplast A/S Holtedam 1 3050 Humlebaek - Denmark
CONTACT PERSON	Brian Schmidt Coloplast Corp 1601 West River Road North Minneapolis, Minnesota 55411 USA
DATE PREPARED	29 September 2011
CLASSIFICATION	Gastrointestinal tube & accessories 876.5980 Class II Enema kit 876.5210 Class I (Exempt)
COMMON NAME	Rectal Catheter and Accessories; Enema Kit
PROPRIETARY NAME	Peristeen™ Anal Irrigation
PREDICATE DEVICE	K083770, K103254
DEVICE DESCRIPTION	The Peristeen™ Anal Irrigation system is a Class II device, consisting of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times.
INDICATIONS	The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures. Peristeen™ Anal Irrigation is a prescriptive device and should only be prescribed by a licensed physician. Peristeen™ Anal Irrigation has the same indications as the predicate device.
TESTING	The Peristeen rectal catheter has been subjected to biocompatibility and mechanical testing and is

	substantially equivalent to the predicate Peristeen device (K083770, K103254).
TECHNOLOGICAL CHARACTERISTICS	The Peristeen rectal catheter has the same intended use, general design, and fundamental scientific technology as the predicate Peristeen rectal catheter.
SUMMARY OF THE NONCLINICAL TESTS SUBMITTED	In vitro (bench) tests; flexibility, flow rate, balloon inflation, balloon peak pressure, burst diameter/volume, biocompatibility
SUMMARY OF CLINICAL TESTS SUBMITTED (AS APPLICABLE)	Not applicable
CONCLUSIONS DRAWN FROM THE NONCLINICAL AND CLINICAL TESTS	Substantial equivalence of the Peristeen Rectal Catheter is supported by a comparison of the design and intended use compared to the predicate, as well as acceptable results from functional performance and biocompatibility testing.

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

Coloplast A/S
% Mr. Brian Schmidt
Regulatory Affairs Manager
Coloplast Corp
1601 West River Rd North
MINNEAPOLIS MN 55411

JUN - 8 2012

Re: K112860
Trade/Device Name: Peristeen™ Anal Irrigation System
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: May 24, 2012
Received: May 25, 2012

Dear Mr. Schmidt:

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. We remind you, however, 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.

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,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2 Statement of Indications for Use

Indications for Use

510(k) Number (if known): K112860

Device Name: Peristeen™ Anal Irrigation System

Indications for Use:

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Prescription Use ___X___ Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112860

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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% Mr. Brian Schmidt
Regulatory Affairs Manager
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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K112860

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

May 25, 2012

COLOPLAST A/S
C/O COLOPLAST CORP
1601 WEST RIVER ROAD NORTH
MINNEAPOLIS, MINNESOTA 55411
ATTN: BRIAN SCHMIDT

510k Number: K112860

Product: PERISTEEN ANAL IRRIGATION SYST

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

Grayson, Giovanna *

From: Microsoft Outlook
To: 'usbes@coloplast.com'
Sent: Friday, May 25, 2012 11:32 AM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'usbes@coloplast.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

39

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Friday, May 25, 2012 11:31 AM
To: 'usbes@coloplast.com'
Subject: ack letter
Attachments: image002.png

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

May 25, 2012
SCHMIDT
BRIAN
COLOPLAST A/S
C/O COLOPLAST CORP
1601 WEST RIVER ROAD NORTH
MINNEAPOLIS, MINNESOTA 55411
ATTN: BRIAN SCHMIDT

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510(k) Staff

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

March 13, 2012

COLOPLAST A/S
C/O COLOPLAST CORP
1601 WEST RIVER ROAD NORTH
MINNEAPOLIS, MINNESOTA 55411
ATTN: BRIAN SCHMIDT

510k Number: K112860
Product: PERISTEEN ANAL IRRIGATION SYST

Extended Until: 08/14/2012

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

1284

Mcdonald, Lisa *

From: Microsoft Outlook
To: 'usbes@coloplast.com'
Sent: Tuesday, March 13, 2012 4:00 PM
Subject: Relayed: K112860 Extension Letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'usbes@coloplast.com'

Subject: K112860 Extension Letter

Sent by Microsoft Exchange Server 2007

125

March 12, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
ATTN: Dr. Martin Golding

RE: Original 510(k) Application
Peristeen Anal Irrigation System (510k K112860)

Dear Dr. Golding,

Coloplast A/S hereby submits this request for an extension of six months to provide the additional information related to the Peristeen Anal Irrigation System 510(k). This information was requested for 510(k) K112860 in a letter dated February 16, 2012.

This request is provided in duplicate.

Coloplast considers the existence and contents of this submission to be confidential and exempt from public disclosure.

Please contact me for questions or if you need further information.

Best regards,

Brian Schmidt
Regulatory Affairs Manager
Phone: 612.302.4987
Fax: 612.287.4138
Email: usbes@coloplast.com

42

March 12, 2012

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
ATTN: Dr. Martin Golding

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Best regards,

Brian Schmidt
Regulatory Affairs Manager
Phone: 612.302.4987
Fax: 612.287.4138
Email: usbes@coloplast.com

43

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

FEB 16 2012

Coloplast A/S
% Mr. Brian Schmidt
Regulatory Affairs Manager
Coloplast Corporation
1601 West River Road North
MINNEAPOLIS MN 55411

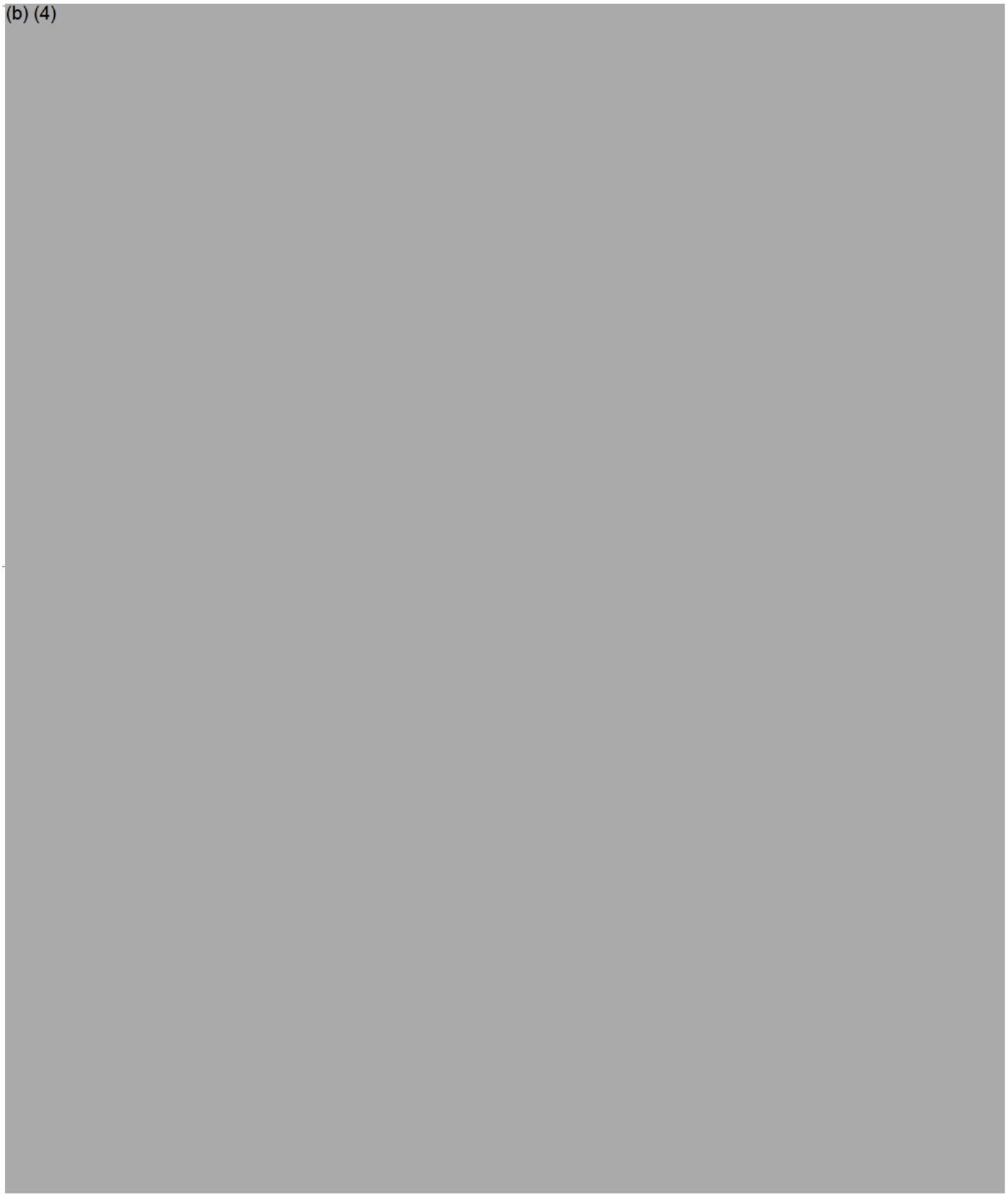
Re: K112860
Trade Name: Peristeen™ Anal Irrigation System
Dated: January 6, 2012
Received: January 9, 2012

Dear Mr. Schmidt:

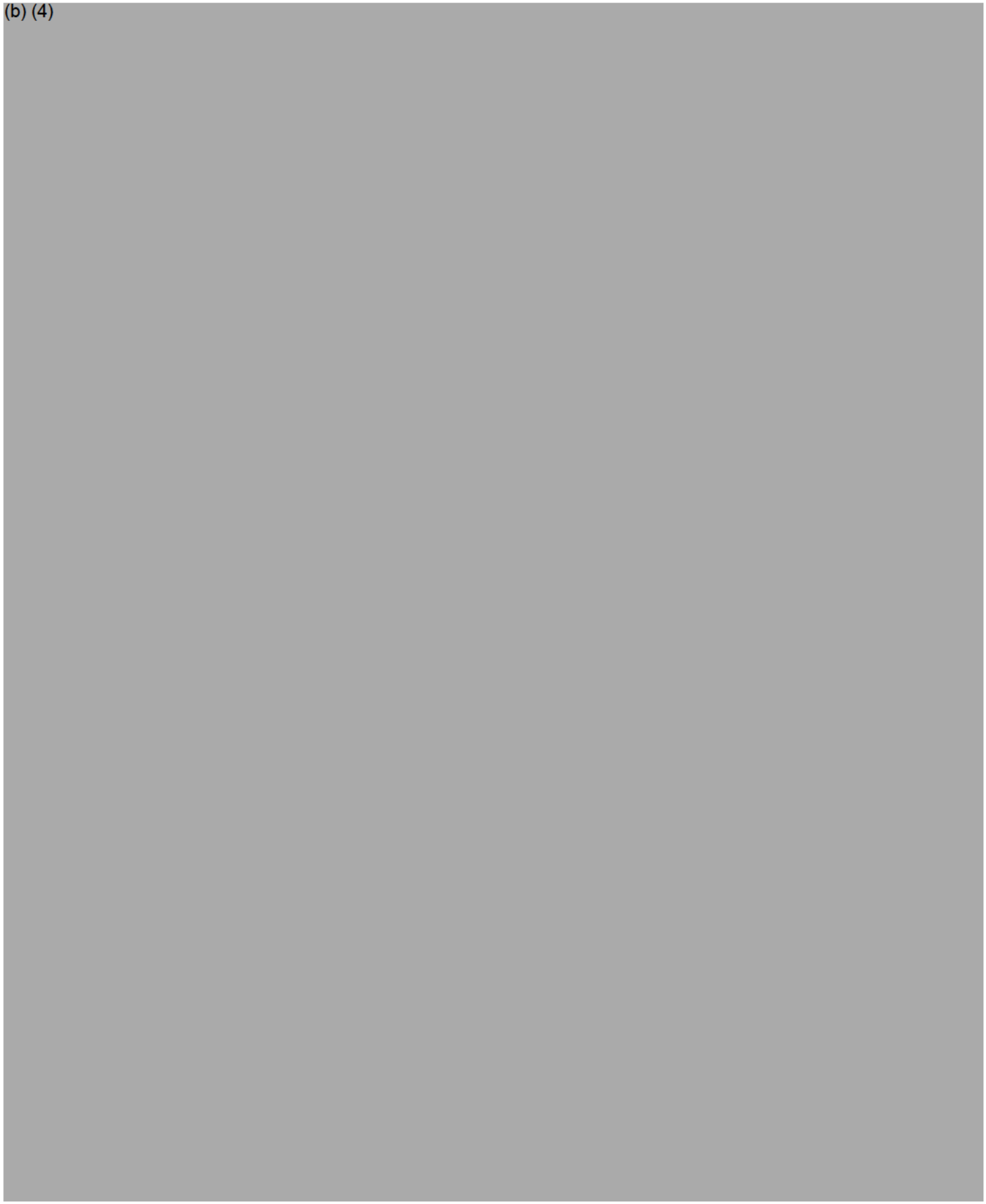
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above. We cannot determine if the device is substantially equivalent to a legally marketed predicate device based solely on the information provided. To complete the review of your submission, we require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

(b) (4)

(b) (4)



(b) (4)



(b) (4)

[redacted]

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 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, "Guidance for Industry and FDA Staff: FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm

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 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 Martin Golding, M.D. at (301) 796-2935. If you need information or assistance concerning the IDE regulations, please

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

Sincerely yours,

Carolyn Y Neuland

Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and
Renal Devices Branch
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

FEB 16 2012

K112860 – Coloplast A/S

cc: DMC
ODE - DRGUD/GRDB – Martin I. Golding

Draft:MGolding:mg:2/7/2012
Final:FMEba:fme:2/7/2012

Division/Branch	Last Name	Date
ODE/ORS		2/14/12
DRGUD/GRDB	Neuland	2/15/12

COMMUNICATION RESULT REPORT (FEB. 21. 2012 9:57AM)

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : FEB. 21. 2012 9:57AM FILE MODE	OPTION	ADDRESS	RESULT	PAGE
MEMORY TX		POTS modem 2	E-1) 3) 1) 1) 1)	0/5

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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10903 New Hampshire Avenue
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FEB 16 2012

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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

January 09, 2012

COLOPLAST A/S
C/O COLOPLAST CORP
1601 WEST RIVER ROAD NORTH
MINNEAPOLIS, MINNESOTA 55411
ATTN: BRIAN SCHMIDT

510k Number: K112860

Product: PERISTEEN ANAL IRRIGATION SYST

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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

97

Grayson, Giovanna *

From: Microsoft Outlook
To: 'usbes@coloplast.com'
Sent: Monday, January 09, 2012 11:46 AM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'usbes@coloplast.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

98

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Monday, January 09, 2012 11:46 AM
To: 'usbes@coloplast.com'
Subject: ack letter
Attachments: image002.png

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

January 09, 2012
SCHMIDT
BRIAN
COLOPLAST A/S
C/O COLOPLAST CORP
1601 WEST RIVER ROAD NORTH
MINNEAPOLIS, MINNESOTA 55411
ATTN: BRIAN SCHMIDT

510k Number: K112860

Product: PERISTEEN ANAL IRRIGATION SYST

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. Please remember 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.

99

Sincerely,

510(k) Staff

100

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

December 02, 2011

COLOPLAST A/S
C/O COLOPLAST CORP
1601 WEST RIVER ROAD NORTH
MINNEAPOLIS, MINNESOTA 55411
ATTN: BRIAN SCHMIDT

510k Number: K112860
Product: PERISTEEN ANAL IRRIGATION SYST

Extended Until: 05/02/2012

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

K15

November 30, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
ATTN: Dr. Martin Golding

RE: Original 510(k) Application
Peristeen Anal Irrigation System (510k K112860)

Dear Dr. Golding,

Coloplast A/S hereby submits this request for an extension of six months to provide the additional information related to the Peristeen Anal Irrigation System 510(k). This information was requested via fax for 510(k) K112860 in a letter dated October 04, 2011. It was noted to Dr. Golding (via email correspondence on November 15, 2011) that although the letter was dated October 4, 2011, Coloplast did not receive the letter until November 7, 2011; therefore, the assumption was made that the date stamp on the letter most likely should have been November 4, 2011.

This request is provided in duplicate.

Coloplast considers the existence and contents of this submission to be confidential and exempt from public disclosure.

Please contact me for questions or if you need further information.

Best regards,

Brian Schmidt
Regulatory Affairs Manager
Phone: 612.302.4987
Fax: 612.287.4138
Email: usbes@coloplast.com

102

November 30, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
ATTN: Dr. Martin Golding

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Regulatory Affairs Manager
Phone: 612.302.4987
Fax: 612.287.4138
Email: usbes@coloplast.com

103

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Coloplast A/S
% Mr. Brian Schmidt
Regulatory Affairs Manager
Coloplast Corporation
1601 West River Road North
MINNEAPOLIS MN 55411

OCT 0 4 2011

Re: K112860
Trade Name: Peristeen™ Anal Irrigation System
Dated: September 29, 2011
Received: September 30, 2011

Dear Mr. Schmidt:

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 the following additional information.

(b) (4)

L04

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 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

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.

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 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 Dr. Martin Golding at (301) 796-5590. If you need information or assistance concerning the IDE regulations, please 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,

Carolyn Y Neuland

Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and Renal Devices Branch
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

FAX HEADER 1:
FAX HEADER 2:

TRANSMITTED/STORED : NOV. 7. 2011 9:31AM FILE MODE	OPTION	ADDRESS	RESULT	PAGE
0598 MEMORY TX		POTS modem 1	OK	3/3

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Coloplast A/S
% Mr. Brian Schmidt
Regulatory Affairs Manager
Coloplast Corporation
1601 West River Road North
MINNEAPOLIS MN 55411

OCT 0 4 2011

Re: K112860
Trade Name: Peristeen™ Anal Irrigation System
Dated: September 29, 2011
Received: September 30, 2011

Dear Mr. Schmidt:

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 the following additional information.

(b) (4)

K112860 – Coloplast A/S

cc: DMC
ODE – DRGUD/GRDB – MartinXGolding

Draft:MXGolding:mxg:11.3.2011
FINAL:FMEba:fme:11/4/2001

Div/Branch	Last Name	Date	Div/Branch	Last Name	Date
ODE/GRDB	Golding	11/8/11			
DRGUD/GRDB	Neuland	11/4/11			

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 30, 2011

COLOPLAST A/S
C/O COLOPLAST CORP
1601 WEST RIVER ROAD NORTH
MINNEAPOLIS, MINNESOTA 55411
ATTN: BRIAN SCHMIDT

510k Number: K112860
Received: 9/30/2011
Product: PERISTEEN ANAL IRRIGATION SYST

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

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

Grayson, Giovanna *

From: Microsoft Exchange
To: 'usbes@coloplast.com'
Sent: Friday, September 30, 2011 3:14 PM
Subject: Relayed: ack letter

Delivery to these recipients or distribution lists is complete, but delivery notification was not sent by the destination:

'usbes@coloplast.com'

Subject: ack letter

Sent by Microsoft Exchange Server 2007

128

Grayson, Giovanna *

From: Grayson, Giovanna *
Sent: Friday, September 30, 2011 3:14 PM
To: 'usbes@coloplast.com'
Subject: ack letter
Attachments: image002.png

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 30, 2011

SCHMIDT
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C/O COLOPLAST CORP
1601 WEST RIVER ROAD NORTH
MINNEAPOLIS, MINNESOTA 55411
ATTN: BRIAN SCHMIDT

510k Number: K112860
Received: 9/30/2011
Product: PERISTEEN ANAL IRRIGATION SYST

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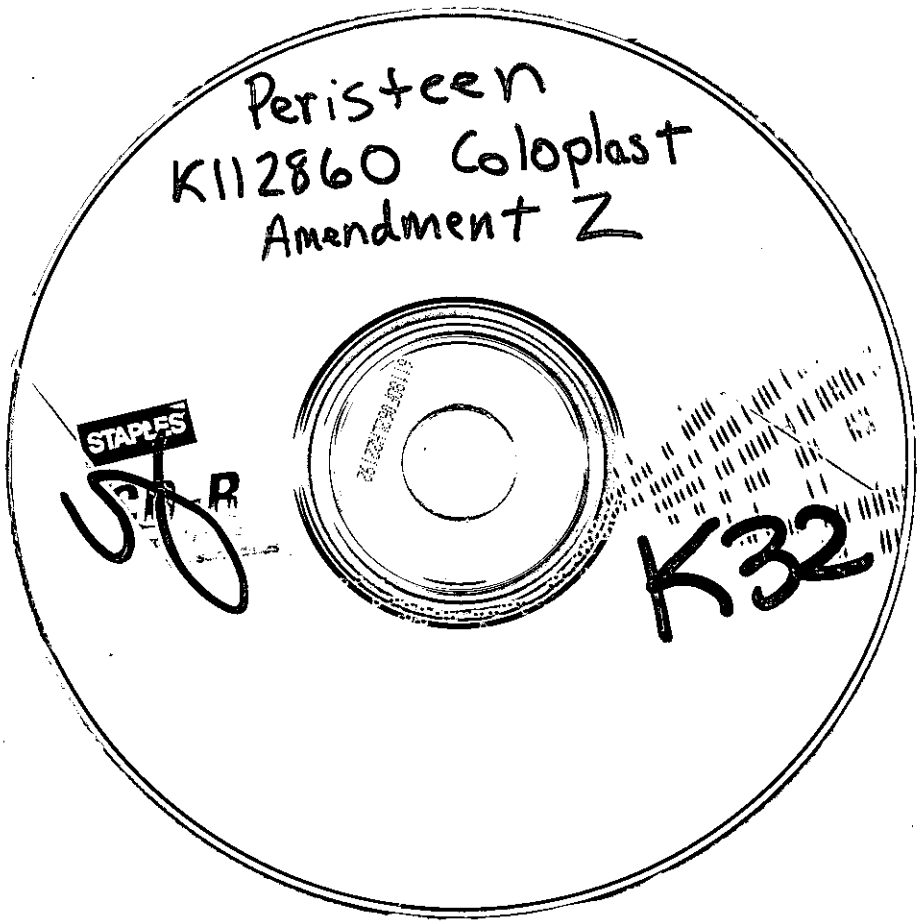
Sincerely,

510(k) Staff

130



K112860

GO / DRGUD

September 29, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

VS

FDA CDRH DMC
SEP 30 2011
Received

RE: **Special 510(k): Device Modification**
Peristeen Anal Irrigation
Originally cleared under K083770 and K103254

Dear Madam/Sir:

Coloplast hereby submits this Special 510(k) Device Modification in duplicate to request clearance for a modification to our Peristeen Anal Irrigation Rectal Catheter. The Peristeen device was originally cleared on November 23, 2009 under K083770 and on January 31, 2011 under K103254. The proposed modifications are outlined as follows:

- Change in design and materials of the regular rectal catheter
- Update of the Instructions for Use

Required information for the Special 510k cover letter is provided below:

Submitter name/address:	Coloplast A/S Holtedam 1 Humlebaek 3050, Denmark
Contact name:	Brian Schmidt
Phone & fax numbers:	612.302.4987 (phone); 612.287.4138 (fax)
510(k) owner:	Coloplast A/S
Establishment registration #:	9610694
Common name:	Rectal Catheter and Accessories; Enema Kit
Trade name:	Peristeen™ Anal Irrigation System
Model number(s):	29121, 29122, 29123
Classification name/number:	876.5980 Gastrointestinal tube & accessories Class II and 876.5210 Enema kit Class I (Exempt)
Product code:	KNT and FCE
Legally marketed predicate	Peristeen™ Anal Irrigation System (K083770, K103254)

We believe that this change is eligible for review as a Special 510(k): Device Modification since the modified device has the same fundamental scientific technology and intended use as the predicate device.

Two (2) paper copies of this submission have been provided. In lieu of one (1) paper copy, Coloplast also provides an electronic version copied to CD-ROM as per FDA's instructions, "Electronic Copies for Pre-Market Submissions" dated March 5, 2007. The electronic copy is an exact duplicate of the paper copy.

If you have any questions regarding this submission, please contact me via the information provided below.

Sincerely,

Brian E. Schmidt
Manager, Regulatory Affairs
Coloplast Corp.
1601 West River Road North
Minneapolis, MN 55411
Telephone: (612) 302-4987
Fax: (612) 287-4138
Email: usbcs@coloplast.com

September 29, 2011

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850

RE: **Special 510(k): Device Modification**
Peristeen Anal Irrigation
Originally cleared under K083770 and K103254

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Common name:	Rectal Catheter and Accessories; Enema Kit
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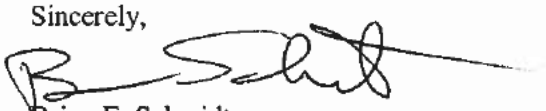
Sincerely,



Brian E. Schmidt
Manager, Regulatory Affairs
Coloplast Corp.
1601 West River Road North
Minneapolis, MN 55411
Telephone: (612) 302-4987
Fax: (612) 287-4138
Email: usbes@coloplast.com

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) COLOPLAST CORP 1601 West River Road N Minneapolis MN 55411 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****8988	2. CONTACT NAME Elizabeth Boots 2.1 E-MAIL ADDRESS usbb@coloplast.com 2.2 TELEPHONE NUMBER (include Area code) 612-302-4992 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 612-287-4138

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:	3.1 Select a center
[X] Premarket notification(510(k)); except for third party	[X] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[X] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 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	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] 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) 06-Sep-2011

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 9010-0120
Expiration Date: August 31, 2010.
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number (if known)
9/29/2011	(b) (4)	TBD

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)*		
Coloplast A/S	(b) (4)		
Division Name *(if applicable)*	Phone Number *(including area code)*		
Coloplast Corp	(612) 302-4987		
Street Address	FAX Number *(including area code)*		
Holtedam 1	(612) 287-4138		
City	State / Province	ZIP/Postal Code	Country
3050 Humlebaek	NA	NA	Denmark
Contact Name			
Elizabeth Boots			
Contact Title	Contact E-mail Address		
VP, US Regulatory Affairs	usbb@coloplast.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
Coloplast Corp			
Division Name *(if applicable)*	Phone Number *(including area code)*		
Coloplast Manufacturing US, LLC	(612) 302-4987		
Street Address	FAX Number *(including area code)*		
1601 West River Rd North	(612) 287-4138		
City	State / Province	ZIP/Postal Code	Country
Minneapolis	MN	55411	USA
Contact Name			
Brian Schmidt			
Contact Title	Contact E-mail Address		
Regulatory Affairs Manager	usbes@coloplast.com		

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ 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
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance
  - ☐ 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

- ☐ Repose 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):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	KNT	2	FCE	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	K083770	1	Peristeen Anal Irrigation System	1	Coloplast A/S
2	K103254	2	Peristeen Anal Irrigation System	2	Coloplast A/S
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

876.5980 Gastrointestinal tube & accessories; 876.5210-Enema Kit

	Trade or Proprietary or Model Name for This Device		Model Number
1	Peristeen Anal Irrigation System	1	29121
2	Peristeen Anal Irrigation Accessory Unit	2	29122
3	Peristeen Anal Irrigation Rectal Catheter	3	29123
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data Included in Submission

☒ Laboratory Testing ☐ Animal Trials ☐ Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code
KNT

C.F.R. Section *(if applicable)*
21 CFR 876.1500 Gastroenterology-Urology Devices

Classification Panel

Device Class

☐ Class I ☒ Class II
☐ Class III ☐ Unclassified

Indications *(from labeling)*

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

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)* TBD

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 Coloplast A/S		Establishment Registration Number (b) (4)
Division Name *(if applicable)*		Phone Number *(including area code)* ( ) +45 4911 2418
Street Address Holtedam 1		FAX Number *(including area code)* ( ) +45 4911 1310
City 3050 Humlebaek	State / Province NA	ZIP/Postal Code NA / Country Denmark
Contact Name Brian Schmidt	Contact Title Regulatory Affairs Manager	Contact E-mail Address usbes@coloplast.com

☐ 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/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address

☐ 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/Postal Code / Country
Contact Name	Contact Title	Contact E-mail Address

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.					
1	Standards No.	Standards Organization	Standards Title See Section 8 and Standards forms provided in Attachment 1 of this 510(k) for a summary of standards referenced in this submission.	Version	Date
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:

Food and Drug Administration
CDRH (HFZ-342)
9200 Corporate Blvd.
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

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
Coloplast A/S

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
Sep 29, 2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
Holtedam 1
Humlebaek 3050
Denmark

4. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 612.302.4987
(Fax) 612.287.4138

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)

Trade name: Peristeen Anal Irrigation System

Classification name: Gastrointestinal Tube & Accessories

Classification number: 21CFR 876.5980

Model numbers: 29121, 29122, 29123

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):

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)

12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11
(Name) Brian Schmidt
(Title) Regulatory Affairs Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12)*
1601 West River Road N
Minneapolis, Minnesota 55431 USA

14. TELEPHONE AND FAX NUMBERS *(Include Area Code)*
(Tel.) 612 302 4987
(Fax) 612 287 4138

15. DATE OF CERTIFICATION
09/29/2011

Form FDA 3674 (11/08) (FRONT)

PSC Graphics (301) 443-1090 EF

Application for a Special 510(k): Device Modification

Peristeen

Submitted By:

Brian Schmidt

September 29, 2011

Table of Contents

1 Screening Checklist

1 Screening Checklist

for all Premarket Notification [510(k)] Submissions

510(k) Number: _____

The cover letter clearly identifies the type of 510(k) submission as **(Check the appropriate box)**:

X	**Special 510(k) -**	**Do Sections 1 and 2**
☐	Abbreviated 510(k) -	Do Sections 1, 3 and 4
☐	Traditional 510(k) or no identification provided -	Do Sections 1 and 4

Section 1: Required Elements for All Types of 510(k) submissions:

	Present or Adequate	Missing or Inadequate
Cover letter, containing the elements listed on page 3-2 of the Premarket Notification [510)] Manual.	☑ Page 1-2	
Table of Contents.	☑ Page 11	
Truthful and Accurate Statement.	☑ Page 20	
Device's Trade Name, Device's Classification Name and Establishment Registration Number.	☑ Page 1,17	
Device Classification Regulation Number and Regulatory Status (Class I, Class II, Class III or Unclassified).	☑ Page **17**	
Proposed Labeling, including the material listed on page 3-4 of the Premarket Notification [510)] Manual.	☑ Page **27**	
Statement of Indications for Use that is on a separate page in the premarket submission.	☑ Page **16**	
Substantial Equivalence Comparison, including comparisons of the new device with the predicate in areas that are listed on page 3-4 of the Premarket Notification [510)] Manual.	☑ Page 23-24	
~~510(k) Summary or 510(k) Statement~~.	☑ Page **17**	
Description of the device (or modification of the device) including diagrams, engineering drawings, photographs or service manuals.	☑ Page **22**	
Identification of legally marketed predicate device. *	☑ Page **17**	
Compliance with performance standards. * [See Section 514 of the Act and 21 CFR 807.87 (d).]	☑ Page **19**	
Class III Certification and Summary. **		☑ - NA, Page
Financial Certification or Disclosure Statement for 510(k) notifications with a clinical study. * [See 21 CFR 807.87 (i)]		☑ - NA, Page
510(k) Kit Certification ***		☑ - NA

*May not be applicable for Special 510(k)s.
**Required for Class III devices, only.
***See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

Section 2: Required Elements for a SPECIAL 510(k) submission:

	Present	Inadequate or Missing
Name and 510(k) number of the submitter's own, unmodified predicate device.	Page 17	
A description of the modified device and a comparison to the sponsor's predicate device.	Pages 23-24	
A statement that the intended use(s) and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the submitter's unmodified predicate device.	Pages 17,27	
Reviewer's confirmation that the modification has not altered the fundamental scientific technology of the submitter's predicate device.	TBD	
A Design Control Activities Summary that includes the following elements (a-c):		
a. Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.	Page 28	
b. Based on the Risk Analysis, an identification of the required verification and validation activities, including the methods or tests used and the acceptance criteria to be applied.	Pages 29-32	
c. A Declaration of Conformity with design controls that includes the following statements:		
A statement that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results of the activities demonstrated that the predetermined acceptance criteria were met. This statement is signed by the individual responsible for those particular activities.	Attachment G	
A statement that the manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review. This statement is signed by the individual responsible for those particular activities.	Attachment G	

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:
******Not Applicable******

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity **[**For a listing of the required elements of a declaration of conformity, **SEE Required Elements for a Declaration of Conformity to a Recognized Standard,** which is posted with the 510(k) boilers on the **H drive.]**		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

Not Applicable

*When completing the review of an abbreviated 510(k), please fill out an Abbreviated Standards Data Form (located on the H drive) and list all the guidance documents, special controls, recognized standards and/or non-recognized standards, which were noted by the sponsor.

Section 4: Additional Requirements for ABBREVIATED and TRADITIONAL 510(k) submissions (If Applicable):

	Present	Inadequate or Missing
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:		
b) Sterilization and expiration dating information:		
i) sterilization process		
ii) validation method of sterilization process		
iii) SAL		
iv) packaging		
v) specify pyrogen free		
vi) ETO residues		
vii) radiation dose		
viii) Traditional Method or Non-Traditional Method		
c) Software Documentation:		

Not Applicable

Items with checks in the Present or Adequate column do not require additional information from the sponsor. Items with checks in the Missing or Inadequate column must be submitted before substantive review of the document.

Passed Screening _____Yes _____No

Reviewer:_____

Concurrence by Review Branch:_____

Date:_____

2 Statement of Indications for Use

Indications for Use

510(k) Number (if known): _____

Device Name: Peristeen™ Anal Irrigation System

Indications for Use:

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Prescription Use ___**X**____ Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) AND/OR (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

3 510(k) Summary

510(k) Owner/SUBMITTER	Coloplast A/S Holtedam 1 3050 Humlebaek - Denmark
CONTACT PERSON	Brian Schmidt Coloplast Corp 1601 West River Road North Minneapolis, Minnesota 55411 USA
DATE PREPARED	29 September 2011
CLASSIFICATION	Gastrointestinal tube & accessories 876.5980 Class II Enema kit 876.5210 Class I (Exempt)
COMMON NAME	Rectal Catheter and Accessories; Enema Kit
PROPRIETARY NAME	Peristeen™ Anal Irrigation
PREDICATE DEVICE	K083770, K103254
DEVICE DESCRIPTION	The Peristeen™ Anal Irrigation system is a Class II device, consisting of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times.
INDICATIONS	The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures. Peristeen™ Anal Irrigation is a prescriptive device and should only be prescribed by a licensed physician. Peristeen™ Anal Irrigation has the same indications as the predicate device.
TESTING	The Peristeen rectal catheter has been subjected to biocompatibility and mechanical testing and is

	substantially equivalent to the predicate Peristeen device (K083770, K103254).
TECHNOLOGICAL CHARACTERISTICS	The Peristeen rectal catheter has the same intended use, general design, and fundamental scientific technology as the predicate Peristeen rectal catheter.
SUMMARY OF THE NONCLINICAL TESTS SUBMITTED	In vitro (bench) tests; flexibility, flow rate, balloon inflation, balloon peak pressure, burst diameter/volume, biocompatibility
SUMMARY OF CLINICAL TESTS SUBMITTED (AS APPLICABLE)	Not applicable
CONCLUSIONS DRAWN FROM THE NONCLINICAL AND CLINICAL TESTS	Substantial equivalence of the Peristeen Rectal Catheter is supported by a comparison of the design and intended use compared to the predicate, as well as acceptable results from functional performance and biocompatibility testing.

4 Standards Data Report for 510(k) – FDA 3654

See Attachment A

5 Truthful and Accurate Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as Regulatory Affairs Manager of Coloplast A/S, 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.

Brian Schmidt

9-29-11

Date

Premarket Notification 510(k) Number

6 Class III Certification and Summary (*if applicable)*

Since this 510(k) does not pertain to a Class III device, the referenced Certification is not applicable to this application.

7 Device Description

The Peristeen™ Anal Irrigation system is a Class II device, consisting of a single-use rectal catheter with a balloon for retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the rectal catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times.

A picture of the current catheter can be found in **Figure 1.**

Figure 1: Current Peristeen Catheter

A picture of the proposed catheter can be found in **Figure 2.**

Figure 2: Proposed Peristeen Catheter

8 Comparison to the Predicate Device

Current (predicate) Device (K083770, K103254):

The design of the proposed Peristeen catheter is in principle similar to the predicate Peristeen catheter except for the choice of materials and changes in some of the production processes. The catheter and balloon materials are changing for polyvinyl chloride (PVC) and chloroprene to (b) (4) . The balloon material is extruded for the new catheter instead of dip molded for the predicate catheter. The new raw catheter is 2K injection molded instead of dip molded as the predicate catheter, and the balloon is welded to the new catheter instead of glued as in the existing catheter. The coating and packaging processes will remain unchanged.

Engineering drawings for the predicate Peristeen catheter are provided in **Attachment B**.

Modified Device:

Proposed modifications to the Peristeen rectal catheter are as follows:

Table 1. Materials

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	**Modified Peristeen This 510(k)**
Catheter Material	PVC (polyvinyl chloride)	(b) (4)
Balloon Material	Chloroprene	
Lubricious coating: - Top coating - Base coating	(b) (4) (b) (4)	

Table 2: Production Processes

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	**Modified Peristeen This 510(k)**
Balloon material	Dip molded	(b) (4)
Rectal Catheter	Dip molded	
Balloon to Catheter attachment	Glued	

Table 3: Other Device Characteristics

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	**Modified Peristeen This 510(k)**
Catheter Length	5.52 in	(b) (4)
Sterility	Non Sterile	
Packaging	Plastic Pouch	
Shelf Life	1.5 years	

Updated engineering drawings for the Peristeen rectal catheter are provided in **Attachment C**.

Other Changes Implemented

Changes made and documented via Letter to File/Change Control are as follows:

Change Made/Date	Reason	Justification for Change
Production of the double lumen tube is transferred from Coloplast A/S (Denmark) to Contract Manufacturer Prozup (Taiwan)	Switch from in-house production to contract manufacturer	Change Control no. LQUG-7LXDFE
Production of the water bag is transferred from Duoplast A/S (Denmark) to Coloplast A/S (Hungary)	Switch from contract manufacturer to in house production	Change Control no. RCHN-7NQC3T
Change in excess pressure valve and lid assembly	This minor adjustment in the specification limits reflects a slight decrease in pressure over time. This small decrease is acceptable because it cannot be detected by the patient and it does not affect the function of the device.	Change Control no. LLAN-7NWBYH LLAN-7NWCFY LLAN-7P5G6B LLAN-7P5GM5
Change in material of the hand pump	The PVC blend used for the hand pump black ball on the PAI control unit will be changed due to material discontinuation at the supplier. The new material (b) (4) has the same formulation as the current material ((b) (4)	Change Control no. TTOP-84GCK3

9 Intended Use

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

10 Proposed Labeling

The following Peristeen Labeling has been modified

- IFU
- Physician Instruction For Use (now called Training Guide for Health Care Professionals)
- Peristeen User Guide.

The modifications include additions/updates to the Contraindications and Precautions sections in the labeling along with the addition of new pictures of the catheter. A summary of the updated contraindications and precautions can be found below:

Contraindications

- Added "Complex diverticular disease"
- Added "Abdominal or anal surgery within the last 3 months"
- Removed "During the spinal shock phase" (which is now a precaution)

Precautions

- Added "Ischemic colitis"
- Added "Recent colonic biopsy or polypectomy"
- Added "Diverticular disease"
- Added "Spinal Cord Shock phase"
- Added "Cancer in the abdominal or pelvic region"
- Added "Fecal impaction"
- Added "Long Term steroid therapy"
- Added "Children under 2 years of age"
- Added "Severe cognitive impairment (unless caregiver is available to supervise/administer)

The changes to the "Contraindications" and "Precaution" statements in the Peristeen labeling are not a direct result of the design/material changes being presented in this Special 510(k). Since there are changes being made to the IFU to add new pictures of the catheters, it was decided to modify the contraindications and precautions to better align the labeling with the risk analysis.

A copy of the predicate Peristeen labeling (Instructions for Use, Physician Instruction for Use, Peristeen User Guide) is provided as **Attachment D**.

A copy of the proposed Peristeen labeling (Instructions for Use, Training Guide for HealthCare Professionals, Peristeen User Guide) is provided as **Attachment E.**

11 Summary of Design Control activities

11.1 Risk Analysis Summary

The risk analysis method used to assess the impact of the modifications was a Failure Modes and Effects Analysis (FMEA). A summary of the proposed modifications and their corresponding risks and mitigations is provided in **Table 4**.

11.2 Summary of Verification and/or Validation

The design verification tests that were performed as an outcome of the risk analysis are summarized in **Table 5** including acceptance criteria and results.

Table 4: Modifications and Corresponding Risks

Modification	Reason for the Change	Potential Risk	Risk Mitigation
Catheter including the balloon redesigned with new materials	Improved ease of use	Device may no longer be biocompatible	Biocompatibility testing
		Fails performance testing	Design verification testing (Table 5)
		Fails stability	Shelf life report
		End user cannot use the redesigned rectal catheter correctly	IFU
Change in manufacturing processes	Produce a more consistent product	Device may no longer be biocompatible	Biocompatibility testing
		Fails performance testing	Design verification testing (Table 5)
		Fails stability	Shelf life report
		End user experience an inconsistent product	Design verification testing (Table 5)

Table 5: Design Verification Tests Summary

Significant Requirements	Specifications (Acceptance Criteria)	Verification Method/ Rationale	Verification results (Pass/ Fail) with Average ± Stdev
Device must be biocompatible	(b) (4)		

Significant Requirements	Specifications (Acceptance Criteria)	Verification Method/ Rationale	Verification results (Pass/ Fail)
Device performance must be equivalent or better to predicate device ***25 products out of sample size of 30 must pass the test. The failed subjects must not be related to design failures.***	*Device must pass the engineering tests mentioned below*	*Testing conducted on a sample size of 30 rectal catheters*	*Catheters are within the respective specification limits*
	(b) (4)		

Significant Requirements	Specifications (Acceptance Criteria)	Verification Method/ Rationale	Verification results (Pass/ Fail) with Average ± Stdev
Device must meet performance specifications at 1 years shelf life (to be extended via stability protocol)	(b) (4)		

11.3 Clinical Data

Human clinical data was not required to support these device modifications.

11.4 Declaration of Conformity with Design Controls

A declaration of conformity with design controls is provided within **Attachment G.**

11.5 Summary of Biocompatibility information

The following tests have been conducted and demonstrate that the Peristeen Rectal Catheter is biocompatible:

- Cytotoxicity – XXT
- ISO Systemic Toxicity Study
- ISO Intracutaneous Toxicity Study
- ISO Guinea Pig Maximization Test
- Ames Study
- Subacute 14-Day Intraperitoneal Repeat Dose
- Subchronic 14-Day Intravenous Repeat Dose

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-1:2009 Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-156	
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☒	☐
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If yes, was the guidance document followed in preparation of this 510k?	☒	☐

Title of guidance: Required biocompatibility training and toxicological profile for evaluation of medical devices (G95-1)

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

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[6] The online search for CDRH Guidance Documents can be found at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED ◆		
DESCRIPTION		
JUSTIFICATION		
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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-3:2003 R(2009) Biological Evaluation of Medical Devices-Part 3: Tests for genotoxicity, carcinogenicity, and reproducti

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#2-117	
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.	☒	☐
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Title of guidance: Required biocompatibility training and toxicological profile for evaluation of medical devices (G95-1)

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JUSTIFICATION

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STANDARD TITLE [1]

ISO 10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for in vitro cytotoxicity

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Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#2-153	
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☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-10:2002, AC 2006 Biological Evaluation of Medical Devices-Part 10: Tests for irritation and delayed type hypersensitivi

Please answer the following questions	Yes	No
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FDA Recognition number [3]	#2-152	
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DESCRIPTION		
JUSTIFICATION		
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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-11:2006 Biological Evaluation of Medical Devices-Part 11: Tests for systemic toxicity

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#2-118	
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: Required biocompatibility training and toxicological profile for evaluation of medical devices (G95-1)

[1] The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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.

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

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		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

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Paperwork Reduction Act Statement

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ISO 10993-12:2007 Biological Evaluation of Medical Devices-Part 12: Sample preparation and reference materials

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☒	☐
FDA Recognition number [3]	#2-135	
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?	☒	☐
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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: Required biocompatibility training and toxicological profile for evaluation of medical devices (G95-1)

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[2] Authority [21 U.S.C. 360d], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

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		
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TYPE OF DEVIATION OR OPTION SELECTED ⁺		
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JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

EN 980 (2008): Graphical symbols for use in the labeling of medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☐	☒
FDA Recognition number [3] # _____		
Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?	☐	☒
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If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5] ?	☐	☐
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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: _____

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SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

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		
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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

EN 1041 (2008): Information supplied by the manufacturer with medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2] ?	☐	☒
FDA Recognition number [3] # _____		
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.	☐	☒
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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: _____

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

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		
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TYPE OF 510(K) SUBMISSION

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STANDARD TITLE [1]

ISO 14971: 2007 Medical Devices-Application of risk management to medical devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#5-40	
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.	☒	☐
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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: _____

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STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

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TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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TYPE OF 510(K) SUBMISSION

☐ Traditional ☒ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	#14-229	
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.	☒	☐
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Title of guidance: _____

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STANDARD TITLE

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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		
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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]

ASTM D2240 Standard Test Method for Rubber Property—Durometer Hardness

Please answer the following questions	Yes	No
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3] # _____		
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], http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm

[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 http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

CONFORMANCE WITH STANDARD SECTIONS*

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		
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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Rockville, MD 20850

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QUICK REFERENCE GUIDE FOR THE USER
PERISTEEN ANAL IRRIGATION SYSTEM

Non-Sterile. Single Patient Use Only. Latex Free.

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

Intended Use:
The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

For more information on the Peristeen Anal Irrigation System, including complete user instructions, intended use, contra-indications, and precautions, consult the **Peristeen Anal Irrigation User Guide.**

To use this system safely and effectively, you should get training from your doctor or home health care nurse before using it.

The first time you use this system, you should do so when your doctor or heath care nurse is present.

PERISTEEN ANAL IRRIGATION - DESCRIPTION

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	**RECTAL CATHETER WITH BALLOON**	**RECTAL CATHETER** allows flow of water into lower colon; inflated **BALLOON** keeps water in rectum/colon during irrigation	Use 1 time only, discard after use
2.	**CONTROL UNIT & PUMP (see symbol key below)**	The **CONTROL UNIT** allows air or water to go through the system; **The PUMP** inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (every other day for 6 months)
3.	Two (2) plastic **TUBES** with **CONNECTORS**	1 **TUBE** moves water from the bag into the rectal catheter; 1 **TUBE** allows air to be pumped in or out of the **BALLOON**; the **CONNECTORS** attach the **TUBES** to the **CONTROL UNIT** and the **LID**	Use 90 times (every other day for 6 months)
4.	Screw-on **LID** with flip-top and suction tube	The **LID** keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (every other day for 6 months)
5.	**WATER BAG**	The **WATER BAG** holds the water for the irrigation	Use 15 times (every other day for 1 month)
6.	**STRAP**	The **STRAPs** wrap around your leg and hold the **CONTROL UNIT** and **TUBES** in place	Use 90 times (every other day for 6 months)
7.	**STORAGE CASE**	The **STORAGE CASE** holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

 = **RESTING/DEVICE STORAGE**

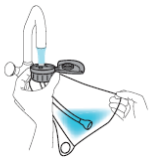
 = **INFLATE BALLOON**

 = **PUMP WATER**

 = **DEFLATE BALLOON/RELEASE AIR**

PREPARATION

Anal irrigation is usually done while sitting on the toilet.



1

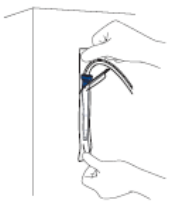
Screw the LID onto the top of the WATER BAG. Open the flip-top on the LID and fill the WATER BAG to the top with lukewarm water. The water level in the BAG might go down while you are filling the BAG because the BAG will unfold, but you should keep adding water until the BAG is full. Even though you do not need all the water in the filled BAG to do the irrigation, the system works best when the BAG is full. Close the flip-top on the LID by clicking it in place.

2

Put the TUBE with the grey connector into the LID. Lock the CONNECTOR by turning it one-half turn clockwise.

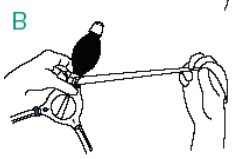
3

Peel open the CATHETER package about 1 inch, but leave the catheter in the package. Put the TUBE with the blue CONNECTOR into the RECTAL CATHETER. Lock the CONNECTOR by turning it one-half turn clockwise.



4

Attach the catheter package to a wall or door next to the toilet by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.



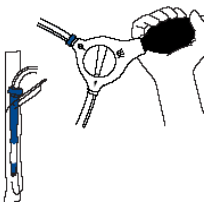
5

Attach the CONTROL UNIT and attached TUBES to the thigh with the STRAP:

A. Put the strap around the base of the pump

B. Slide the strap through the buckle and pull tight

C. Adjust the strap to fit comfortably around your thigh



6

Turn the knob on the CONTROL UNIT to the water symbol .
Squeeze the pump 2 to 3 times; this will fill the catheter package with water.
Turn the knob on the control unit to the balloon symbol to prevent any more water from going into the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put it into the rectum.

INSERTING THE RECTAL CATHETER

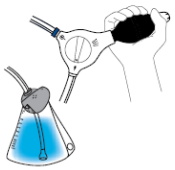
7

Make sure the knob on the control unit is pointing to the balloon symbol .
Insert the rectal catheter carefully into the rectum in the way that your doctor or nurse has trained you. Do not use force; the catheter should slide in smoothly.

When the catheter is in the right position, inflate the balloon by squeezing the pump slowly. Your doctor or nurse will work with you to decide how many times you should squeeze the pump. For an average size adult it is approximately 3 to 4 times. For smaller individuals and adolescents it will be less. Your doctor or nurse will write down the number of times to pump on the *Health Care Notes* form that they gave you.

If the balloon feels uncomfortable because it is too big, turn the knob to the air symbol to deflate it.
Turn the knob to the balloon symbol if you want to inflate the balloon again.

IRRIGATION (PUMPING WATER INTO COLON)

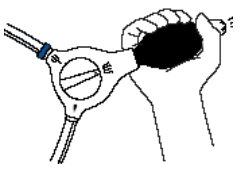


8

Turn the knob on the control unit counter-clockwise to the water symbol .
Squeeze the PUMP slowly – about once per second - until the right amount of water has flowed in. Your doctor or nurse will train you on how much water to use, and they will write down the number of times to pump on the *Health Care Notes* form that they gave you.

If water leaks past the BALLOON, you can inflate the balloon more by turning the knob on the control unit clockwise to the balloon symbol and squeezing the PUMP one more time. Turn the knob counter-clockwise to the water symbol to continue irrigation.

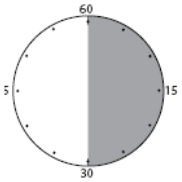
REMOVING THE RECTAL CATHETER



9

To deflate the balloon, turn the knob on the control unit counter-clockwise to the air symbol
Often the catheter will slide out by itself. If it does not, remove the CATHETER by gently pulling it out.

EMPTYING THE BOWELS



10

Within a few minutes, the colon will start to empty into the toilet.
If nothing happens, you can push on the lower part of your abdomen, cough, or move the upper part of your body to help encourage the emptying process.
The amount of time it takes for to empty the bowels will be different for each person, but usually it will take about thirty minutes. After doing the irrigation a few times, you will become more comfortable and have a better idea of how long it will take.

STORAGE AND MAINTENANCE OF SYSTEM

11

1. Unlock the connectors from the lid and the catheter.
2. Discard the single use catheter.
3. Open the flip-top on the LID and pour excess water out of the bag.
4. Rinse the surface of all the parts with warm water and a small amount of mild soap. Rinse all the soap off.
5. Set the knob on the CONTROL UNIT to the Resting Symbol 
6. Allow the parts to dry and pack them loosely in the nylon bag
7. Make sure that the tubes with connectors and the tube in the water bag do not get kinked in the storage case.
8. Do not keep the parts or the storage case in direct sunlight
9. Store the case in a place where the temperature is between 35° and 77° F.

PAI Catalog Numbers

Product	Catalog number	Components
Peristeen Anal Irrigation System	29121	1 Control unit 2 rectal catheters 1 Bag 2 straps
Peristeen Anal Irrigation Accessory Unit	29122	15 rectal catheters 1 Bag
Peristeen Anal Irrigation Rectal Catheter	29123	10 rectal catheters
Peristeen Anal Irrigation Strap	29124	1 set of 2 straps
Peristeen Anal Irrigation Tube	29125	2 tubes with blue connectors
Peristeen Anal Irrigation System	29126	1 Control unit 2 rectal catheters-small 1 Bag 2 straps
Peristeen Anal Irrigation Accessory Unit	29127	15 rectal catheters-small 1 Bag
Peristeen Anal Irrigation Rectal Catheter	29128	10 rectal catheters-small

PERISTEEN™ ANAL IRRIGATION USER GUIDE

TABLE OF CONTENTS

I. DESCRIPTIVE INFORMATION

Non Sterile. Single Patient Use Only. Latex Free.

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

A. Indications for Use

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

B. Description of the device:

Peristeen Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.

Figure 1: Peristeen Anal Irrigation (PAI) System

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	**RECTAL CATHETER WITH BALLOON**	**RECTAL CATHETER** allows flow of water into lower colon; inflated **BALLOON** keeps water in rectum/colon during irrigation	Use 1 time only, discard after use
2.	**CONTROL UNIT & PUMP (see symbol key below)**	The **CONTROL UNIT** allows air or water to go through the system; **The PUMP** inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (every other day for 6 months)
3.	Two (2) plastic **TUBES** with **CONNECTORS**	1 **TUBE** moves water from the bag into the rectal catheter; 1 **TUBE** allows air to be pumped in or out of the **BALLOON**; the **CONNECTORS** attach the **TUBES** to the **CONTROL UNIT** and the **LID**	Use 90 times (every other day for 6 months)
4.	Screw-on **LID** with flip-top and suction tube	The **LID** keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (every other day for 6 months)
5.	**WATER BAG**	The **WATER BAG** holds the water for the irrigation	Use 15 times (every other day for 1 month)
6.	**STRAP**	The **STRAPs** wrap around your leg and hold the **CONTROL UNIT** and **TUBES** in place	Use 90 times (every other day for 6 months)
7.	**STORAGE CASE**	The **STORAGE CASE** holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

PAI System Rectal Catheter

The PAI rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is provided non-sterile and is intended for single use only. Photographs of the un-inflated, inflated, and a simulated use model of the catheter are provided in **Figure 2.**

Figure 2: Un-inflated, Inflated, and Simulated Model PAI Rectal Balloon Catheter

PAI System Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/ butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake.

The control unit housing has a manually operated knob that has the following four positions:

 Storage  Inflate balloon  Pump water into rectum  Deflate balloon

Figure 3: PAI Control Unit

The rectal catheter and the water bag are connected to the Control Unit via silicone tubing with color-coded connectors. Water flows through the larger tubes and air flows through the smaller tube. The blue connector attaches to the rectal catheter; the gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.

PAI System Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.

Figure 4: PAI Lid/Connector/Tubing Figure , PAI Lid/Suction Tube Assembly

PAI System Water Bag

The polyethylene bag is designed to hold water or isotonic saline solution for irrigation. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.

Figure 5: PAI Water Bag & Tubing

PAI System General Information

For ease of use, polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the nylon case provided with the PAI System; the storage case also protects the components from exposure to direct sunlight.

The PAI Rectal Balloon Catheter is provided non-sterile in a sealed pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Quick Reference Guide and the User Guide). The catheter is intended for single use only.

The other components of the PAI system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.

Figure 6: PAI System Storage Case, Catheter package

C. When the device should not be used (contraindications):

Peristeen Anal Irrigation must not be used in the following situations:

- During the spinal shock phase
- Known obstruction of the large bowel
- Acute inflammatory bowel disease
- Diverticulitis
- If you are pregnant and have never used anal irrigation before, you should not start up the irrigation procedure during pregnancy.

D. Warnings and Precautions

WARNINGS:

WARNING
Contact your doctor or nurse immediately if you notice during or after anal irrigation:

Severe anal bleeding
Severe and sustained abdominal pain or back pain, with or without fever

Anal irrigation should always be carried out with care. Although bowel perforation is extremely rare, it is a potential complication to anal irrigation and will require immediate admission to hospital.

PRECAUTIONS:

Always consult your health care professional before starting up the irrigation procedure. When anal irrigation is initiated, special caution must be shown if you:

- Suffer from an inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
- Have any anorectal condition which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids
- Have had irradiation therapy in the abdominal or pelvic region
- Have had recent abdominal or anal surgery
- Suffer from autonomic dysreflexia
- Have a regular intake of anticoagulant medication with vitamin K antagonists, as normally small and harmless rectal bleedings may be difficult to stop
- Are pregnant and have previous experience with anal irrigation, please consult your doctor to carefully evaluate if you may continue irrigating.
- Have diarrhea, as the cause for diarrhea must be identified.
- Use rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.

If any of the above conditions apply to you, anal irrigation must only be initiated after careful consideration and instruction by your health care professional.

Do not use soap or any other cleanser to clean the inside of the system and do not run a soap solution or cleanser through the system. The soap or cleanser or soap may react with the materials of the system and may cause irritation.

II. OPERATING INFORMATION

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

 = **RESTING/DEVICE STORAGE**

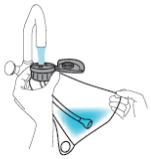
 = **INFLATE BALLOON**

 = **PUMP WATER**

 = **DEFLATE BALLOON/RELEASE AIR**

PREPARATION

Anal irrigation is usually done while sitting on the toilet.

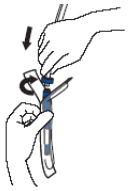


1

Screw the LID onto the top of the WATER BAG. Open the flip-top on the LID and fill the WATER BAG to the top with lukewarm water. The water level in the BAG might go down while you are filling the BAG because the BAG will unfold, but you should keep adding water until the BAG is full. Even though you do not need all the water in the filled BAG to do the irrigation, the system works best when the BAG is full. Close the flip-top on the LID by clicking it in place.

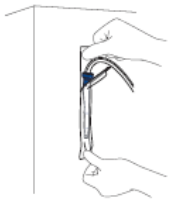
2

Put the TUBE with the grey connector into the LID. Lock the CONNECTOR by turning it one-half turn clockwise.



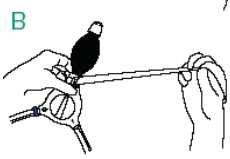
3

Peel open the CATHETER package about 1 inch, but leave the catheter in the package. Put the TUBE with the blue CONNECTOR into the RECTAL CATHETER. Lock the CONNECTOR by turning it one-half turn clockwise.



4

Attach the catheter package to a wall or door next to the toilet by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.



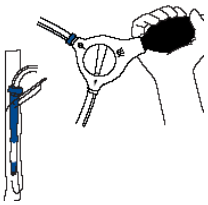
5

Attach the CONTROL UNIT and attached TUBES to the thigh with the STRAP:

A. Put the strap around the base of the pump

B. Slide the strap through the buckle and pull tight

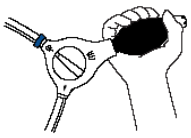
C. Adjust the strap to fit comfortably around your thigh



6

Turn the knob on the CONTROL UNIT to the water symbol .
Squeeze the pump 2 to 3 times; this will fill the catheter package with water.
Turn the knob on the control unit to the balloon symbol to prevent any more water from going into the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put it into the rectum.

INSERTING THE RECTAL CATHETER



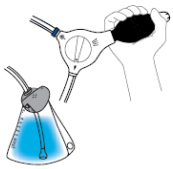
7

Make sure the knob on the control unit is pointing to the balloon symbol .
Insert the rectal catheter carefully into the rectum in the way that your doctor or nurse has trained you. Do not use force; the catheter should slide in smoothly.

When the catheter is in the right position, inflate the balloon by squeezing the pump slowly. Your doctor or nurse will work with you to decide how many times you should squeeze the pump. For an average size adult it is approximately 3 to 4 times. For smaller individuals and adolescents it will be less. Your doctor or nurse will write down the number of times to pump on the *Health Care Notes* form that they gave you.

If the balloon feels uncomfortable because it is too big, turn the knob to the air symbol to deflate it.
Turn the knob to the balloon symbol if you want to inflate the balloon again.

IRRIGATION (PUMPING WATER INTO COLON)



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Turn the knob on the control unit counter-clockwise to the water symbol .
Squeeze the PUMP slowly – about once per second - until the right amount of water has flowed in. Your doctor or nurse will train you on how much water to use, and they will write down the number of times to pump on the *Health Care Notes* form that they gave you.

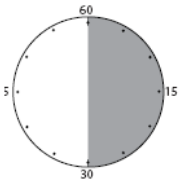
If water leaks past the BALLOON, you can inflate the balloon more by turning the knob on the control unit clockwise to the balloon symbol and squeezing the PUMP one more time. Turn the knob counter-clockwise to the water symbol to continue irrigation.

REMOVING THE RECTAL CATHETER

9

To deflate the balloon, turn the knob on the control unit counter-clockwise to the air symbol 
Often the catheter will slide out by itself. If it does not, remove the CATHETER by gently pulling it out.

EMPTYING THE BOWELS



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Within a few minutes, the colon will start to empty into the toilet.
If nothing happens, you can push on the lower part of your abdomen, cough, or move the upper part of your body to help encourage the emptying process.
The amount of time it takes for to empty the bowels will be different for each person, but usually it will take about thirty minutes. After doing the irrigation a few times, you will become more comfortable and have a better idea of how long it will take.

STORAGE AND MAINTENANCE OF SYSTEM

11

1. Unlock the connectors from the lid and the catheter.
2. Discard the single use catheter.
3. Open the flip-top on the LID and pour excess water out of the bag.
4. Rinse the outer surface of all the parts with warm water and a small amount of mild soap. Rinse all the soap off. So not run soap solution or cleanser through the system.
5. Set the knob on the CONTROL UNIT to the Resting Symbol 
6. Allow the parts to dry and pack them loosely in the nylon bag
7. Make sure that the tubes with connectors and the tube in the water bag do not get kinked in the storage case.
8. Do not keep the parts or the storage case in direct sunlight
9. Store the case in a place where the temperature is between 35° and 77° F.

III. TROUBLESHOOTING INFORMATION:

Who can perform anal irrigation?
Anal irrigation is for people who suffer from fecal incontinence, chronic constipation or have to spend a long time on bowel management procedures. You must be examined by a health care professional and receive professional instruction before starting the irrigation. After receiving instruction and training, the majority will be able to perform anal irrigation on their own.

How often should I irrigate?
Anal irrigation may be performed every other day or as recommended by your doctor or nurse.

How long does the irrigation take?
The time used for irrigation is individual. When using anal irrigation you approximately use 30-45 minutes on bowel management daily.

How much air and water should I use?
The required amount of air to pump into the balloon and water to pump into the rectum is individual and your doctor or nurse will tell you how much to use. They will write the amounts of air and water to pump on your Health Care Notes form. You should not increase the amount of water uncritically since the bowel may retain it and release it over time in small amounts.

Why is the temperature of the water important?
The water must have body temperature (approx. 36-38°C). If it is too hot, it may harm the delicate lining of the rectum; if it is too cold, cramps may occur.

How quickly should I pump the water?
If the water is pumped too quickly into the bowel, you may experience discomfort such as sweating, dizziness and stomach ache. We recommend approximately one pump per second or more slowly as recommended by your doctor or nurse.

Can I stop the irrigation if I want a break?
In case of discomfort and you feel the need for a break, stop the water flow and wait until it subsides. When you are ready, resume pumping. If the discomfort does not disappear, contact your health care professional immediately.

What should I do if the irrigation water and/or feces do not come out (no emptying)?
You may be heavily constipated and a clean-out of the bowel is necessary. Contact your health care professional for assistance.

The reason could also be that you have not had enough to drink and are dehydrated, so the bowel has absorbed the irrigation water. Try irrigating once more using the normal amount of water and remember to drink more water. If another attempt at irrigation does not help, contact your doctor or nurse.

What should I do if water seeps into the toilet?
If water seeps past the balloon and into the toilet there is no need to change the irrigation procedure if the irrigation still works.

You can stop the pumping of water, wait for a while and fill some more water into the bowel. Make sure the catheter is placed in the correct position right above the sphincters. If water still seeps into the toilet, you can fill more air into the balloon and resume pumping water into the bowel.

What if I experience leakages after irrigation?
If you experience leakages after irrigation you might have used too much water. Make sure to use the amount of water recommended by your health care professional. You can also try to stay a little longer at the toilet. Contact your health care professional if you continue experiencing leakages.

What if I experience defecation between irrigations?
If you experience defecation between irrigations, the cause may be insufficient emptying after irrigation owing to constipation or hard stools. Contact your health care professional for different solutions, e.g. frequency of irrigation, amount of water and/or medication.

How should I store my Peristeen Anal Irrigation system?
The system and the rectal catheters should be stored at a temperature of between 2° and 25° Celsius and away from direct sunlight. Ensure the tubing is not kinked when stored.

How do I clean my Peristeen Anal Irrigation system?
The tube can be cleaned by turning the knob on the control unit to the water symbol and pumping the dirty water out of the tube. You may choose to change the tube with the blue connectors more frequently if you desire. The surface of all the components (excluding the single use catheter) can be washed in mild soapy water, and rinsed thoroughly. Remember to keep the Control Unit knob in the Resting/Storage position when you are not using the PAI System.

What do I do when travelling?
The bowels absorb water, so when travelling in countries where it is not safe to drink the water, care should be taken to use distilled water or isotonic saline for irrigation.

Flatulence
Anal irrigation empties the bowel of feces and air. Experience shows that the release of gas from the rectum will be considerably reduced once irrigation is practiced regularly.

Adaptation period
An adaptation period of approx. 10 days may be expected. The procedure must be individually adjusted together with your health care professional regarding the amount of air to pump into the balloon, water to pump into the rectum, as well as recommended frequency of irrigating.

IV. DISEASE AND SELF-CARE INFORMATION

The bowel system
The bowels are part of the digestive system, the primary function of which is to break down the food we eat. The food passes through the stomach and the small bowel (small intestine), where it is broken down and useful components are absorbed into the body. What is left continues to the large bowel (colon and rectum).

The large bowel receives a liquid mixture of digested food and juices from the small bowel. The main function of the large bowel is to absorb water and salts and to store the waste products (feces) before they are transported to the rectum. The large bowel in an average size adult receives about 1,500 ml small bowel content a day and converts this into 150-200 ml of fecal matter. The bowel absorbs the remainder.

On average it takes 1-3 days for food to pass through the entire digestive tract, though this can vary greatly from person to person. The time it takes for food to pass through the digestive system is called the transit time.

The large bowel has two muscles, which make peristaltic movements when contracting. With the aid of peristalsis, the feces are moved onward from the large bowel into the rectum. Peristalsis is affected by a number of factors such as diet, posture and exercise.

Peristalsis is a wavelike muscular contraction that transports digested food through the intestines to the rectum. The two colon muscles; one longitudinal muscle along the colon and one circular muscle around the colon make the contraction.

There are two sphincters in the rectum controlling the defecation process. The internal sphincter is an extension of the colon musculature and is controlled by reflex, i.e. we cannot consciously control it. The external sphincter can be controlled consciously by the brain.

There are two sphincters in the rectum affecting the evacuation – the internal and the external sphincter. The function of the anal sphincters is to maintain continence and prevent leakage.

Once the rectum receives feces from the large bowel, it is registered in a set of nerve endings. These nerve endings send a signal to the brain that the rectum is full and that it is time to go to the toilet. At this point you can choose to wait for a more suitable time. If you wait too long however, the urge will disappear and the feces will be forced back into the large bowel.

When you decide to go to the toilet, you activate the defecation reflex by relaxing the external sphincter. Typically, the presence of approx. 150 ml of feces will result in a reflex relaxation of the internal sphincter. The external sphincter relaxes and the feces are expelled with the aid of gravity and muscle contractions in the rectum.

Causes of bowel dysfunction
There are many causes of bowel dysfunction and reasons for initiating anal irrigation. The most frequent reasons are mentioned below. In order to receive appropriate and effective treatment, a diagnosis from your health care professional is essential.

Neurological disorders
The defecation mechanism, i.e. the nerves that send a signal to your brain telling you when you need to go to the toilet, may be impaired due to a medical condition or disease, such as: a spinal cord injury, spina bifida, multiple sclerosis, Parkinson’s disease, apoplexia, Alzheimer’s disease or brain tumors.

Sensory disorders
The sensory function of the rectal mucosa may be impaired. This can occur after surgery, as a result of colitis, compaction, rectal prolapse or as a result of surgical correction of congenital absence or abnormality of the anal opening (anal atresia).

Muscular disorders
Damage to the sphincter muscle due to external injuries, tumours or their surgical removal, perineal tear from a vaginal birth, straining from constipation or rectal prolapse.

Psychological/psychiatric disorders
Caused by psychoses, depression, depersonalisation or role conflicts (in children and adults) as well as a result of sexual abuse.

Reduced tissue elasticity
Frequent in old age or after multiple births.

The effect of food and exercise
Food plays an important role in managing your bowels. It is important to find the right balance of stool consistency to avoid either constipation or liquid stools, which will increase the risk of fecal incontinence.

Dietary fiber generally soften stool and reduce the passage time. Too much fiber, however, can worsen symptoms of bloating and stomach pain.

It is worth noting that some food and liquids such as coffee and artificial sweeteners have a mild laxative effect. It is always important to drink plenty of fluids.

Finally physical exercise has a mechanical effect on the bowels, which improves bowel movement.

Constipation
Constipation and fecal incontinence are both symptoms of bowel dysfunction and you often experience both fecal incontinence and constipation at the same time.

Bowel function and defecation habits vary from one person to another. Some have daily bowel movements, others every second or third day. Owing to the extensive variation in the normal defecation pattern, it is difficult to offer a clear definition of constipation.

Constipation occurs when the bowel's movements are reduced. This prolongs transit time in the large bowel and more fluid is absorbed from the feces than with normal transit time, resulting in hard and lumpy stools. This will often result in general discomfort and in some cases disturbed bladder-emptying patterns.

Constipation is generally perceived as:

• Fewer than three defecations a week.
• Prolonged lavatory visits with straining and soreness in the rectum.
• Hard, sparse and lumpy stools.

Because of this natural variation, changes in digestive and bowel movement patterns will be perceived differently depending on what one is accustomed to.

Fecal incontinence
Fecal incontinence can be defined as lack of control of bowel evacuation resulting in involuntary defecation. Anal incontinence also includes incontinence for air (flatus).

In many cases, fecal incontinence occurs as the result of insufficient sensation in the rectal region. In other words, you do not register the urge to defecate. At the same time, control of the internal and external sphincters may be entirely or partially lacking.

Chronic constipation, in which the rectum wall is severely over-stretched, may result in fecal incontinence as the normal defecation reflexes are deactivated by the chronic stretch. At the same time, fluid passes around the fecal mass in the bowel. Often the internal sphincter has reduced function because it is expanded and liquid stools mixed with dry and hard stool may pass.

V. USER ASSISTANCE INFORMATION:

Coloplast in brief

Coloplast A/S is a Danish company founded in 1957 with more than 7,000 employees.

Coloplast develops, manufactures and markets medical devices and services to improve quality of life of the people who depend on these devices:

- Ostomy products for people with a stoma
- Continence care products for people with bladder and bowel management problems
- Urology products used in surgery procedures of the urinary system and male reproductive system
- Wound dressings for the treatment of chronic wounds
- Skin care products for prevention and treatment of conditions from simple irritation to fungal infections and skin breakdown

Coloplast A/S has sales and subsidiary companies worldwide.

Coloplast A/S
Holtedam 1
DK-3050 Humlebæk
www.coloplast.com

Device Description:

Peristeen Anal Irrigation system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water or isotonic saline solution, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.

Figure 1: Peristeen Anal Irrigation (PAI) System

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	**RECTAL CATHETER WITH BALLOON**	**RECTAL CATHETER** allows flow of water into lower colon; inflated **BALLOON** keeps water in rectum/colon during irrigation	Use 1 time only, discard after use
2.	**CONTROL UNIT & PUMP (see symbol key below)**	The **CONTROL UNIT** allows air or water to go through the system; **The PUMP** inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (every other day for 6 months)
3.	Two (2) plastic **TUBES** with **CONNECTORS**	1 **TUBE** moves water from the bag into the rectal catheter; 1 **TUBE** allows air to be pumped in or out of the **BALLOON**; the **CONNECTORS** attach the **TUBES** to the **CONTROL UNIT** and the **LID**	Use 90 times (every other day for 6 months)
4.	Screw-on **LID** with flip-top and suction tube	The **LID** keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (every other day for 6 months)
5.	**WATER BAG**	The **WATER BAG** holds the water for the irrigation	Use 15 times (every other day for 1 month)
6.	**STRAP**	The **STRAPs** wrap around your leg and hold the **CONTROL UNIT** and **TUBES** in place	Use 90 times (every other day for 6 months)
7.	**STORAGE CASE**	The **STORAGE CASE** holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

PAI System Rectal Catheter

The PAI rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is provided non-sterile and is intended for single use only. Photographs of the un-inflated, inflated, and a simulated use model of the catheter are provided in **Figure 2.**

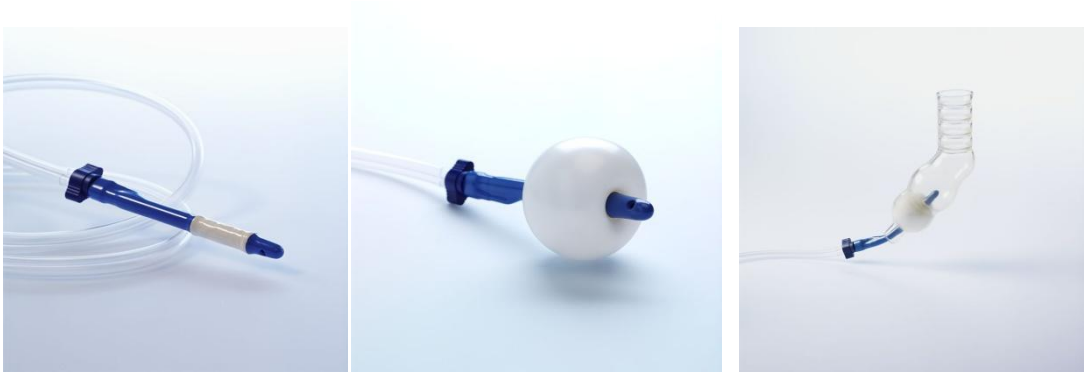


Figure 2: Un-inflated, Inflated, and Simulated Model PAI Rectal Balloon Catheter

PAI System Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/
butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake.

The control unit housing has a manually operated knob that has the following four positions:

 Storage  Inflate balloon  Pump water into rectum  Deflate balloon

Figure 3: PAI Control Unit

The rectal catheter and the water bag are connected to the Control Unit via silicone tubing with color-coded connectors. Water flows through the larger tubes and air flows through the smaller tube. The blue connector attaches to the rectal catheter; the gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.

PAI System Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.

Figure 4: PAI Lid/Connector/Tubing Figure , PAI Lid/Suction Tube Assembly

PAI System Water Bag

The polyethylene bag is designed to hold water or isotonic saline solution for irrigation. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.

Figure 5: PAI Water Bag & Tubing

PAI System General Information

For ease of use, polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the nylon case provided with the PAI System; the storage case also protects the components from exposure to direct sunlight.

The PAI Rectal Balloon Catheter is provided non-sterile in a sealed pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Quick Reference Guide and the User Guide). The catheter is intended for single use only.

The other components of the PAI system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.

Figure 6: PAI System Storage Case, Catheter package

Indications:

The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Contraindications:

Peristeen Anal Irrigation must not be used in the following situations:

- During the spinal shock phase
- Known obstruction of the large bowel
- Acute inflammatory bowel disease
- Diverticulitis
- If you are pregnant and have never used anal irrigation before, you should not start up the irrigation procedure during pregnancy.

Warnings and Precautions:

Warnings:

Make sure that your patients know that they must contact you immediately if they notice during or after anal irrigation:

- Severe anal bleeding
- Severe and sustained abdominal pain or back pain, with or without fever

Anal irrigation should always be carried out with care. Although bowel perforation is extremely rare, it is a potential complication to anal irrigation and will require immediate admission to hospital.

Precautions:
Patients should be advised of contraindications, warnings, precautions, and instructions for use before starting up the irrigation procedure. When anal irrigation is initiated, special caution must be shown for the following patient conditions:
•Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
•Any anorectal condition which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids
•Previous irradiation therapy in the abdominal or pelvic region
•Recent abdominal or anal surgery
•Autonomic dysreflexia
•Regular intake of anticoagulant medication with vitamin K antagonists; normally small and harmless rectal bleeding may be difficult to stop
•Patient who are pregnant and who have had previous experience with anal irrigation; evaluate carefully to determine if irrigating is recommended
•Patients with diarrhea; the cause for diarrhea must be identified.
•Use of rectal medication for other diseases as the effect of such medication may be diluted by the anal irrigation.

If any of the above conditions apply, anal irrigation must only be initiated after careful consideration and instruction.

Instructions for Use:

Each patient and/or caregiver should be trained in the following steps and should perform these steps with physician assistance to ensure that all steps are understood and can be accomplished independently.

Operating Information

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

 = **RESTING/DEVICE STORAGE**

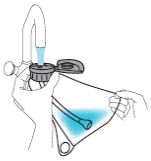
 = **INFLATE BALLOON**

 = **PUMP WATER**

 = **DEFLATE BALLOON/RELEASE AIR**

PREPARATION

Anal irrigation is usually done while sitting on the toilet.



1

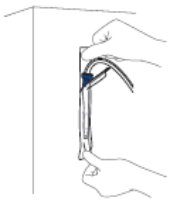
Screw the LID onto the top of the WATER BAG. Open the flip-top on the LID and fill the WATER BAG to the top with lukewarm water. The water level in the BAG might go down while you are filling the BAG because the BAG will unfold, but you should keep adding water until the BAG is full. Even though you do not need all the water in the filled BAG to do the irrigation, the system works best when the BAG is full. Close the flip-top on the LID by clicking it in place.

2

Put the TUBE with the grey connector into the LID. Lock the CONNECTOR by turning it one-half turn clockwise.

3

Peel open the CATHETER package about 1 inch, but leave the catheter in the package. Put the TUBE with the blue CONNECTOR into the RECTAL CATHETER. Lock the CONNECTOR by turning it one-half turn clockwise.



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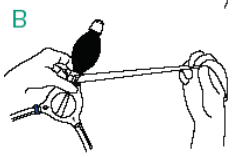
Attach the catheter package to a wall or door next to the toilet by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.



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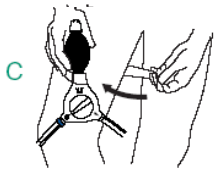
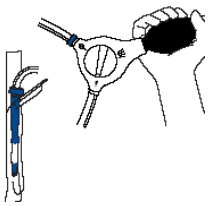


Attach the CONTROL UNIT and attached TUBES to the thigh with the STRAP:

A. Put the strap around the base of the pump

B. Slide the strap through the buckle and pull tight

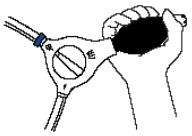
C. Adjust the strap to fit comfortably around your thigh



6

Turn the knob on the CONTROL UNIT to the water symbol .
Squeeze the pump 2 to 3 times; this will fill the catheter package with water.
Turn the knob on the control unit to the balloon symbol to prevent any more water from going into the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put it into the rectum.

INSERTING THE RECTAL CATHETER



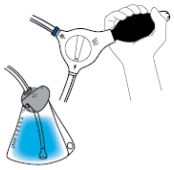
7

Make sure the knob on the control unit is pointing to the balloon symbol .
Insert the rectal catheter carefully into the rectum in the way that your doctor or nurse has trained you. Do not use force; the catheter should slide in smoothly.

When the catheter is in the right position, inflate the balloon by squeezing the pump slowly. Your doctor or nurse will work with you to decide how many times you should squeeze the pump. For an average size adult it is approximately 3 to 4 times. For smaller individuals and adolescents it will be less. Your doctor or nurse will write down the number of times to pump on the Health Care Notes form that they gave you.

If the balloon feels uncomfortable because it is too big, turn the knob to the air symbol to deflate it.
Turn the knob to the balloon symbol if you want to inflate the balloon again.

IRRIGATION (PUMPING WATER INTO COLON)



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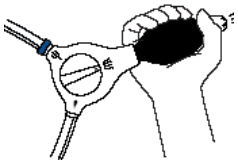
Turn the knob on the control unit counter-clockwise to the water symbol .

Squeeze the PUMP slowly – about once per second - until the right amount of water has flowed in. Your doctor or nurse will train you on how much water to use, and they will write down the number of times to pump on the Health Care Notes form that they gave you. If water leaks past the BALLOON, you can inflate the balloon more by turning the knob on the control unit clockwise to the balloon symbol and squeezing the PUMP one more time. Turn the knob counter-clockwise to the water symbol to continue irrigation.

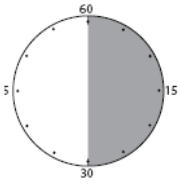
REMOVING THE RECTAL CATHETER



9

To deflate the balloon, turn the knob on the control unit counter-clockwise to the air symbol
Often the catheter will slide out by itself. If it does not, remove the CATHETER by gently pulling it out.

EMPTYING THE BOWELS



10

Within a few minutes, the colon will start to empty into the toilet.
If nothing happens, you can push on the lower part of your abdomen, cough, or move the upper part of your body to help encourage the emptying process.
The amount of time it takes for to empty the bowels will be different for each person, but usually it will take about thirty minutes. After doing the irrigation a few times, you will become more comfortable and have a better idea of how long it will take.

STORAGE AND MAINTENANCE OF SYSTEM

11

1. Unlock the connectors from the lid and the catheter.
2. Discard the single use catheter.
3. Open the flip-top on the LID and pour excess water out of the bag.
4. Rinse the surface of all the parts with warm water and a small amount of mild soap. Rinse all the soap off.
5. Set the knob on the CONTROL UNIT to the Resting Symbol 
6. Allow the parts to dry and pack them loosely in the nylon bag
7. Make sure that the tubes with connectors and the tube in the water bag do not get kinked in the storage case.
8. Do not keep the parts or the storage case in direct sunlight
9. Store the case in a place where the temperature is between 35° and 77° F.

Physician Notes:

Peristeen Anal Irrigation is designed to be carried out independently or with the assistance of a caregiver in the user's home. It is important that a healthcare professional supervises the first use of Peristeen Anal Irrigation to help the patient use the system safely, optimally and with confidence. Once a patient and/or caregiver has completed irrigation under supervision, they may try the procedure alone. Sometimes more than one training session is required so each patient should be considered individually in terms of their readiness and capability to do so. Subsequent irrigations should be followed-up by consultations in person or by telephone until the patient and/or caregiver has fully adapted the procedure to meet the individual needs and until they are confident to continue the procedure independently. If a patient is heavily and/or chronically constipated, it may be necessary to thoroughly clean out their bowels before starting Peristeen Anal Irrigation.

Physicians should prescribe irrigation based upon a comprehensive evaluation of the nature of the patient's fecal incontinence and the frequency of either constipation or soiling episodes. Generally, Coloplast recommends that anal irrigation be performed every other day; more or less frequent irrigation may be advised depending upon individual patient needs.

Prior to starting Peristeen Anal Irrigation for the first time, please take time to describe the procedure to your patient, answer any questions, and help manage their expectations. To avoid potential disappointment or concern that anal irrigation does not work for them, explain that an initial period of adjustment is perfectly normal and is required to establish their personalised routine. An anal irrigation bowel diary is a good way of keeping track of progress during this period (see table). Peristeen Anal Irrigation can work successfully within a few days but for some individuals it can take 4 to 6 weeks for the treatment to settle down and become routine.

11 Jun

12 Jun

13 Jun

For new users of Peristeen Anal Irrigation, the irrigation routine should be tailored to meet their individual requirements. It is helpful to ensure the patient understands that, at first, some trial and error will be required to optimise the process and establish their personalised routine. For some people it can take 4 to 6 weeks to adapt the routine. Make sure to complete a **Health Care Notes form** for the patient and/or caregiver to refer to. The **Anatomy Notes** sheets can also be used to make notes and special recommendations on an individual basis.

There are several parameters that can be adjusted if required:
1. Amount of air in the catheter balloon
2. Amount of water used for irrigation
3. Frequency of irrigation

Amount of air in the catheter balloon
The function of the balloon is to hold the catheter in place in the rectum; the degree to which the balloon must be inflated to achieve this (i.e. the number of pumps of air required) depends on the condition of the individual's sphincter and rectum. The average size adult will probably require 3 to 4 pumps of air in the balloon (maximum 5 pumps); for smaller patients, 1 to 2 pumps may be sufficient. Insufficient air can cause water to leak or the catheter to slide out of the rectum. If water leaks during the procedure, patients and/or caregivers should attempt pumping one more time to a maximum of 5 pumps in total. Conversely, too much air can cause the balloon to be expelled. If this happens, repeating the procedure using a little less air should be attempted. The frequency of expulsions often decreases as a patient becomes used to the procedure.

Please use the following notes to guide the amount of air pumped into the balloon for an average size adult patient:

• Intact sphincter reflexes and muscle tone: 1 to 3 pumps
• Flaccid bowels or low sphincter tone: 3 to 5 pumps. If the catheter still slides out of the rectum, it may be supported by holding in place
• Strong anorectal reflexes: The balloon may be expelled after only 1 to 2 pumps; careful insertion and inflation of the balloon is necessary, using less air

For smaller patients, 1 to 2 pumps is recommended.

Amount of water for irrigation
The volume of water required to effectively empty the bowel depends on several factors including the patient's bowel condition, their diet and the frequency of irrigation.

When first using Peristeen Anal Irrigation in adults, a water volume of 500 ml is recommended, and irrigation should be performed daily. This volume can be gradually increased, over the next few weeks, until the individual feels they are completely empty and have no accidents between irrigations. Increases in volume should be done slowly, especially in younger patients and patients with spina bifida. Many adult patients eventually use a volume in the region of 750 ml; however, studies have shown that the amount of water varies from 200 to 1500 ml in adults. Some patients with upper neurone damage experience evacuation of the bowel at low water volumes (e.g. 200 to 300 ml); in some cases the irrigation procedure might need to be repeated to ensure sufficient emptying.

If leakage occurs after the irrigation try:

• Advising the patient to stay on the toilet a little longer to allow complete emptying of the bowel
• Reducing the volume of water
• Two half volume irrigations (e.g. two 250 ml irrigations instead of one 500 ml irrigation)

If irrigation water is not expelled after sitting on the toilet for 20 to 30 minutes, it could be that the bowel has absorbed the water because the patient is dehydrated or that the irrigation fluid is captured in impacted stools:

• Repeat the irrigation using the same volume of water
• Advise the patient to drink more fluids – at least 1.5 litres per day and more in hot weather

The recommended rate for pumping water into the bowel is one pump per second. Pumping water into the bowel too quickly may cause discomfort, sweating, dizziness and stomach pain; if this occurs, the procedure can be paused at any time and resumed when the discomfort has passed and the patient feels ready. If the discomfort does not pass, the irrigation should be stopped and the patient's usual bowel care routine followed to achieve emptying.

Water should be at body temperature (36 to 38°C). If the water is too hot it may damage the mucous membranes lining the bowel and if it is too cold it may trigger reflexes and increase spasms. Plain tap water is recommended or bottled water when travelling in countries where drinking tap water is not recommended.

Frequency of irrigation
For patients who are new to Peristeen Anal Irrigation, it is recommended to irrigate on a daily basis. After one or two weeks some patients find that irrigation can be tried every second day. As the frequency of irrigation is decreased, it may be necessary to adjust other parameters; for example, the volume of water may need to be increased to achieve complete emptying. Some patients will find it necessary to irrigate every day but eventually most patients settle into a routine of irrigation every other day. Conducting irrigation at approximately the same time each day seems to work best for most people, but is not essential. Eating and drinking stimulate the bowel, so about 30 minutes after a meal gives the best chance of the irrigation working with the natural activity of the bowel and achieving the best emptying. The most convenient time can be chosen by the patient to fit in with their daily routine. Alternatively, it can be varied to fit around a changing routine giving the patient the maximum possible freedom.

The system and the rectal catheters should be stored at a temperature of between 2° and 25° Celsius and away from direct sunlight. The tubing should not be kinked when being stored.

The tubes can be cleaned by turning the knob on the control unit to the water symbol and pumping the dirty water out of the tube. Patients may choose to change the tube with the blue connectors more frequently if desired. The outer surface of all the components (excluding the single use catheter) can be washed in mild soapy water and rinsed thoroughly. The Control Unit knob should be in the Resting/Storage position when the PAI System is not in use.

Product Evaluation:

Coloplast requests physicians to notify the company of any complications which may develop with the use of this device, and requests return of any used devices or components associated with the complication. For safe handling during shipment and upon receipt, Coloplast requests that devices be decontaminated prior to shipment. This is requested even though Coloplast will autoclave-sterilize any opened product returned. Alteration for the purposes of venting to prevent additional damage will be performed as required. If necessary, Coloplast may analyze the device, and the patient and physician may be asked to allow Coloplast to perform tests that might alter the condition of the device.

Any complications from the use of this device should be brought to our immediate attention by contacting: Quality Assurance, Product Evaluations Department, Coloplast Corp.,1601 West River Road North, Minneapolis, MN 55411
Toll-free telephone (800) 338-7908 in USA; or outside USA: (612) 337-7800

Product Order Information

To order, please contact your local sales representative or Coloplast Customer Service Department at: Coloplast, 1601 West River Road North, Minneapolis, MN 55411; Toll-free telephone: (800) 258-3476; or outside USA: (612) 337-7800; or fax (866) 216-4161 or outside USA: (612) 337-7803.

INSTRUCTIONS FOR USE
PERISTEEN ANAL IRRIGATION SYSTEM

Non-Sterile. Single Patient Use Only. Does not contain natural rubber latex.

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

Intended Use:
The Peristeen Anal Irrigation System is intended to instill water into the colon through a rectal catheter – which incorporates an inflatable balloon – inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen Anal Irrigation System is indicated for use by children (2 years -<12 years old), adolescent (12 years - <18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

For more information on the Peristeen Anal Irrigation System, including complete user instructions, consult the **Peristeen User Guide.**

For a copy of the Peristeen User Guide or a copy of the Peristeen Training for Health Professionals Guide, please call Coloplast customer service at 1-800-258-3476.

Warning
Anal irrigation procedure should always be carried out with care. Bowel perforation is an extremely rare, but serious and potentially lethal complication to anal irrigation and will require immediate admission to a hospital, often requiring surgery.

Contact your doctor immediately, if during or after anal irrigation you experience any of the following:
- **Severe and sustained abdominal pain or back pain, especially if combined with fever**
- **Sustained anal bleeding**

Contraindications

Peristeen Anal Irrigation must **not** be used in the following situations:
- Known obstruction of the large bowel due to strictures or tumors
- Acute inflammatory bowel disease
- Diverticulitis
- Complex diverticular disease
- Abdominal or anal surgery within the last 3 months
- In patients who are pregnant and have not used the system before*

*If the patient is pregnant and has never used anal irrigation before, they should not start the irrigation procedure during pregnancy.

Precautions
Always consult a physician/health care professional with experience in using Peristeen before starting up the irrigation procedure. If you are heavily constipated an initial and thorough clean-out of your bowels is advisable before starting up the irrigation procedure. Please consult your health care professional.

Special caution must be shown if you have or have had any of the following:

- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
- Ischemic colitis
- Any Anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids (third or fourth degree hemorrhoids)
- Irradiation therapy in the abdominal or pelvic region
- Diverticular disease
- Previous abdominal or anal surgery
- Recent colonic biopsy or polypectomy
- Spinal cord shock phase
- Autonomic dysreflexia
- Cancer in the abdominal or pelvic region
- Fecal impaction
- Long term steroid therapy
- Anticoagulant therapy or bleeding disorder
- Change stool pattern like sudden diarrhea of unknown origin. The cause for diarrhea must be identified
- Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.
- Severe cognitive impairment (unless caregiver is available to supervise/administer)
- Children under 2 years of age

If any of the above conditions apply to you, anal irrigation must only be initiated after careful investigation and instruction by your health care professional.
When you use anal irrigation you must consult a physician in case of:

- Onset of any of the above mentioned conditions
- Blood in feces, weight loss, abdominal pain
- Changes in the frequency, color and consistency of the stools
- Concurrent use of laxatives or other rectal medications

For hygienic reasons the Peristeen Anal Irrigation system must only be used by the same person. Do not share with others.

Please read the whole instruction including warnings, contraindications and precautions before carrying out the anal irrigation procedure

It is vital for your safety that you consult a physician/health care professional with experience using Peristeen before starting up the irrigation procedure.
We also require that you receive thorough instruction from a health care professional before using this product

Your first irrigation must be supervised by a health care professional.

PERISTEEN ANAL IRRIGATION - DESCRIPTION

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	**RECTAL CATHETER WITH BALLOON**	**RECTAL CATHETER** allows flow of water into lower colon; inflated **BALLOON** keeps water in rectum/colon during irrigation	Use 1 time only, discard after use (single use only) **Note:** Reuse of the single use rectal catheter may create a potential risk to the user.
2.	**CONTROL UNIT & PUMP (see symbol key below)**	The **CONTROL UNIT** allows air or water to go through the system; **The PUMP** inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (equal to irrigating every other day for 6 months)
3.	Two (2) plastic **TUBES** with **CONNECTORS**	1 **TUBE** moves water from the bag into the rectal catheter; 1 **TUBE** allows air to be pumped in or out of the **BALLOON**; the **CONNECTORS** attach the **TUBES** to the **CONTROL UNIT** and the **LID**	Use 90 times (equal to irrigating every other day for 6 months)
4.	Screw-on **LID** with flip-top and suction tube	The **LID** keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (equal to irrigating every other day for 6 months)
5.	**WATER BAG**	The **WATER BAG** holds the water for the irrigation	Use 15 times (equal to irrigating every other day for 1 month)
6.	**STRAP**	The **STRAPs** wrap around your leg and hold the **CONTROL UNIT** and **TUBES** in place	Use 90 times (equal to irrigating every other day for 6 months)
7.	**STORAGE CASE**	The **STORAGE CASE** holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

 = **FINISH**

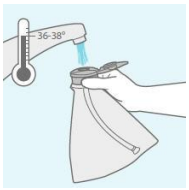
 = **INFLATE BALLOON**

 = **PUMP WATER**

 = **DEFLATE BALLOON/RELEASE AIR**

Preparation

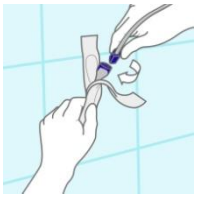
Anal irrigation is most commonly carried out while sitting on the toilet.



1. Open the lid and fill the bag to the top with lukewarm water (96-100 F). As the bag unfolds, the water level will fall and refilling is necessary. Although you need less water for the irrigation, the bag must be filled completely to function properly. Close the lid by clicking it into place.

Note: Use clean tap water. If you do not have access to clean tap water, then we recommend using bottled water. Do not add any additives to the water.

2. Attach the tube with the grey connector to the grey screw top. Lock the connector by turning it (one half turn) 90 clockwise.



3. Open the catheter packaging about 1 inch but leave the catheter in the packaging.

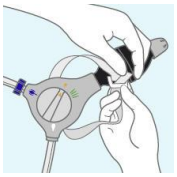
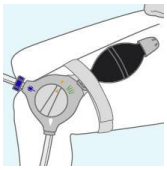
Attach the tube with the blue connector to the rectal catheter by pushing them together and turn until the connect locks. Lock the connector by turning it one-half turn clockwise.

4. Attach the catheter packaging to a vertical surface by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.

5. Turn the knob on the control unit to the water symbol and pump water into the catheter packaging (2 to 3 pumps) to activate the coating.

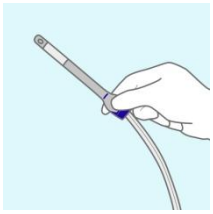
Turn the knob on the control unit to the balloon symbol to prevent any more water from going in the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put into the rectum. Remove the lubricated catheter from the packaging and use it immediately.

Tip: For extra stability when pumping, you can attach the control unit to the thigh by using the strap:

A  B 	Attach the control unit and tubing to the thigh by using the strap: A. Place the strap around the base of the pump. Slide the strap through the buckle and pull tight. B. Fit the pump to your thigh, adjusting the strap for a comfortable fit.

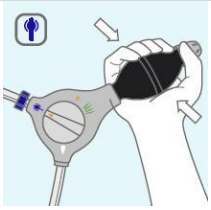
Insertion of rectal catheter

6. Ensure the knob on the control unit is pointing to the balloon symbol . As instructed by your health care professional, insert the rectal catheter carefully into the rectum without using force. The catheter should slide in smoothly.

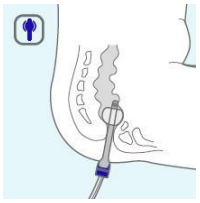


When inserting the catheter, hold it by the finger grip. The finger grip is the widest part of the catheter. Your healthcare professional will instruct you how far to insert the catheter.

Inflation of balloon



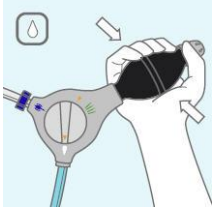
7. Start pumping gently to inflate the balloon. Your health care professional will advise you how many times to pump. A few pumps are usually enough. Your healthcare professional will write down the number of times to pump on the Health Care Notes form they gave you.



Note: Do not overinflate the balloon. The balloon on the small catheter must not be pumped more than twice. The balloon on the regular catheter must not be pumped more than five times.

Note: If you sense that the balloon is too big, turn the knob to the air symbol to deflate it. When ready turn to the balloon symbol to inflate the balloon once again.

Insertion of water



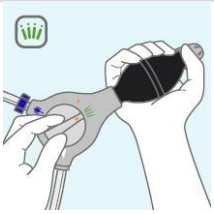
8. Turn the knob on the control unit counter-clockwise to the water symbol . Squeeze the pump slowly-about once per second-until the right amount of water has flowed in. Your healthcare professional will train you on how much water to use and they will write down the number of times to pump on the Health Care Notes form they gave you.

If water leaks, try inflating the balloon further by turning the knob on the control unit clockwise to the balloon symbol and pump one more time. Turn the knob anti-clockwise to the water symbol and resume irrigation.

In case of discomfort, turn the knob of the control unit to the balloon symbol

to stop the water flow and wait until it ceases. When you are ready, turn the knob back to the water symbol and resume pumping. If the discomfort continues, deflate the balloon, remove the catheter and contact your health care professional immediately.

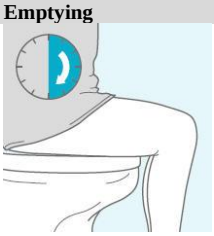
Removal of rectal catheter



9. Turn the knob on the control unit counter-clockwise to the air symbol to deflate the balloon. Often the catheter will slide out by itself; if not, pull the catheter gently.

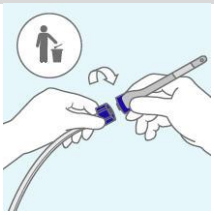
Note: Do not remove the catheter before the balloon is completely deflated
Note: For most efficient result remove the catheter immediately after the balloon has deflated

Emptying



10. Soon the colon will start to empty itself. If nothing happens, try to press, cough or move the upper part of your body to activate the emptying process. The drainage time is individual, but on average it takes thirty minutes.

Conclusion



11. Unlock the connectors from the lid and the catheter. Discard the single use catheter.

Pour excess water out of the bag.

When storing the system, turn the knob on the control unit anti-clockwise to the finish symbol. When the knob is placed in this position, any remaining water in the tubes will run out. Ensure the tubes are not kinked when stored in the storage case and that the system and all its parts are kept away from sharp objects.

The set and the rectal catheter should be stored at room temperature (max. 77 F) and out of direct sunlight.

Frequently Asked Questions:

What should I do if irrigation water and/or feces do not come out (no emptying)?
Try one or more of the following: sitting in the brace position (leaning/bending forward), coughing, standing up, abdominal massage. If water is still not expelled, then you may be heavily constipated and a clean-out of the bowel might be necessary. You might also be dehydrated, so remember to drink plenty of water and repeat the irrigation again the day after. Contact your health care professional for assistance.

Should I use lubricant on the rectal catheter?
No. The rectal catheter is pre-coated with a lubricant, which is activated when water is added to the catheter packaging (see step 6 for more details). Adding extra lubricant can damage the balloon.

Why is the temperature of the water important?
The water must be lukewarm (96-100°F). If it is too hot, it may harm the delicate lining of the bowel; if it is too cold, stomach cramps may occur.

Can I stop the irrigation if I want a break?
If you feel the need for a break, turn the knob on the control unit to the balloon symbol. When you are ready, turn the knob back to the water symbol and resume pumping.

Can I re-use the rectal catheter?
The rectal catheter is for single use only and should be disposed of after each irrigation.

What kind of water should I use when traveling?
If you don't have access to clean tap water, then we recommend using bottled water.

How do I change the water bag?
Remove the grey screw top from the bag and screw it onto a replacement bag. Avoid kinking the suction pipe placed on the grey screw top.

How do I clean my Peristeen Anal Irrigation system?
The surface of all the components (not including the single use catheter) can be washed in mild soapy water.

It is possible to replace the tube with the blue connector if it becomes soiled.

How should my Peristeen Anal Irrigation system be stored?
The set and the rectal catheter should be stored at room temperature (max. 77 F) and out of direct sunlight. When storing the system, ensure that you turn the knob on the control unit to the finish symbol  . Also ensure that tubes are not kinked and that the systems is kept away from sharp objects.

Product Evaluation:

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www.us.coloplast.com

Manufacturer:

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DK-3050 Humlebæk
www.coloplast.com

PERISTEEN™ ANAL IRRIGATION USER GUIDE

TABLE OF CONTENTS

I. DESCRIPTIVE INFORMATION

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Caution: Federal law restricts this device to sale by or on the order of a physician.

A. Indications for Use

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

B. Description of the device:

Peristeen Anal Irrigation system consists of a single-use rectal catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.

Figure 1: Peristeen Anal Irrigation System

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	**RECTAL CATHETER WITH BALLOON**	**RECTAL CATHETER** allows flow of water into lower colon; inflated **BALLOON** keeps water in rectum/colon during irrigation	Use 1 time only, discard after use (single use only) **Note:** Reuse of the single use rectal catheter may create a potential risk to the user.
2.	**CONTROL UNIT & PUMP (see symbol key below)**	The **CONTROL UNIT** allows air or water to go through the system; **The PUMP** inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (equal to irrigating every other day for 6 months)
3.	Two (2) plastic **TUBES** with **CONNECTORS**	1 **TUBE** moves water from the bag into the rectal catheter; 1 **TUBE** allows air to be pumped in or out of the **BALLOON**; the **CONNECTORS** attach the **TUBES** to the **CONTROL UNIT** and the **LID**	Use 90 times (equal to irrigating every other day for 6 months)
4.	Screw-on **LID** with flip-top and suction tube	The **LID** keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (equal to irrigating every other day for 6 months)
5.	**WATER BAG**	The **WATER BAG** holds the water for the irrigation	Use 15 times (equal to irrigating every other day for 1 month)
6.	**STRAP**	The **STRAPs** wrap around your leg and hold the **CONTROL UNIT** and **TUBES** in place	Use 90 times (equal to irrigating every other day for 6 months)
7.	**STORAGE CASE**	The **STORAGE CASE** holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

Peristeen Rectal Catheter

The Peristeen rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is provided non-sterile and is intended for single use only. Photographs of the un-inflated, inflated, and a simulated use model of the catheter are provided in **Figure 2.**

Figure 2: Un-inflated, Inflated, and Simulated Model Peristeen Rectal Balloon Catheter

Peristeen Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake.

The control unit housing has a manually operated knob that has the following four positions:

 Finish  Inflate balloon  Pump water  Deflate balloon

Figure 3: Peristeen Control Unit

The rectal catheter and the water bag are connected to the Control Unit via silicone tubing with color-coded connectors. Water flows through the larger tubes and air flows through the smaller tube. The blue connector attaches to the rectal catheter; the gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.

Peristeen Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.

Figure 4: Peristeen Lid/Connector/Tubing Assembly

Peristeen Lid/Suction Tube

Peristeen Water Bag

The polyethylene bag is designed to hold water for irrigation. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.

Figure 5: Peristeen Water Bag & Tubing

Peristeen System General Information

For ease of use, polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the nylon case provided with the Peristeen System; the storage case also protects the components from exposure to direct sunlight.

The Peristeen Rectal Balloon Catheter is provided non-sterile in a sealed pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Instructions for Use and the User Guide). The catheter is intended for single use only.

The other components of the Peristeen system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.

Figure 6: Peristeen Storage Case, Catheter package

Indications:
The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Warning
Anal irrigation procedure should always be carried out with care. Bowel perforation is an extremely rare, but serious and potentially lethal complication to anal irrigation and will require immediate admission to a hospital, often requiring surgery

Contact your doctor immediately, if during or after anal irrigation you experience any of the following:

- **Severe and sustained abdominal pain or back pain, especially if combined with fever**
- **Sustained anal bleeding**

Contraindications:
Peristeen Anal Irrigation must **not** be used in the following situations:

- Known obstruction of the large bowel due to strictures or tumors
- Acute inflammatory bowel disease
- Diverticulitis
- Complex diverticular disease
- Abdominal or anal surgery within the last 3 months
- In patients who are pregnant and have not used the system before*

*If the patient is pregnant and has never used anal irrigation before, they should not start the irrigation procedure during pregnancy.

Precautions

Always consult a physician/health care professional with experience in using Peristeen before starting up the irrigation procedure. If you are heavily constipated an initial and thorough clean-out of your bowels is advisable before starting up the irrigation procedure. Please consult your health care professional.

Special caution must be shown if you have or have had any of the following:

- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
- Ischemic colitis
- Any Anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids (third or fourth degree hemorrhoids)
- Irradiation therapy in the abdominal or pelvic region
- Diverticular disease
- Previous abdominal or anal surgery

- Recent colonic biopsy or polypectomy
- Spinal cord shock phase
- Autonomic dysreflexia
- Cancer in the abdominal or pelvic region
- Fecal impaction
- Long term steroid therapy
- Anticoagulant therapy or bleeding disorder
- Change stool pattern like sudden diarrhea of unknown origin. The cause for diarrhea must be identified
- Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.
- Severe cognitive impairment (unless caregiver is available to supervise/administer)
- Children under 2 years of age

If any of the above conditions apply to you, anal irrigation must only be initiated after careful investigation and instruction by your health care professional.
When you use anal irrigation you must consult a physician in case of:

- Onset of any of the above mentioned conditions
- Blood in feces, weight loss, abdominal pain
- Changes in the frequency, color and consistency of the stools
- Concurrent use of laxatives or other rectal medications

For hygienic reasons the Peristeen Anal Irrigation system must only be used by the same person. Do not share with others.

II. OPERATING INFORMATION

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

 = **FINISH**

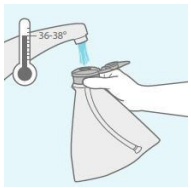
 = **INFLATE BALLOON**

 = **PUMP WATER**

 = **DEFLATE BALLOON/RELEASE AIR**

Preparation

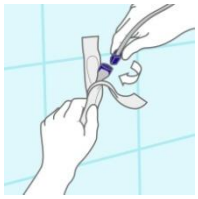
Anal irrigation is most commonly carried out while sitting on the toilet.



1. Open the lid and fill the bag to the top with lukewarm water (96-100 F). As the bag unfolds, the water level will fall and refilling is necessary. Although you need less water for the irrigation, the bag must be filled completely to function properly. Close the lid by clicking it into place.

Note: Use clean tap water. If you do not have access to clean tap water, then we recommend using bottled water. Do not add any additives to the water.

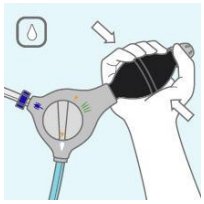
2. Attach the tube with the grey connector to the grey screw top. Lock the connector by turning it (one half turn) 90 clockwise.



3. Open the catheter packaging about 1 inch but leave the catheter in the packaging.

Attach the tube with the blue connector to the rectal catheter by pushing them together and turn until the connect locks. Lock the connector by turning it one-half turn clockwise.

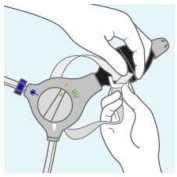
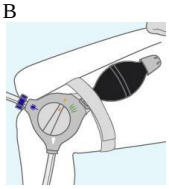
4. Attach the catheter packaging to a vertical surface by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.



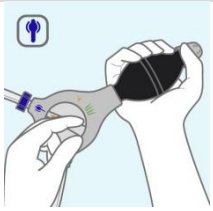
5. Turn the knob on the control unit to the water symbol and pump water into the catheter packaging (2 to 3 pumps) to activate the coating.

Turn the knob on the control unit to the balloon symbol to prevent any more water from going in the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put into the rectum. Remove the lubricated catheter from the packaging and use it immediately.

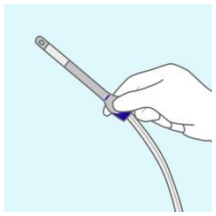
Tip: For extra stability when pumping, you can attach the control unit to the thigh by using the strap:

A 	Attach the control unit and tubing to the thigh by using the strap: A. Place the strap around the base of the pump. Slide the strap through the buckle and pull tight.
B 	B. Fit the pump to your thigh, adjusting the strap for a comfortable fit.

Insertion of rectal catheter

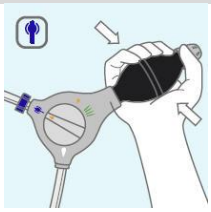


6. Ensure the knob on the control unit is pointing to the balloon symbol  . As instructed by your health care professional, insert the rectal catheter carefully into the rectum without using force. The catheter should slide in smoothly.

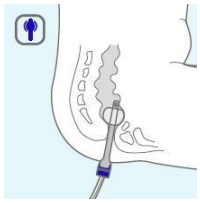


When inserting the catheter, hold it by the finger grip. The finger grip is the widest part of the catheter. Your healthcare professional will instruct you how far to insert the catheter.

Inflation of balloon



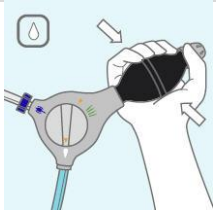
7. Start pumping gently to inflate the balloon. Your health care professional will advise you how many times to pump. A few pumps are usually enough. Your healthcare provider will write down the number of times to pump on the Health Care Notes form they gave you.



Note: Do not overinflate the balloon. The balloon on the small catheter must not be pumped more than twice. The balloon on the regular catheter must not be pumped more than five times.

Note: If you sense that the balloon is too big, turn the knob to the air symbol  to deflate it. When ready turn to the balloon symbol  to inflate the balloon once again.

Insertion of water



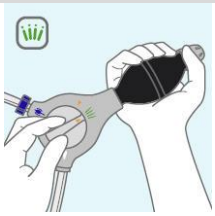
8. Turn the knob on the control unit counter-clockwise to the water symbol  . Squeeze the pump slowly-about once per second-until the right amount of water has flowed in. Your healthcare provider will train you on how much water to use and they will write down the number of times to pump on the Health Care Notes form they gave you.

If water leaks, try inflating the balloon further by turning the knob on the control unit clockwise to the balloon symbol  and pump one more time. Turn the knob anti-clockwise to the water symbol  and resume irrigation.

In case of discomfort, turn the knob of the control unit to the balloon symbol

to stop the water flow and wait until it ceases. When you are ready, turn the knob back to the water symbol and resume pumping. If the discomfort continues, deflate the balloon, remove the catheter and contact your health care professional immediately.

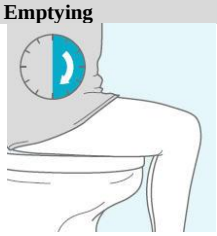
Removal of rectal catheter



9. Turn the knob on the control unit counter-clockwise to the air symbol to deflate the balloon. Often the catheter will slide out by itself; if not, pull the catheter gently.

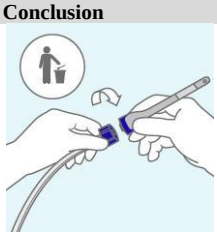
Note: Do not remove the catheter before the balloon is completely deflated
Note: For most efficient result remove the catheter immediately after the balloon has deflated

Emptying



10. Soon the colon will start to empty itself. If nothing happens, try to press, cough or move the upper part of your body to activate the emptying process. The drainage time is individual, but on average it takes thirty minutes.

Conclusion



11. Unlock the connectors from the lid and the catheter. Discard the single use catheter.

Pour excess water out of the bag.

When storing the system, turn the knob on the control unit anti-clockwise to the finish symbol . When the knob is placed in this position, any remaining water in the tubes will run out. Ensure the tubes are not kinked when stored in the storage case and that the system and all its parts are kept away from sharp objects.

The set and the rectal catheter should be stored at room temperature (max. 77 F) and out of direct sunlight.

III. TROUBLESHOOTING INFORMATION:

Who can perform anal irrigation?

Anal irrigation is for people with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation and/or time-consuming bowel management procedures. You must be examined by a health care professional and receive professional instruction before starting the irrigation. After receiving instruction and training, the majority will be able to perform anal irrigation on their own.

How often should I irrigate?

Anal irrigation may be performed every other day or as recommended by your doctor or nurse.

How long does the irrigation take?

The time used for irrigation is individual. When using anal irrigation you approximately use 30-45 minutes on bowel management daily.

How much air and water should I use?

The required amount of air to pump into the balloon and water to pump into the rectum is individual and your doctor or nurse will tell you how much to use. They will write the amounts of air and water to pump on your Health Care Notes form. You should not increase the amount of water uncritically since the bowel may retain it and release it over time in small amounts.

Why is the temperature of the water important?
The water must be lukewarm (96-100°F). If it is too hot, it may harm the delicate lining of the bowel; if it is too cold, stomach cramps may occur.

How quickly should I pump the water?
If the water is pumped too quickly into the bowel, you may experience discomfort such as sweating, dizziness and stomach ache. We recommend one pump per second or as recommended by your doctor or nurse.

Can I stop the irrigation if I want a break?
If you feel the need for a break, turn the knob on the control unit to the balloon symbol  . When you are ready, turn the knob back to the water symbol  and resume pumping.

What should I do if the irrigation water and/or feces do not come out (no emptying)?
Try one or more of the following: sitting in the brace position (leaning/bending forward), coughing, standing up, abdominal massage. If water is still not expelled, then you may be heavily constipated and a clean-out of the bowel might be necessary. You might also be dehydrated, so remember to drink plenty of water and repeat the irrigation again the day after. Contact your health care professional for assistance.

What should I do if water leaks into the toilet?
If water leaks past the balloon and into the toilet there is no need to change the irrigation procedure if the irrigation still works.

You can stop the pumping of water, wait for a while and fill some more water into the bowel. Make sure the catheter is placed in the correct position right above the sphincters. If water still seeps into the toilet, you can fill more air into the balloon and resume pumping water into the bowel.

What if I experience leakages after irrigation?
If you experience leakages after irrigation you might have used too much water. Make sure to use the amount of water recommended by your health care professional. You can also try to stay a little longer at the toilet. Contact your health care professional if you continue experiencing leakages.

What if I experience defecation between irrigations?
If you experience defecation between irrigations, the cause may be insufficient emptying after irrigation owing to constipation or hard stools. Contact your health care professional for different solutions, e.g. frequency of irrigation, amount of water and/or medication.

How should my Peristeen Anal Irrigation system be stored?
The system and the rectal catheter should be stored at room temperature (maximum 77° F) and out of direct sunlight. When storing the system, ensure that you turn the knob on the control unit to the finish symbol  . Also ensure that tubes are not kinked and that the systems is kept away from sharp objects.

How do I clean my Peristeen Anal Irrigation system?

The tube can be cleaned by turning the knob on the control unit to the water symbol and pumping the dirty water out of the tube. You may choose to change the tube with the blue connectors more frequently if you desire. The surface of all the components (excluding the single use catheter) can be washed in mild soapy water, and rinsed thoroughly. Remember to keep the Control Unit knob in the Resting/Storage position when you are not using the Peristeen System.

What do I do when travelling?
The bowels absorb water, so when travelling in countries where it is not safe to drink the water, care should be taken to use distilled or bottled water for irrigation.

Flatulence
Anal irrigation empties the bowel of feces and air. Experience shows that the release of gas from the rectum will be considerably reduced once irrigation is practiced regularly.

Adaptation period
An adaptation period of approx. 10 days may be expected. The procedure must be individually adjusted together with your health care professional regarding the amount of air to pump into the balloon, water to pump into the rectum, as well as recommended frequency of irrigating.

IV. DISEASE AND SELF-CARE INFORMATION

The bowel system
The bowels are part of the digestive system, the primary function of which is to break down the food we eat. The food passes through the stomach and the small bowel (small intestine), where it is broken down and useful components are absorbed into the body. What is left continues to the large bowel (colon and rectum).

The large bowel receives a liquid mixture of digested food and juices from the small bowel. The main function of the large bowel is to absorb water and salts and to store the waste products (feces) before they are transported to the rectum. The large bowel in an average size adult receives about 1,500 ml small bowel content a day and converts this into 150-200 ml of fecal matter. The bowel absorbs the remainder.

On average it takes 1-3 days for food to pass through the entire digestive tract, though this can vary greatly from person to person. The time it takes for food to pass through the digestive system is called the transit time.

The large bowel has two muscles, which make peristaltic movements when contracting. With the aid of peristalsis, the feces are moved onward from the large bowel into the rectum. Peristalsis is affected by a number of factors such as diet, posture and exercise.

Peristalsis is a wavelike muscular contraction that transports digested food through the intestines to the rectum. The two colon muscles; one longitudinal muscle along the colon and one circular muscle around the colon make the contraction.

There are two sphincters in the rectum controlling the defecation process. The internal sphincter is an extension of the colon musculature and is controlled by reflex, i.e. we cannot consciously control it. The external sphincter can be controlled consciously by the brain.

There are two sphincters in the rectum affecting the evacuation – the internal and the external sphincter. The function of the anal sphincters is to maintain continence and prevent leakage.

Once the rectum receives feces from the large bowel, it is registered in a set of nerve endings. These nerve endings send a signal to the brain that the rectum is full and that it is time to go to the toilet. At this point you can choose to wait for a more suitable time. If you wait too long however, the urge will disappear and the feces will be forced back into the large bowel.

When you decide to go to the toilet, you activate the defecation reflex by relaxing the external sphincter. Typically, the presence of approx. 150 ml of feces will result in a reflex relaxation of the internal sphincter. The external sphincter relaxes and the feces are expelled with the aid of gravity and muscle contractions in the rectum.

Causes of bowel dysfunction
There are many causes of bowel dysfunction and reasons for initiating anal irrigation. The most frequent reasons are mentioned below. In order to receive appropriate and effective treatment, a diagnosis from your health care professional is essential.

Neurological disorders
The defecation mechanism, i.e. the nerves that send a signal to your brain telling you when you need to go to the toilet, may be impaired due to a medical condition or disease, such as: a spinal cord injury, spina bifida, multiple sclerosis, Parkinson's disease, apoplexia, Alzheimer's disease or brain tumors.

Sensory disorders
The sensory function of the rectal mucosa may be impaired. This can occur after surgery, as a result of colitis, compaction, rectal prolapse or as a result of surgical correction of congenital absence or abnormality of the anal opening (anal atresia).

Muscular disorders
Damage to the sphincter muscle due to external injuries, tumours or their surgical removal, perineal tear from a vaginal birth, straining from constipation or rectal prolapse.

Psychological/psychiatric disorders
Caused by psychoses, depression, depersonalisation or role conflicts (in children and adults) as well as a result of sexual abuse.

Reduced tissue elasticity
Frequent in old age or after multiple births.

The effect of food and exercise
Food plays an important role in managing your bowels. It is important to find the right balance of stool consistency to avoid either constipation or liquid stools, which will increase the risk of fecal incontinence.

Dietary fiber generally soften stool and reduce the passage time. Too much fiber, however, can worsen symptoms of bloating and stomach pain.

It is worth noting that some food and liquids such as coffee and artificial sweeteners have a mild laxative effect. It is always important to drink plenty of fluids.

Finally physical exercise has a mechanical effect on the bowels, which improves bowel movement.

Constipation
Constipation and fecal incontinence are both symptoms of bowel dysfunction and you often experience both fecal incontinence and constipation at the same time.

Bowel function and defecation habits vary from one person to another. Some have daily bowel movements, others every second or third day. Owing to the extensive variation in the normal defecation pattern, it is difficult to offer a clear definition of constipation.

Constipation occurs when the bowel's movements are reduced. This prolongs transit time in the large bowel and more fluid is absorbed from the feces than with normal transit time, resulting in hard and lumpy stools. This will often result in general discomfort and in some cases disturbed bladder-emptying patterns.

Constipation is generally perceived as:

• Fewer than three defecations a week.
• Prolonged lavatory visits with straining and soreness in the rectum.
• Hard, sparse and lumpy stools.

Because of this natural variation, changes in digestive and bowel movement patterns will be perceived differently depending on what one is accustomed to.

Fecal incontinence
Fecal incontinence can be defined as lack of control of bowel evacuation resulting in involuntary defecation. Anal incontinence also includes incontinence for air (flatus).

In many cases, fecal incontinence occurs as the result of insufficient sensation in the rectal region. In other words, you do not register the urge to defecate. At the same time, control of the internal and external sphincters may be entirely or partially lacking.

Chronic constipation, in which the rectum wall is severely over-stretched, may result in fecal incontinence as the normal defecation reflexes are deactivated by the chronic stretch. At the same time, fluid passes around the fecal mass in the bowel. Often the internal sphincter has reduced function because it is expanded and liquid stools mixed with dry and hard stool may pass.

V. USER ASSISTANCE INFORMATION:

Coloplast in brief

Coloplast A/S is a Danish company founded in 1957 with more than 7,000 employees.

Coloplast develops, produce and market products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. Coloplast calls this intimate healthcare. Our business includes:

- Chronic Care refers to our two largest business areas, Ostomy and Continence Care. These are chronic areas because the people who live with an ostomy or who are incontinent will have to use our products on a daily basis – many for the re-minder of their lives.
- Urology Care products for surgical treatment of urological disorders, such as erectile dysfunction, urinary incontinence, weak pelvic muscles, kidney stones and enlarged prostate.
- Wound Care products for wound healing and skin care. Coloplast specialize in moist wound healing.
- Skin care products improve comfort and prevent skin conditions for people with injured or at-risk skin e.g. hospital patients and stoma-users.

Coloplast A/S operates globally with sales subsidiaries in our principal markets worldwide.

Coloplast A/S
Holtedam 1
DK-3050 Humlebæk
www.coloplast.com

Device Description:

Peristeen Anal Irrigation system consists of a single-use rectal catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.

Figure 1: Peristeen Anal Irrigation System

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	**RECTAL CATHETER WITH BALLOON**	**RECTAL CATHETER** allows flow of water into lower colon; inflated **BALLOON** keeps water in rectum/colon during irrigation	Use 1 time only, discard after use (single use only) **Note:** Reuse of the single use rectal catheter may create a potential risk to the user.
2.	**CONTROL UNIT & PUMP (see symbol key below)**	The **CONTROL UNIT** allows air or water to go through the system; **The PUMP** inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (equal to irrigating every other day for 6 months)
3.	Two (2) plastic **TUBES** with **CONNECTORS**	1 **TUBE** moves water from the bag into the rectal catheter; 1 **TUBE** allows air to be pumped in or out of the **BALLOON**; the **CONNECTORS** attach the **TUBES** to the **CONTROL UNIT** and the **LID**	Use 90 times (equal to irrigating every other day for 6 months)
4.	Screw-on **LID** with flip-top and suction tube	The **LID** keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (equal to irrigating every other day for 6 months)
5.	**WATER BAG**	The **WATER BAG** holds the water for the irrigation	Use 15 times (equal to irrigating every other day for 1 month)
6.	**STRAP**	The **STRAPs** wrap around your leg and hold the **CONTROL UNIT** and **TUBES** in place	Use 90 times (equal to irrigating every other day for 6 months)
7.	**STORAGE CASE**	The **STORAGE CASE** holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

Peristeen Rectal Catheter

The Peristeen rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is provided non-sterile and is intended for single use only. Photographs of the un-inflated, inflated, and a simulated use model of the catheter are provided in **Figure 2.**

Figure 2: Un-inflated, Inflated, and Simulated Model Peristeen Rectal Balloon Catheter

Peristeen System Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/
butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake.

The control unit housing has a manually operated knob that has the following four positions:

 Finish  Inflate balloon  Pump water  Deflate balloon/release air

Figure 3: Peristeen Control Unit

The rectal catheter and the water bag are connected to the Control Unit via silicone tubing with color-coded connectors. Water flows through the larger tubes and air flows through the smaller tube. The blue connector attaches to the rectal catheter; the gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.

Peristeen System Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.

Figure 4: Peristeen Lid/Connector/Tubing Peristeen Lid/Suction Tube Assembly

Peristeen System Water Bag

The polyethylene bag is designed to hold water for irrigation. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.

Figure 5: Peristeen Water Bag & Tubing

Peristeen System General Information

For ease of use, polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the nylon case provided with the Peristeen System; the storage case also protects the components from exposure to direct sunlight.

The Peristeen Rectal Balloon Catheter is provided non-sterile in a sealed pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Instructions for Use and the Peristeen User Guide). The catheter is intended for single use only.

The other components of the Peristeen system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.

Figure 6: Peristeen System Storage Case, Catheter package

Indications:

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Warning

Anal irrigation procedure should always be carried out with care. Bowel perforation is an extremely rare, but serious and potentially lethal complication to anal irrigation and will require immediate admission to a hospital, often requiring surgery

Contact your doctor immediately, if during or after anal irrigation you experience any of the following:

- **Severe and sustained abdominal pain or back pain, especially if combined with fever**
- **Sustained anal bleeding**

Contraindications:

Peristeen Anal Irrigation must **not** be used in the following situations:

- Known obstruction of the large bowel due to strictures or tumors
- Acute inflammatory bowel disease
- Diverticulitis
- Complex diverticular disease
- Abdominal or anal surgery within the last 3 months
- In patients who are pregnant and have not used the system before*

*If the patient is pregnant and has never used anal irrigation before, they should not start the irrigation procedure during pregnancy.

Precautions

Always consult a physician/health care professional with experience in using Peristeen before starting up the irrigation procedure. If you are heavily constipated an initial and thorough clean-out of your bowels is advisable before starting up the irrigation procedure. Please consult your health care professional.

Special caution must be shown if you have or have had any of the following:

- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
- Ischemic colitis
- Any Anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids (third or fourth degree hemorrhoids)
- Irradiation therapy in the abdominal or pelvic region
- Diverticular disease
- Previous abdominal or anal surgery
- Recent colonic biopsy or polypectomy
- Spinal cord shock phase
- Autonomic dysreflexia
- Cancer in the abdominal or pelvic region
- Fecal impaction
- Long term steroid therapy
- Anticoagulant therapy or bleeding disorder
- Change stool pattern like sudden diarrhea of unknown origin. The cause for diarrhea must be identified
- Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.
- Severe cognitive impairment (unless caregiver is available to supervise/administer)
- Children under 2 years of age

If any of the above conditions apply to you, anal irrigation must only be initiated after careful investigation and instruction by your health care professional.

When you use anal irrigation you must consult a physician in case of:

- Onset of any of the above mentioned conditions
- Blood in feces, weight loss, abdominal pain
- Changes in the frequency, color and consistency of the stools
- Concurrent use of laxatives or other rectal medications

For hygienic reasons the Peristeen Anal Irrigation system must only be used by the same person. Do not share with others.

Instructions for Use:

Each patient and/or caregiver should be trained in the following steps and should perform these steps with physician assistance to ensure that all steps are understood and can be accomplished independently.

Operating Information

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

 = **FINISH**

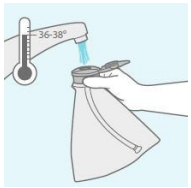
 = **INFLATE BALLOON**

 = **PUMP WATER**

 = **DEFLATE BALLOON/RELEASE AIR**

Preparation

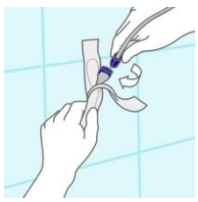
Anal irrigation is most commonly carried out while sitting on the toilet.



1. Open the lid and fill the bag to the top with lukewarm water (96-100 °F). As the bag unfolds, the water level will fall and refilling is necessary. Although you need less water for the irrigation, the bag must be filled completely to function properly. Close the lid by clicking it into place.

Note: Use clean tap water. If you do not have access to clean tap water, then we recommend using bottled water. Do not add any additives to the water.

2. Attach the tube with the grey connector to the grey screw top. Lock the connector by turning it (one half turn) 90° clockwise.



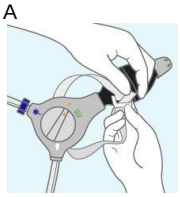
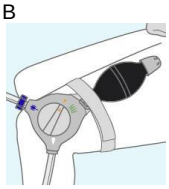
3. Open the catheter packaging about 1 inch but leave the catheter in the packaging.

Attach the tube with the blue connector to the rectal catheter by pushing them together and turn until the connect locks. Lock the connector by turning it one-half turn clockwise.

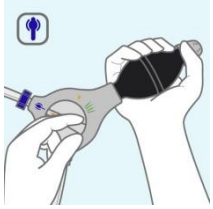
4. Attach the catheter packaging to a vertical surface by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.

5. Turn the knob on the control unit to the water symbol and pump water into the catheter packaging (2 to 3 pumps) to activate the coating.
Turn the knob on the control unit to the balloon symbol to prevent any more water from going in the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put into the rectum. Remove the lubricated catheter from the packaging and use it immediately.

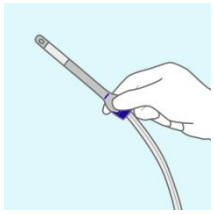
Tip: For extra stability when pumping, you can attach the control unit to the thigh by using the strap:

A  B 	Attach the control unit and tubing to the thigh by using the strap: A. Place the strap around the base of the pump. Slide the strap through the buckle and pull tight. B. Fit the pump to your thigh, adjusting the strap for a comfortable fit.

Insertion of rectal catheter

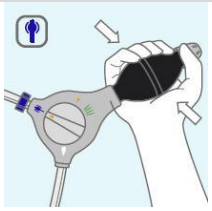


6. Ensure the knob on the control unit is pointing to the balloon symbol . As instructed by your health care professional, insert the rectal catheter carefully into the rectum without using force. The catheter should slide in smoothly.

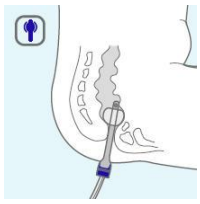


When inserting the catheter, hold it by the finger grip. The finger grip is the widest part of the catheter. Your healthcare professional will instruct you how far to insert the catheter.

Inflation of balloon



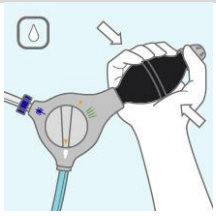
7. Start pumping gently to inflate the balloon. Your health care professional will advise you how many times to pump. A few pumps are usually enough. Your healthcare provider will write down the number of times to pump on the Health Care Notes form they gave you.



Note: Do not overinflate the balloon. The balloon on the small catheter must not be pumped more than twice. The balloon on the regular catheter must not be pumped more than five times.

Note: If you sense that the balloon is too big, turn the knob to the air symbol to deflate it. When ready turn to the balloon symbol to inflate the balloon once again.

Insertion of water

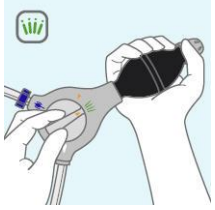


8. Turn the knob on the control unit counter-clockwise to the water symbol . Squeeze the pump slowly-about once per second-until the right amount of water has flowed in. Your healthcare provider will train you on how much water to use and they will write down the number of times to pump on the Health Care Notes form they gave you.

If water leaks, try inflating the balloon further by turning the knob on the control unit clockwise to the balloon symbol and pump one more time. Turn the knob anti-clockwise to the water symbol and resume irrigation.

In case of discomfort, turn the knob of the control unit to the balloon symbol to stop the water flow and wait until it ceases. When you are ready, turn the knob back to the water symbol and resume pumping. If the discomfort continues, deflate the balloon, remove the catheter and contact your health care professional immediately.

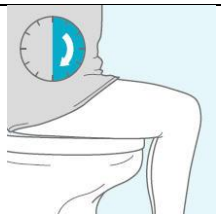
Removal of rectal catheter



9. Turn the knob on the control unit counter-clockwise to the air symbol to deflate the balloon. Often the catheter will slide out by itself; if not, pull the catheter gently.

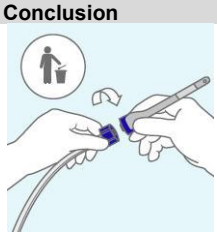
Note: Do not remove the catheter before the balloon is completely deflated
Note: For most efficient result remove the catheter immediately after the balloon has deflated

Emptying



10. Soon the colon will start to empty itself. If nothing happens, try to press, cough or move the upper part of your body to activate the emptying process. The drainage time is individual, but on average it takes thirty minutes.

Conclusion



11. Unlock the connectors from the lid and the catheter. Discard the single use catheter.

Pour excess water out of the bag.

When storing the system, turn the knob on the control unit anti-clockwise to the finish symbol  . When the knob is placed in this position, any remaining water in the tubes will run out. Ensure the tubes are not kinked when stored in the storage case and that the system and all its parts are kept away from sharp objects.

The set and the rectal catheter should be stored at room temperature (max. 77°F) and out of direct sunlight.

Physician Notes:

Peristeen Anal Irrigation is designed to be carried out independently or with the assistance of a caregiver in the user's home. It is important that a healthcare professional supervises the first use of Peristeen Anal Irrigation to help the patient use the system safely, optimally and with confidence. Once a patient and/or caregiver has completed irrigation under supervision, they may try the procedure alone. Sometimes more than one training session is required so each patient should be considered individually in terms of their readiness and capability to do so. Subsequent irrigations should be followed-up by consultations in person or by telephone until the patient and/or caregiver has fully adapted the procedure to meet the individual needs and until they are confident to continue the procedure independently. If a patient is heavily and/or chronically constipated, it may be necessary to thoroughly clean out their bowels before starting Peristeen Anal Irrigation.

Physicians should prescribe irrigation based upon a comprehensive evaluation of the nature of the patient's fecal incontinence and the frequency of either constipation or soiling episodes. Generally, Coloplast recommends that anal irrigation be performed every other day; more or less frequent irrigation may be advised depending upon individual patient needs.

Prior to starting Peristeen Anal Irrigation for the first time, please take time to describe the procedure to your patient, answer any questions, and help manage their expectations. To avoid potential disappointment or concern that anal irrigation does not work for them, explain that an initial period of adjustment is perfectly normal and is required to establish their personalised routine. An anal irrigation bowel diary is a good way of keeping track of progress during this period (see table 1). Peristeen Anal Irrigation can work successfully within a few days but for some individuals it can take 4 to 6 weeks for the treatment to settle down and become routine.

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For new users of Peristeen Anal Irrigation, the irrigation routine should be tailored to meet their individual requirements. It is helpful to ensure the patient understands that, at first, some trial and error will be required to optimise the process and establish their personalised routine. For some people it can take 4 to 6 weeks to adapt the routine. Make sure to complete a **Health Care Notes form** for the patient and/or caregiver to refer to. The **Anatomy Notes** sheets can also be used to make notes and special recommendations on an individual basis.

There are several parameters that can be adjusted if required:
1. Amount of air in the catheter balloon
2. Amount of water used for irrigation
3. Frequency of irrigation

Amount of air in the catheter balloon
The function of the balloon is to hold the catheter in place in the rectum; the degree to which the balloon must be inflated to achieve this (i.e. the number of pumps of air required) depends on the condition of the individual's sphincter and rectum. The average size adult will probably require 3 to 4 pumps of air in the balloon (maximum 5 pumps); for smaller patients, 1 to 2 pumps may be sufficient. Insufficient air can cause water to leak or the catheter to slide out of the rectum. If water leaks during the procedure, patients and/or caregivers should attempt pumping one more time to a maximum of 5 pumps in total. Conversely, too much air can cause the balloon to be expelled. If this happens, repeating the procedure using a little less air should be attempted. The frequency of expulsions often decreases as a patient becomes used to the procedure.

Please use the following notes to guide the amount of air pumped into the balloon for an average size adult patient:

• Intact sphincter reflexes and muscle tone: 1 to 3 pumps
• Flaccid bowels or low sphincter tone: 3 to 5 pumps. If the catheter still slides out of the rectum, it may be supported by holding in place
• Strong anorectal reflexes: The balloon may be expelled after only 1 to 2 pumps; careful insertion and inflation of the balloon is necessary, using less air

For smaller patients, 1 to 2 pumps is recommended.

Amount of water for irrigation
The volume of water required to effectively empty the bowel depends on several factors including the patient's bowel condition, their diet and the frequency of irrigation.

When first using Peristeen Anal Irrigation in adults, a water volume of 500 ml is recommended, and irrigation should be performed daily. This volume can be gradually increased, over the next few weeks, until the individual feels they are completely empty and have no accidents between irrigations. Increases in volume should be done slowly, especially in younger patients and patients with spina bifida. Many adult patients eventually use a volume in the region of 750 ml; however, studies have shown that the amount of water varies from 200 to 1500 ml in adults. Some patients with upper neurone damage experience evacuation of the bowel at low water volumes (e.g. 200 to 300 ml); in some cases the irrigation procedure might need to be repeated to ensure sufficient emptying.

If leakage occurs after the irrigation try:

• Advising the patient to stay on the toilet a little longer to allow complete emptying of the bowel
• Reducing the volume of water
• Two half volume irrigations (e.g. two 250 ml irrigations instead of one 500 ml irrigation)

If irrigation water is not expelled after sitting on the toilet for 20 to 30 minutes, it could be that the bowel has absorbed the water because the patient is dehydrated or that the irrigation fluid is captured in impacted stools:

• Repeat the irrigation using the same volume of water
• Advise the patient to drink more fluids – at least 1.5 litres per day and more in hot weather

The recommended rate for pumping water into the bowel is one pump per second. Pumping water into the bowel too quickly may cause discomfort, sweating, dizziness and stomach pain; if this occurs, the procedure can be paused at any time and resumed when the discomfort has passed and the patient feels ready. If the discomfort does not pass, the irrigation should be stopped and the patient's usual bowel care routine followed to achieve emptying.

Water should be lukewarm (96 to 100°F). If the water is too hot it may damage the mucous membranes lining the bowel and if it is too cold it may trigger reflexes and increase spasms. Plain tap water is recommended or bottled water when travelling in countries where drinking tap water is not recommended.

Frequency of irrigation
For patients who are new to Peristeen Anal Irrigation, it is recommended to irrigate on a daily basis. After one or two weeks some patients find that irrigation can be tried every second day. As the frequency of irrigation is decreased, it may be necessary to adjust other parameters; for example, the volume of water may need to be increased to achieve complete emptying. Some patients will find it necessary to irrigate every day but eventually most patients settle into a routine of irrigation every other day. Conducting irrigation at approximately the same time each day seems to work best for most people, but is not essential. Eating and drinking stimulate the bowel, so about 30 minutes after a meal gives the best chance of the irrigation working with the natural activity of the bowel and achieving the best emptying. The most convenient time can be chosen by the patient to fit in with their daily routine. Alternatively, it can be varied to fit around a changing routine giving the patient the maximum possible freedom.

The system and the rectal catheters should be stored at room temperature (maximum 77°F) and out of direct sunlight. When storing the system, ensure that you turn the knob on the control unit to the Finish symbol  . Also ensure that the tubes are not kinked and that the system is kept away from sharp objects.

The tubes can be cleaned by turning the knob on the control unit to the water symbol and pumping the dirty water out of the tube. Patients may choose to change the tube with the blue connectors more frequently if desired. The outer surface of all the components (excluding the single use catheter) can be washed in mild soapy water and rinsed thoroughly. The Control Unit knob should be in the Finish position when the Peristeen System is not in use.

Product Evaluation:

Coloplast requests physicians to notify the company of any complications which may develop with the use of this device, and requests return of any used devices or components associated with the complication. For safe handling during shipment and upon receipt, Coloplast requests that devices be decontaminated prior to shipment. This is requested even though Coloplast will autoclave-sterilize any opened product returned. Alteration for the purposes of venting to prevent additional damage will be performed as required. If necessary, Coloplast may analyze the device, and the patient and physician may be asked to allow Coloplast to perform tests that might alter the condition of the device.

Any complications from the use of this device should be brought to our immediate attention by contacting: Quality Assurance, Product Evaluations Department, Coloplast Corp.,1601 West River Road North, Minneapolis, MN 55411
Toll-free telephone (800) 338-7908 in USA; or outside USA: (612) 337-7800

Product Order Information

To order, please contact your local sales representative or Coloplast Customer Service Department at: Coloplast, 1601 West River Road North, Minneapolis, MN 55411; Toll-free telephone: (800) 258-3476; or outside USA: (612) 337-7800; or fax (866) 216-4161 or outside USA: (612) 337-7803.

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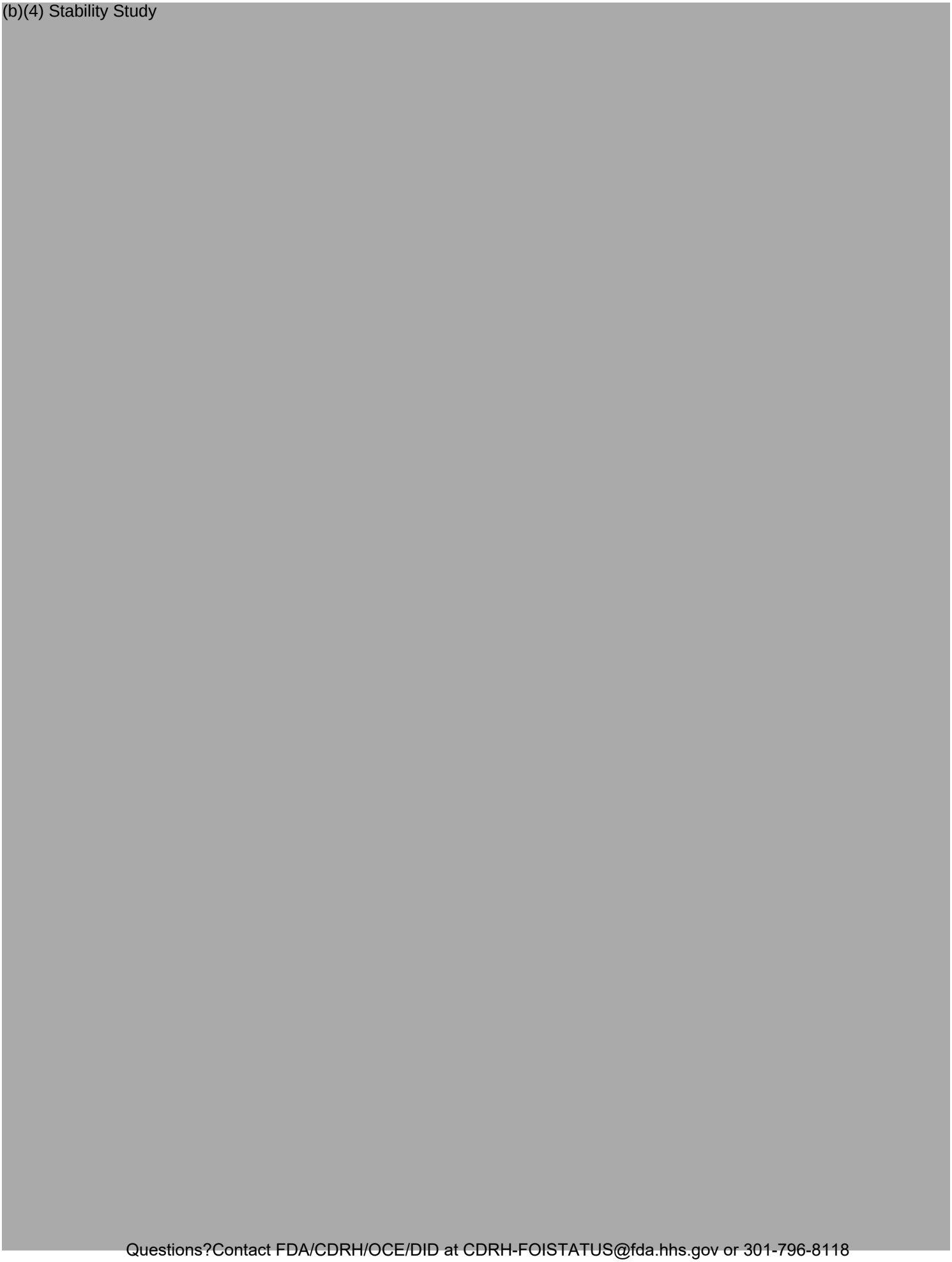

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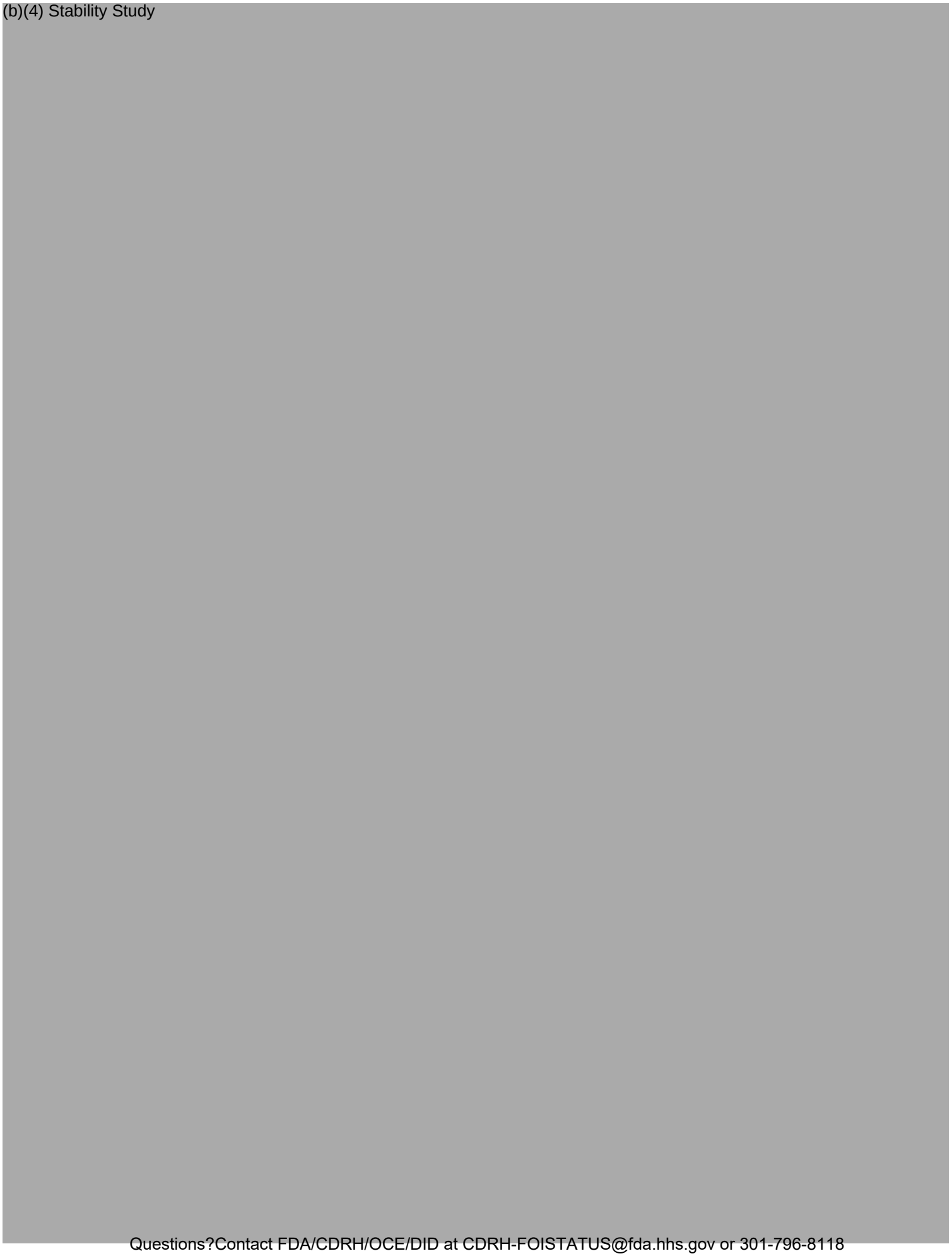
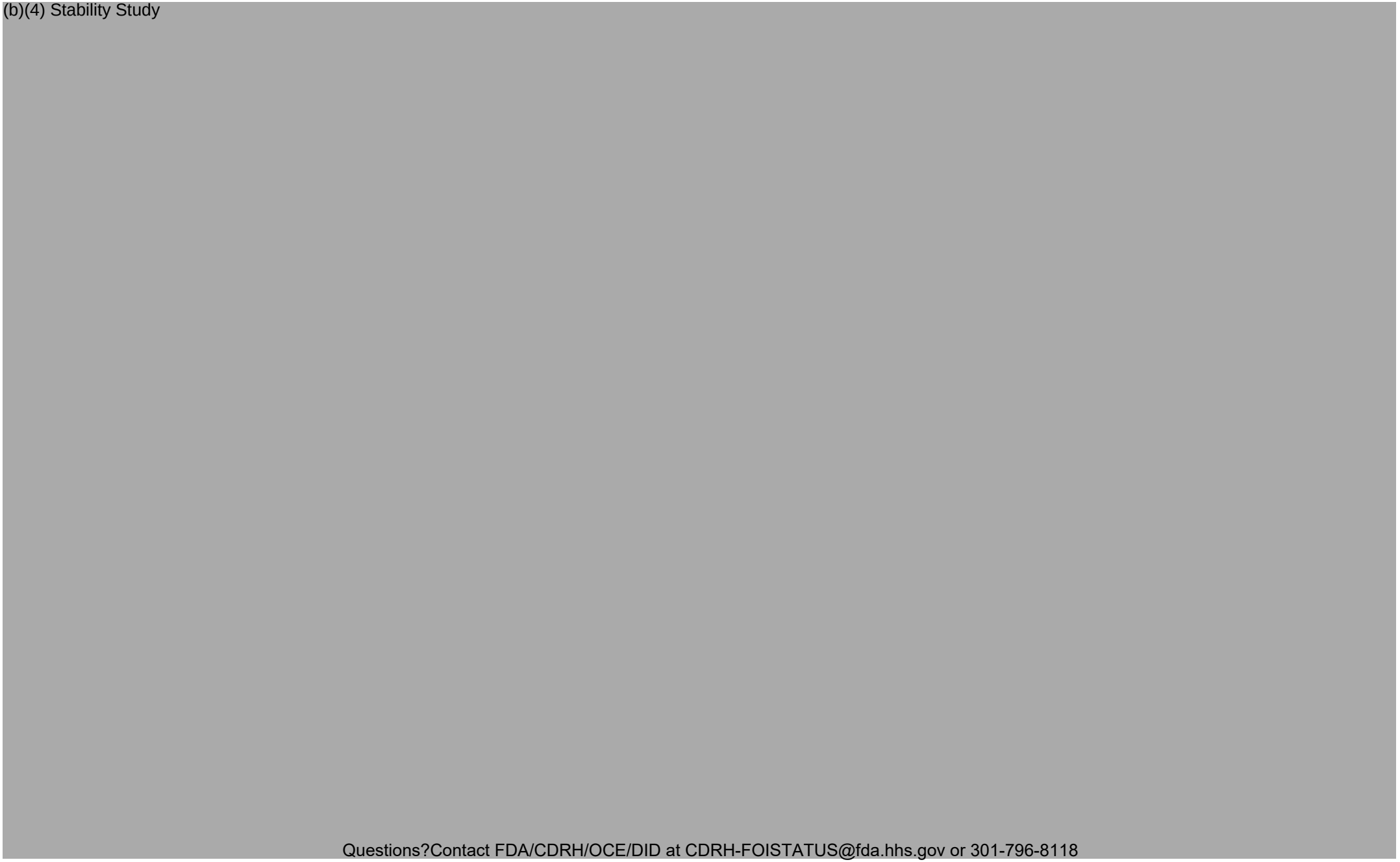
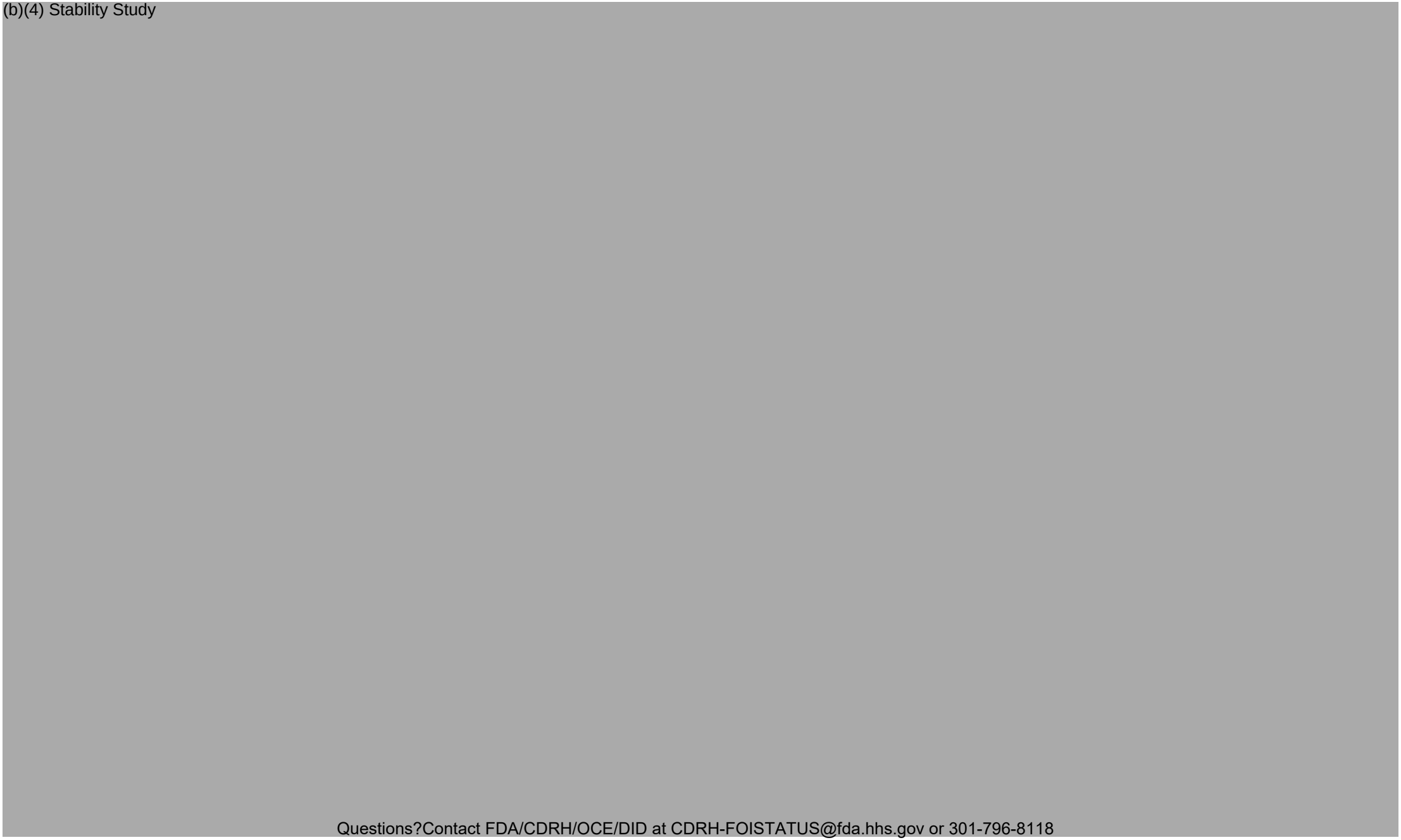
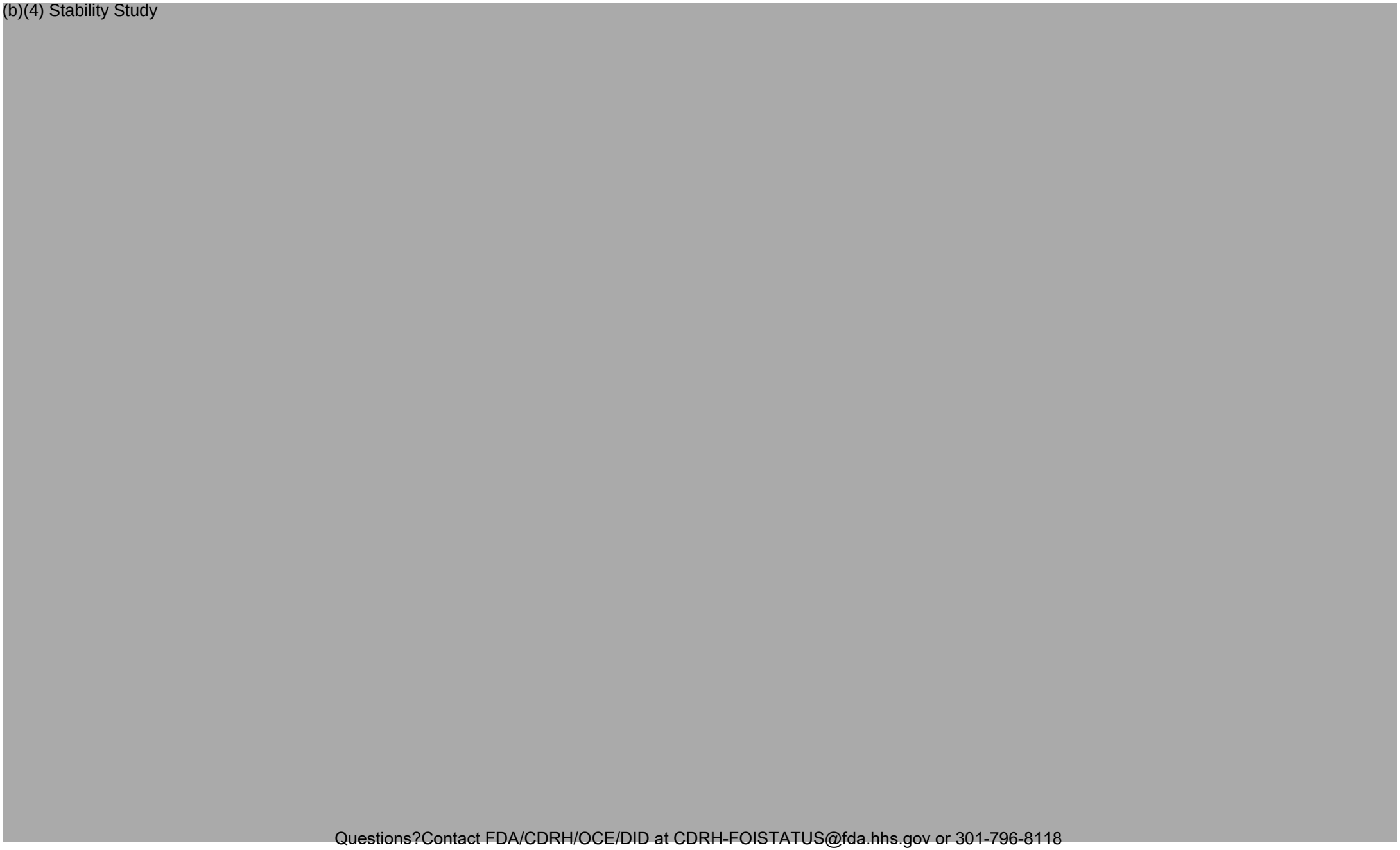
(b)(4) Stability Study









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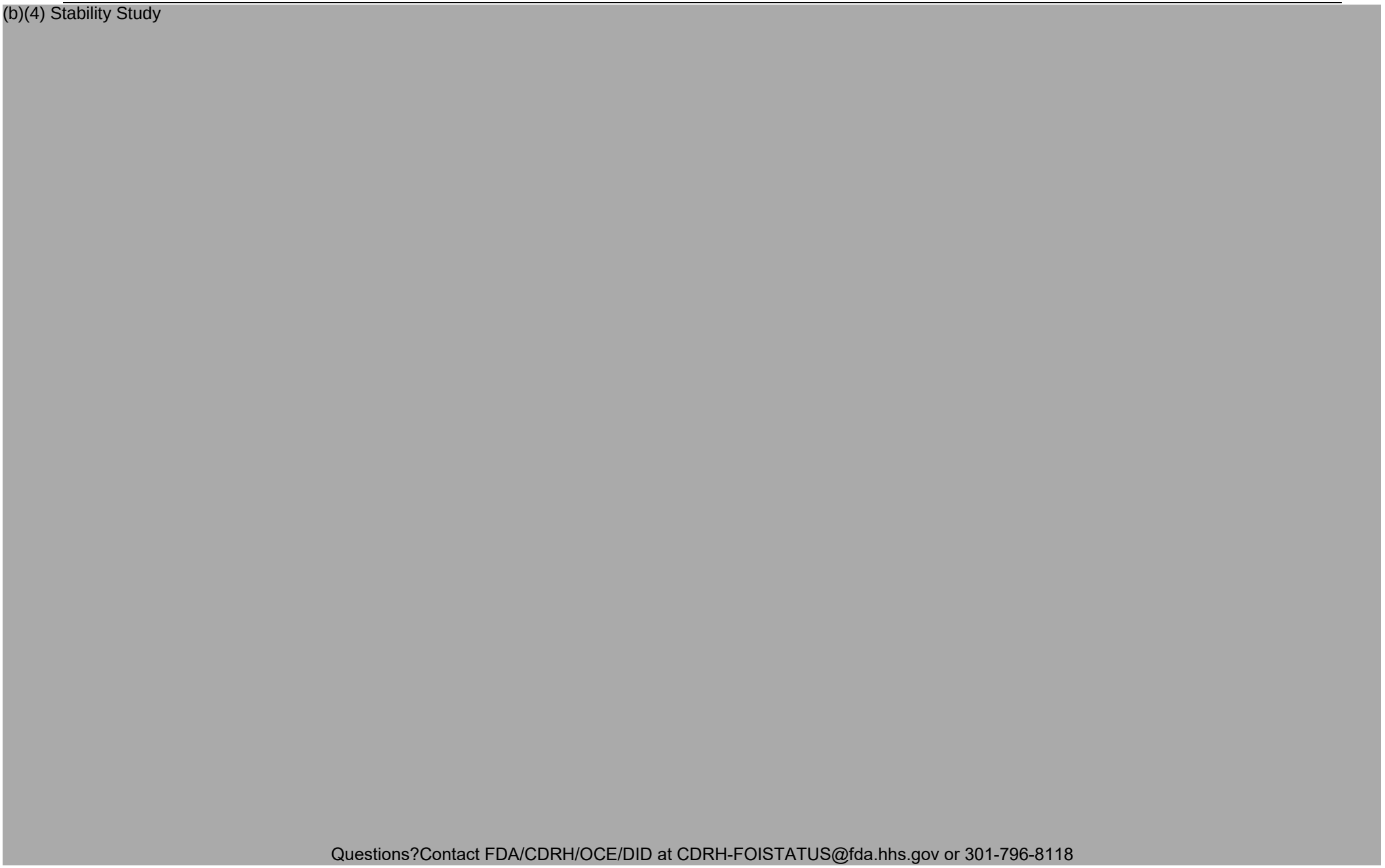

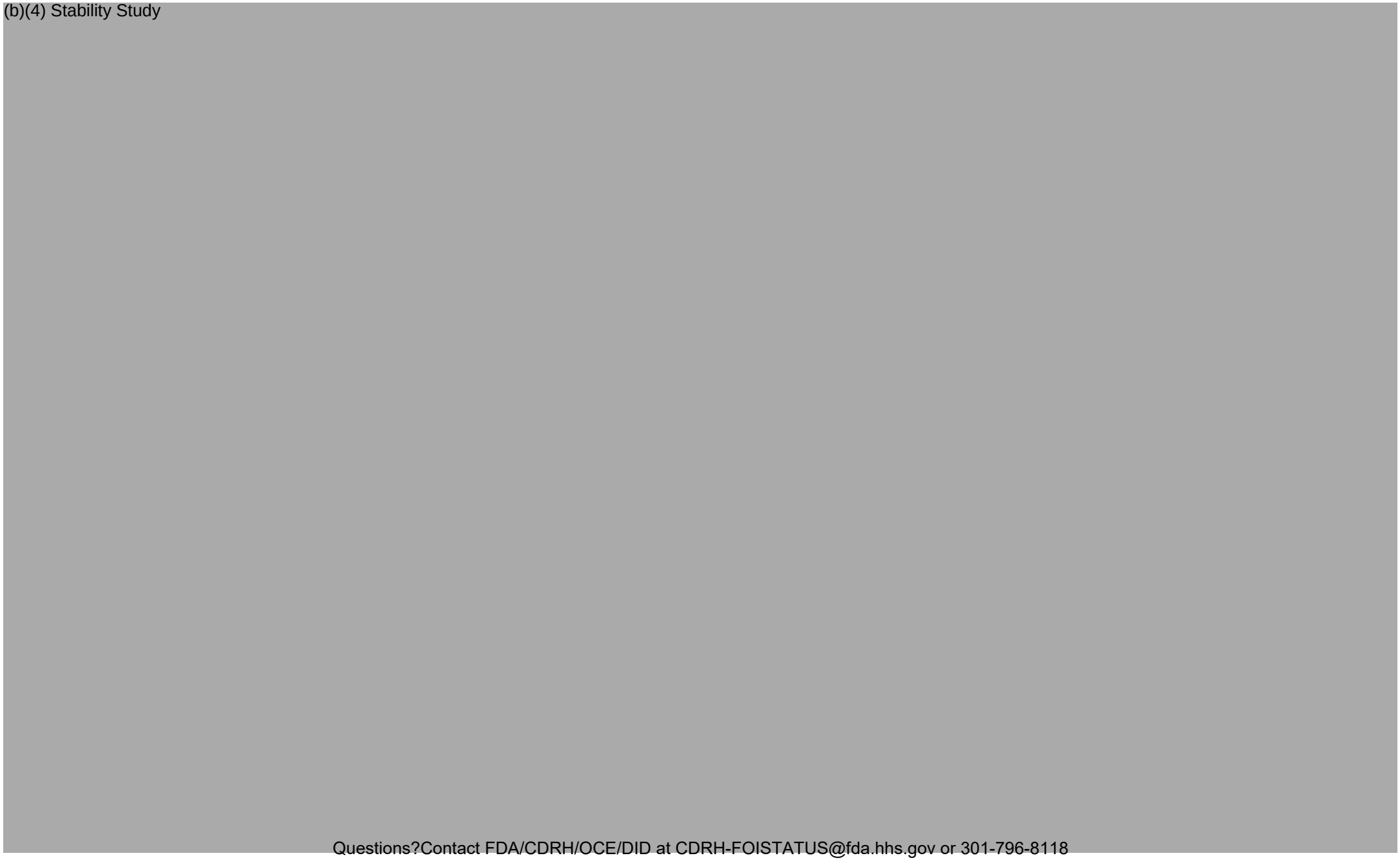

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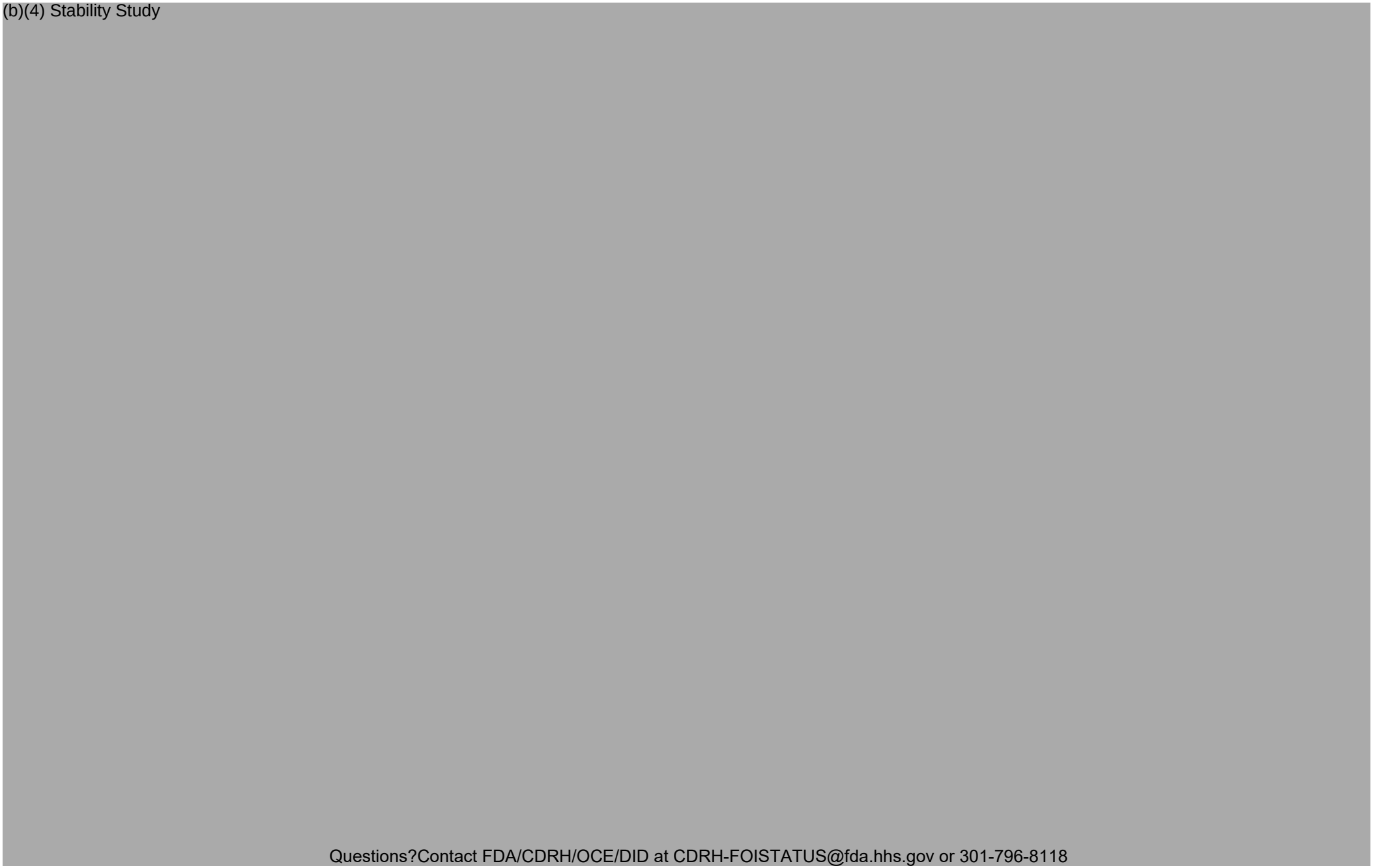

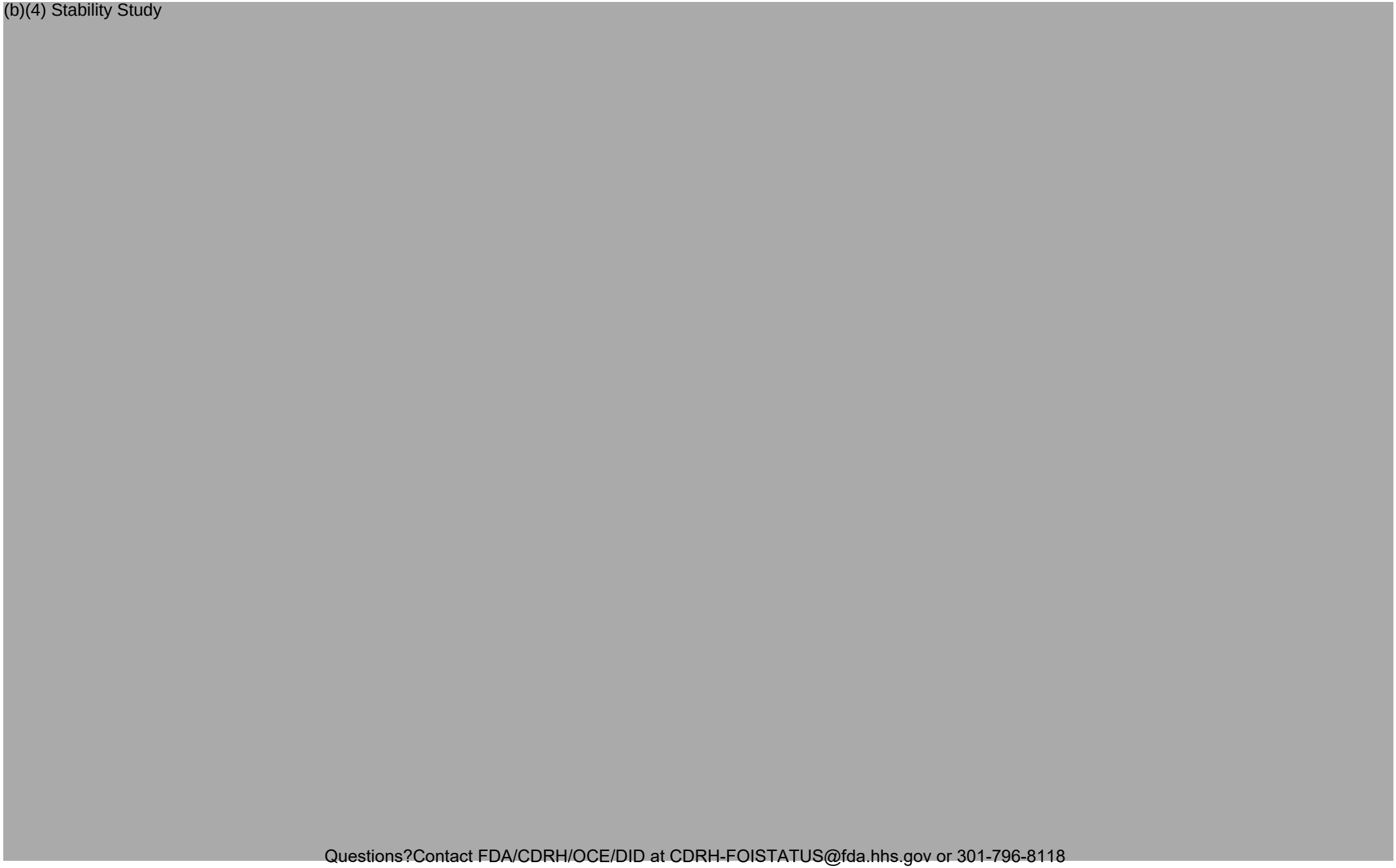

(b)(4) Stability Study

(b)(4) Stability Study

SIGNATURE PAGE

Date (GMT)	Signed by
2011/09/01 11:43:55	Pia Oelgaard
Justification	Issuer; QA Project Manager

2011/09/07 08:39:27	Jens Høg Truelsen
Justification	GRD PM

Justification	

Justification	

Justification	

Justification	

This is an electronically signed document

Coloplast

Declaration of Conformity with Design Controls

Verification Activities

To the best of my knowledge, all verification and validation activities required by the risk analysis for the modification were performed by the designated individual(s), and the results demonstrated that the predetermined acceptance criteria were met.

20/9-2011

Jens Høg Truelsen
Senior Project Manager, Global R&D
Coloplast A/S

Date

Manufacturing Facility

The manufacturing facility, Coloplast in Hungary, is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Camilla Pagh

20/9-2011

Camilla Hjort Pagh
Director, Q&E Quality
Coloplast A/S

Date

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Marian Golding

Subject: 510(k) Number K112860/S2

To: The Record

Please list CTS decision code SE

☐ Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
☐ Hold (Additional Information or Telephone Hold).
☒ Final Decision (SE, SE with Limitations, NSE (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

- ☐ NO NSE for lack of predicate
- ☐ NI NSE for new intended use
- ☐ NQ NSE for new technology that raises new questions of safety and effectiveness
- ☐ NU NSE for new intended use AND new technology raising new questions of safety and effectiveness
- ☐ NP NSE for lack of performance data
- ☐ NS NSE no response
- ☐ NL NSE for lack of performance data AND no response
- ☐ NM NSE pre-amendment device call for PMAs (515i)
- ☐ NC NSE post-amendment device requires PMAs
- ☐ NH NSE for new molecular entity requires PMA
- ☐ TR NSE for transitional device

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) (Located in Appendix A, Original Submission)		✓	
Is this a combination product? (Please specify category N, 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.)		✓	
‌! the application include a completed FORM FDA 3674, Certification with Requirements of ..nicalTrials.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			

4

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

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

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
876.5980	II	KNT

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Carolyn Y Neuland (Branch Chief) GRDB (Branch Code) 6/7/12 (Date)

Final Review: (Division Director) 6/8/12 (Date)

dlr

DEPARTMENT OF HEALTH AND HUMAN SERVICES **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K112860 Supplement S002

Date: 6/7/12
To: The Record
From: Martin Golding, M.D.

Office: ODE
Division: DRGUD
Branch: GRDB

510(k) Holder: Coloplast A/S
Device Name: Peristeen™ Anal Irrigation (PAI) System
Contact: Brian Schmidt, Regulatory Affairs Manager
Address: 1601 West River Road
Minneapolis, MN 55411
Phone: (612) 302-4987
Fax: (612) 287-4138
Email: usbes@coloplast.com

(b) (4)

(b) (4)

[redacted]

III. 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 #3654 http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf			x
Clinical Trials Form http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf			x

III. Device Description

The Peristeen™ Anal Irrigation system is a Class II device, consisting of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times.

Figure 1: Peristeen Anal Irrigation System

The Peristeen Anal Irrigation (PAI) System (see Figure 1) is intended for intermittent use to allow the flow of water into the colon that facilitates emptying of the colon/bowel in spinal cord injury patients with neurogenic bowel dysfunction. The PAI System consists of a single-use irrigation catheter (see Figure 2) that incorporates an inflatable balloon to keep the catheter in place during the procedure and retain the water that flows into the colon, preventing leakage while irrigating. The rectal catheter is non-sterile, intended for single-use.

Figure 2: Proposed Peristeen Catheter

The control unit (see Figure 3) is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake. The control unit housing has a manually operated knob that has the four positions indicated in Figure 3:

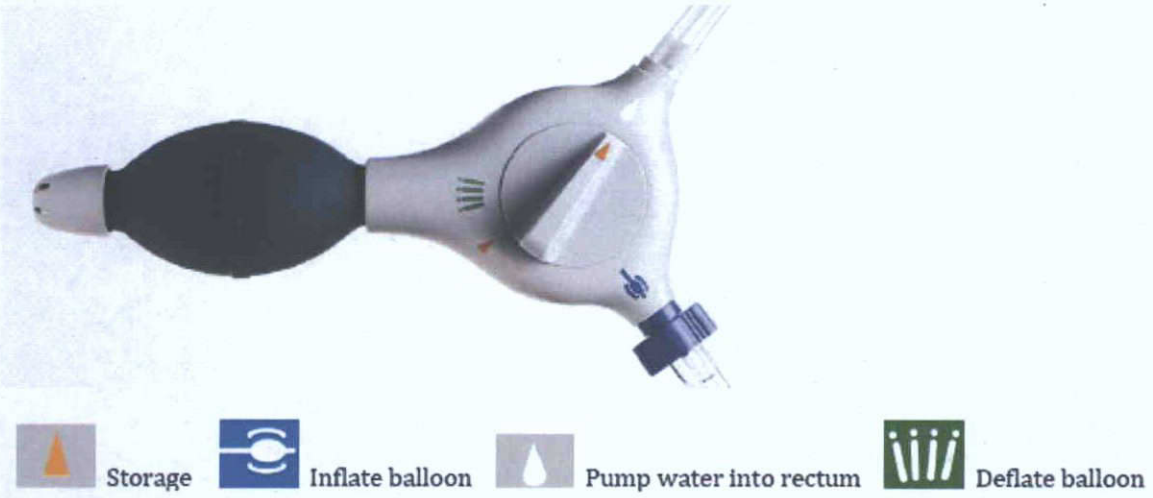

Figure 3: Peristeen Anal Irrigation System Control Unit

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	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)? Are validated "cleaning" instructions included for the end user?	x*		

*All components are reusable for a specified number of times except for the rectal catheters which are labeled as single use only. The end user is instructed to clean the reusable components with soap and water

IV. Device Comparison

(b) (4)

Table 1: Materials

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Material	PVC (polyvinyl chloride)	(b) (4)
Balloon Material	Chloroprene	
Lubricious coating: - Top coating - Base coating	 PVP (Poly Vinyl Pyrrolidone) Polyurethane	

Table 2: Production Processes

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Balloon material	Dip molded	(b) (4)
Rectal Catheter	Dip molded	
Balloon to Catheter attachment	Glued	

Table 3: Other Device Characteristics

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Length	5.52 in	(b) (4)
Sterility	Non Sterile	
Packaging	Plastic Pouch	
Shelf Life	1.5 years	

V. Labeling/User Guide

The sponsor has provided the following comparison between the proposed and predicate labeling in an email attachment provided on October 20, 2011.

Table 4: Changes to Contraindications

New User Guide	Predicate User Guide
Anal irrigation procedure should always be carried out with care. Bowel perforation is an extremely rare, **but serious and potentially lethal complication** to anal irrigation and will require immediate admission to a hospital, **often requiring surgery**	Anal irrigation should always be carried out with care. Although bowel perforation is extremely rare, it is a potential complication to anal irrigation and will require immediate admission to hospital.
Severe and sustained abdominal pain or back pain, **especially if combined with fever**	Severe and sustained abdominal pain or back pain, with or without fever
Sustained anal bleeding	Severe anal bleeding
During the spinal shock phase	During the spinal shock phase
Known obstruction of the large bowel due to strictures or tumors	Known obstruction of the large bowel
Diverticulitis	Diverticulitis
Acute inflammatory bowel disease	Acute inflammatory bowel disease
ADDED-Abdominal or anal surgery within the last 3 months	Was not a previous contraindication
If you are pregnant and have never used anal irrigation before, you should not start up the irrigation procedure during pregnancy	If you are pregnant and have never used anal irrigation before, you should not start up the irrigation procedure during pregnancy

Table 5: Changes to Precautions

New User Guide	Predicate User Guide
ADDED-If you are heavily constipated an initial and thorough clean-out of your bowels is advisable before starting up the irrigation procedure.	This statement was not in the predicate guide.
Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)	Suffer from an Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
Ischemic colitis	Was not a previous precaution
Any Anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids **(third or fourth degree hemorrhoids)**	Any Anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids
Irradiation therapy in the abdominal or pelvic region	Have had Irradiation therapy in the abdominal or pelvic region
Diverticular disease	Was not a previous precaution
Previous abdominal or anal surgery	Have had recent abdominal or anal surgery
Recent colonic biopsy or polypectomy	Was not a previous precaution
~~**Spinal Cord Shock Phase**~~	Was previously a contraindication
Autonomic dysreflexia	Suffer from Autonomic dystreflexia
Cancer in the abdominal or pelvic region	Was not a previous precaution
Fecal impaction	Was not a previous precaution
Long term steroid therapy	Was not a previous precaution
Anticoagulant therapy or bleeding disorder	Have a regular intake of anticoagulant medication with vitamin K antagonists, as normally small and harmless rectal bleeding may be difficult to stop
Change stool pattern like sudden diarrhea of unknown origin. The cause for diarrhea must be identified	Have diarrhea, as the cause of the diarrhea must be identified.

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New User Guide	Predicate User Guide
Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.	Use Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.
Severe cognitive impairment (unless caregiver is available to supervise/administer)	Was not a previous precaution
Children under 2 years of age	Was not a previous precaution
REMOVED	Are pregnant and have previous experience with anal irrigation, please consult your doctor to carefully evaluate if you may continue irrigating.

Table 6: Changes to Instructions

New User Guide	Predicate User Guide
The water must be lukewarm **(96-100°F).** If it is too hot, it may harm the delicate lining of the **bowel**; if it is too cold, **stomach** cramps may occur.	The water must be lukewarm (36-38°C). If it is too hot, it may harm the delicate lining of the rectum; if it is too cold, cramps may occur.
If you feel the need for a break, turn the knob on the control unit to the balloon symbol. When you are ready, turn the knob back to the water symbol and resume pumping.	In case of discomfort and you feel the need for a break, stop the water flow and wait until it subsides. When you are ready, resume pumping. If the discomfort does not disappear, contact your health care professional immediately.
Try one or more of the following: sitting in the brace position (leaning/bending forward), coughing, standing up, abdominal massage. If water is still not expelled, then you may be heavily constipated and a clean-out of the bowel might be necessary. You might also be dehydrated, so remember to drink plenty of water and repeat the irrigation again the day after. Contact your health care professional for assistance.	You may be heavily constipated and a clean-out of the bowel is necessary. Contact your health care professional for assistance. The reason could also be that you have not had enough to drink and are dehydrated, so the bowel has absorbed the irrigation water. Try irrigating once more using the normal amount of water and remember to drink more water. If another attempt at irrigation does not help, contact your doctor or nurse.
The system and the rectal catheter should be stored at room temperature (maximum 77° F) and out of direct sunlight. When storing the system, ensure that you turn the knob on the control unit to the finish symbol. Also ensure that tubes are not kinked and that the system is kept away from sharp objects.	The system and the rectal catheters should be stored at a temperature of between 2° and 25° Celsius and away from direct sunlight. Ensure the tubing is not kinked when stored.

Comment:
Changes in user guide represent clarifications and do not affect the safety or efficacy of the device.

Labeling changes include change in contraindications as noted in the indications for use section, and the precautions listed below.

Precautions

Added "Ischemic colitis"
Added "Recent colonic biopsy or polypectomy"
Added "Diverticular disease"
~~Added "Spinal Cord Shock phase" *~~
Added "Cancer in the abdominal or pelvic region"
Added "Fecal impaction"
Added "Long Term steroid therapy"
Added "Children under 2 years of age"
Added "Severe cognitive impairment (unless caregiver is available to supervise/administer)

(Spinal Cord Shock phase was reinserted as a contraindication in Supplement 1.)

Comment:
The labeling adequately describes the usage of the device
The sponsor initially removed the contraindication for patients with acute spinal cord injury, and this has been included again as a contraindication in Supplement 1.
The device is provided non-sterile. The main unit is re-usable; the rectal catheter is for single use only.
There are symbols on the device that are well documented in the user guide.
There are adequate instructions for use.
There are the same contraindications, warnings and precautions as the predicate devices.
No additional contraindications are warranted.

VI. Sterilization/Shelf Life/Reuse

The rectal catheter is supplied non-sterile and is non-reusable. The remainder of the device is non-sterile and reusable.

The shelf life is the same as the predicate.

VII. Materials

The design of the proposed Peristeen catheter is in principle similar to the predicate Peristeen catheter except for the choice of materials and changes in some of the production processes. (b) (4) [redacted]. The coating and packaging processes will remain unchanged.

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Material	PVC (polyvinyl chloride)	(b) (4) [redacted]
Balloon Material	Chloroprene	
Lubricious coating: - Top coating - Base coating	(b) (4) [redacted]	

Change Made/Date	Reason	Justification for Change
Production of the double lumen tube is transferred from Coloplast A/S (Denmark) to Contract Manufacturer Prozup (Taiwan)	Switch from in-house production to contract manufacturer	Change Control no. LQUG-7LXDFE
Production of the water bag is transferred from Duoplast A/S (Denmark) to Coloplast A/S (Hungary)	Switch from contract manufacturer to in house production	Change Control no. RCHN-7NQC3T
Change in excess pressure valve and lid assembly	This minor adjustment in the specification limits reflects a slight decrease in pressure over time. This small decrease is acceptable because it cannot be detected by the patient and it does not affect the function of the device.	Change Control no. LLAN-7NWBYH LLAN-7NWCFY LLAN-7P5G6B LLAN-7P5GM5
Change in material of the hand pump	The PVC blend used for the hand pump black ball on the PAI control unit will be changed due to material discontinuation at the supplier. (b) (4) (b) (4)	Change Control no. TTOP-84GCK3

VIII. Biocompatibility

Data regarding biocompatibility results were requested from the sponsor in our first Additional Information (AI) letter, and Dr. Xin Fu has reviewed the information provided by the sponsor in Supplement 1. Dr. Fu raised a number of biocompatibility concerns in her Supplement 1 review (see biocompatibility consult). Dr. Fu reviewed the responses provided from the sponsor in Supplement 2 regarding biocompatibility deficiencies and has no further concerns.

IX. Software

Not Applicable.

XI. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable

XII. Performance Testing – Bench

Bench testing was reviewed by David Pudwill (see engineering review consult). He considers the bench performance testing provided by the sponsor in Supplement 1 to be acceptable.

XIII. Performance Testing – Animal

Not applicable

XIV. Performance Testing – Clinical

Not applicable

XV. Postmarket Surveillance Information

Not reviewed

XVI. Substantial Equivalence Discussion

The Peristeen™ Anal Irrigation (PAI) System submitted as K112860 is intended to instill water into the colon through a rectal catheter. The device incorporates an inflatable balloon. In the original 510(k) submission, the sponsor removed the contraindication for use in spinal shock phase, and added this to a list of precautions. This modification was withdrawn in Supplement 1 after a request for clinical data was requested. There are now no changes in the intended use of the device.

The sponsor modified the materials used in manufacturing the device. Mr. David Pudwill found that the bench testing was acceptable. In addition, Dr. Xin Fu did an extensive review of the biocompatibility data provided by the sponsor in Supplement 2, and has no remaining biocompatibility concerns.

X. Substantial Equivalence Discussion

	Yes	No	
1. Same Indication Statement?	x		If **YES** = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If **YES** = Stop **NSE**
3. Same Technological Characteristics?	x		If **YES** = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?			If **YES** = Go To 6
5. Descriptive Characteristics Precise Enough?		x	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?	x		If **NO** = Request Data
9. Data Demonstrate Equivalence?	x		Final Decision:

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:

2. Explain why there is or is not a new effect or safety or effectiveness issue:

3. Describe the new technological characteristics:

   The proposed device is composed of new materials as described in Section IV Device Comparison of this memo. Both bench testing and biocompatibility testing were acceptable.

4. Explain how new characteristics could or could not affect safety or effectiveness:

5. Explain how descriptive characteristics are not precise enough:

There were specific concerns raised regarding the bench testing and biocompatibility of the device since there were material changes from the predicate. In Supplement 1 the sponsor provided further information regarding bench testing which was adequate. In Supplement 2, the sponsor adequately responded to the biocompatibility issues which are now resolved.

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:

Bench testing and biocompatibility data was not provided in the original 510(k) submission. An additional information letter was sent to the sponsor with specific questions raised by Mr. Pudwill and Dr. Fu. The sponsor has provided the necessary bench testing in Supplement 1 and biocompatibility information in Supplement 2 which have resolved the remaining concerns regarding the device.

9. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

The sponsor has provided sufficient information to demonstrate that the proposed device is comparable to the predicate device in terms of safety and effectiveness. There have been no changes to the indications for use based on the modified protocol in Supplement 2. The bench and biocompatibility testing have been determined to be adequate. The data demonstrated equivalence to the predicate device.

XVII. Deficiencies

(b) (4)

(b) (4)

[redacted]

(b) (4)

XVIII. Contact History

On Wednesday, October 12th the sponsor's representative Brian Schmidt was notified that their 510(k) submission was being converted to a traditional 510(k). On Thursday, October 20th the sponsor was contacted regarding further clarification of the physician IFU and User Guide. The sponsor responded with information on the same day.

Recommendation The Peristeen™ Anal Irrigation (PAI) System (K112860) is substantially equivalent (SE) to the predicate devices (K083770 and K103254)

Regulation Number: **21 CFR §876.5980**
Regulation Name: Peristeen™ Anal Irrigation (PAI) System
Regulatory Class: II
Product Code: **KNT**

Martin I. Golding, M.D. — Date: 6-7-12

Carolyn Neuland, Ph.D. — Date: 6/7/12

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510(k) SUMMARY REQUIREMENTS 21 CFR 807.92				
All 510(k) summaries shall contain the following information:		Y	N	N/A
1	The submitter's name, address, telephone number, a contact person, and the date the summary was prepared	✓		
2	The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name	✓		
3	An identification of the legally marketed device to which the submitter claims equivalence.	✓		
4	A description of the device that is the subject of the premarket notification submission, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device (e.g., device design, material used, and physical properties)	✓		
5	A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. Or, if the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled	✓		
6	If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. Or, if the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section	✓		
510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information				
7	A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence	✓		
8	A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence			✓
9	The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section	✓		

olding, Martin

From: Fu, Xin
Sent: Wednesday, June 06, 2012 5:10 PM
To: Golding, Martin
Cc: Fu, Xin
Subject: K112860/S2 biocompatibility review

GN 6/7/12

Attachments: K112860S2 BiocomReviewMemo XFU 060612.doc

K112860S2
:omReviewMemo XF

Martin,

Attached please find my review. I don't have concern with the device. Please let me know if you have any question.

Regards,
Xin

Xin Fu, Ph.D., D.A.B.T.
Pharmacologist
CDRH/ODE/DRGUD/ULDB
Tel: (301) 796-6553
"in.fu@fda.hhs.gov

22

Memo to Record

Date: June 6, 2012
From: Xin Fu, Ph.D., D.A.B.T., DRGUD/ULDB
To: Martin Golding, M.D., DRGUD/GRDB
Subject: Biocompatibility Review for K112860/S002
Company: Coloplast A/S

This consult is provided to Dr. Golding in response to his request for review of biocompatibility-related deficiencies from previous review of device, **Peristeen™ Anal Irrigation System,** from Coloplast.

Product code KNT, Class II 21CFR 876.5980, gastrointestinal tube & accessories; Class I 21CFR876.5210 Enema kit

I. INTENDED USE

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter -which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

II. DEVICE DESCRIPTION

The Peristeen™ Anal Irrigation (PAI) system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times.

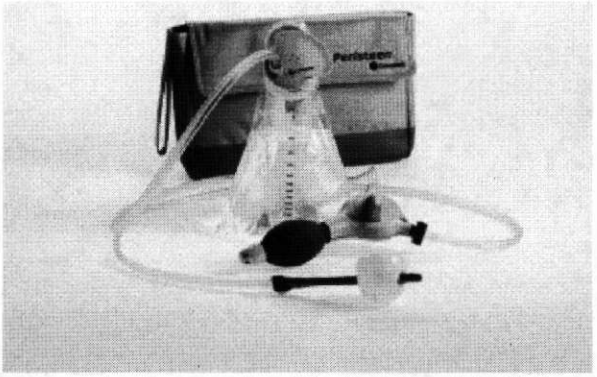


Figure 1: Peristeen Anal Irrigation (PAI) System

The proposed device is modified from the Peristeen device that was previously cleared under K083770 and K103254. The modifications include change in design and materials of the regular rectal catheter and update of the instructions for use. The differences are illustrated in the following picture (left, current Peristeen catheter; right, proposed Peristeen catheter) and described in the following tables.

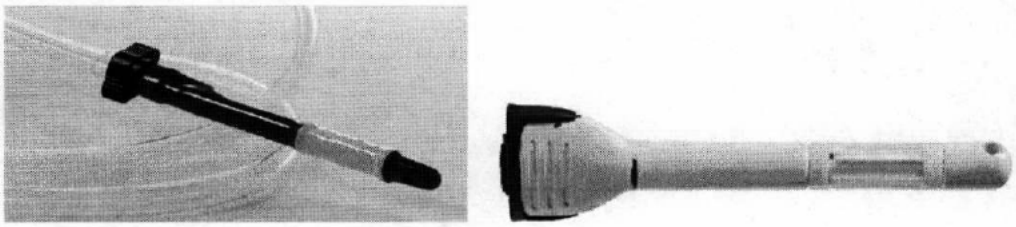


Table 1. Materials

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Material	PVC (polyvinyl chloride)	(b) (4)
Balloon Material	Chloroprene	
Lubricious coating: - Top coating - Base coating	(b) (4) (b) (4)	

Table 2: Production Processes

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Balloon material	(b) (4)	
Rectal Catheter		
Balloon to Catheter attachment		

Table 3: Other Device Characteristics

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Length	5.52 in	(b) (4)
Sterility	Non Sterile	
Packaging	Plastic Pouch	
Shelf Life	1.5 years	

Other changes include:

- Manufacturers are change for production of double lumen tube and water bag
- Change in excess pressure valve and lid assembly – a slight decrease in pressure over time.
- Change in material of the hand pump – (b) (4)

(b) (4)

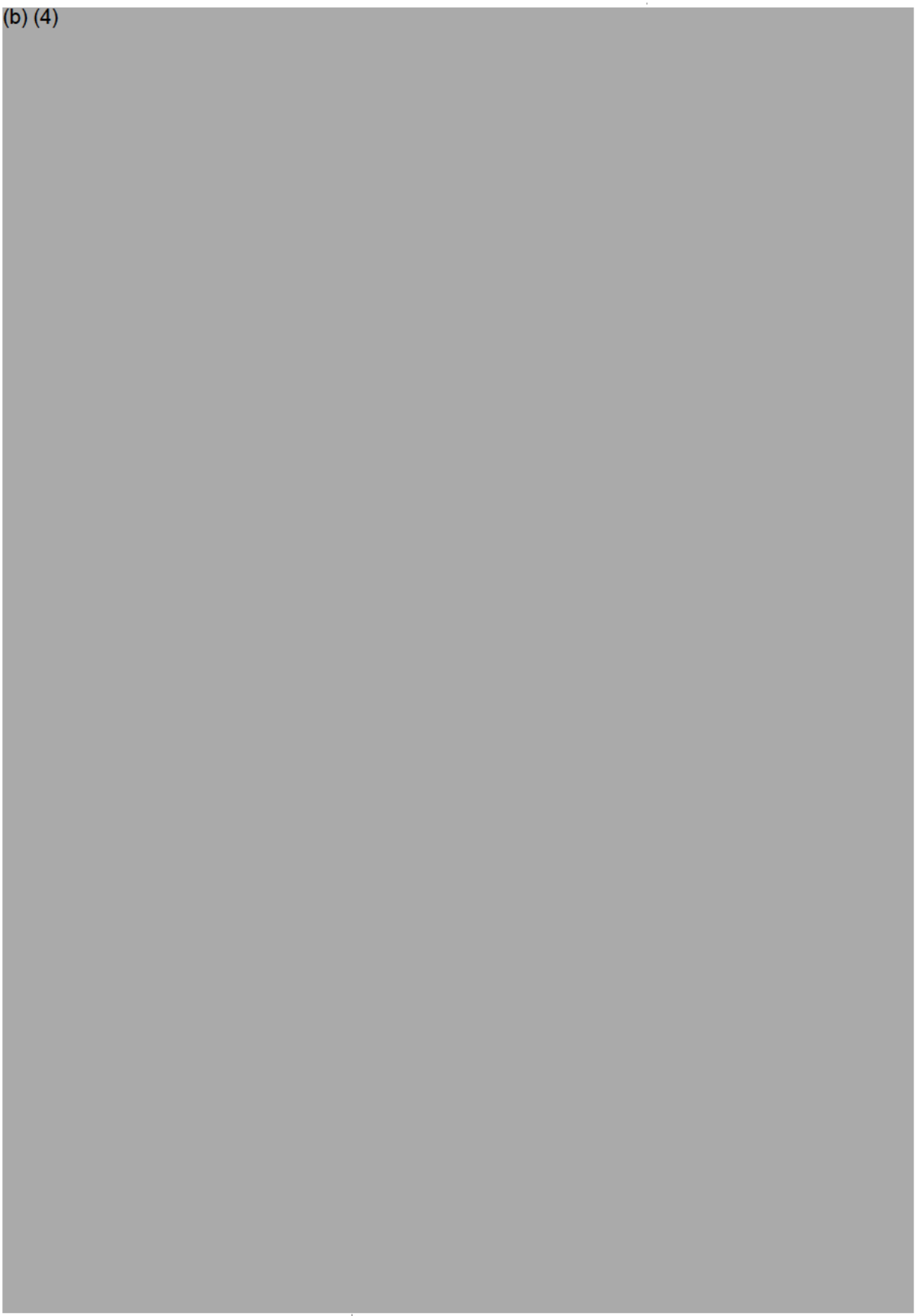
The following sections in bold italics are the deficiencies identified in previous review, followed with the responses from the sponsor and the reviewer's review.

(b) (4)

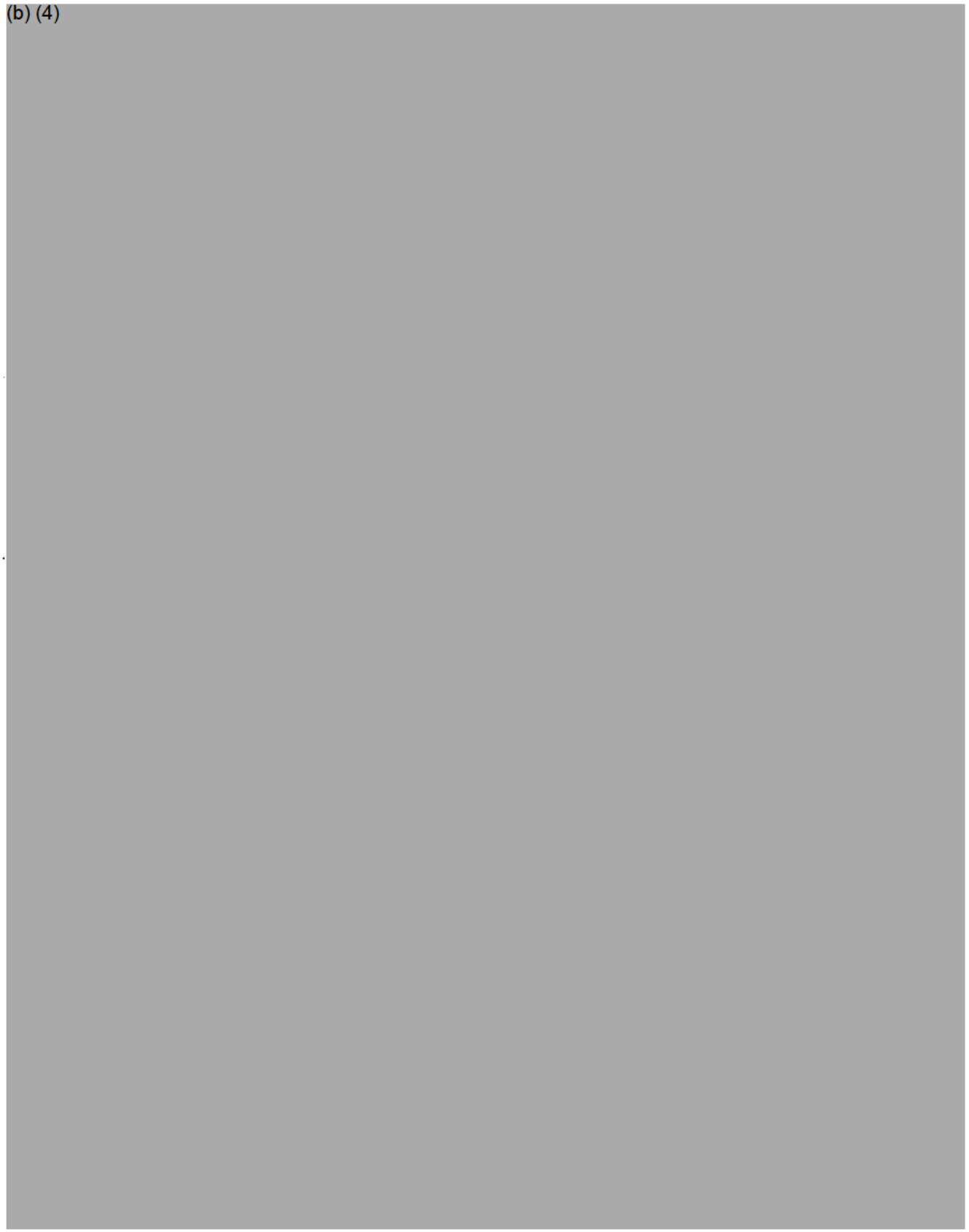
Review comment: *The response is satisfactory.*

(b) (4)

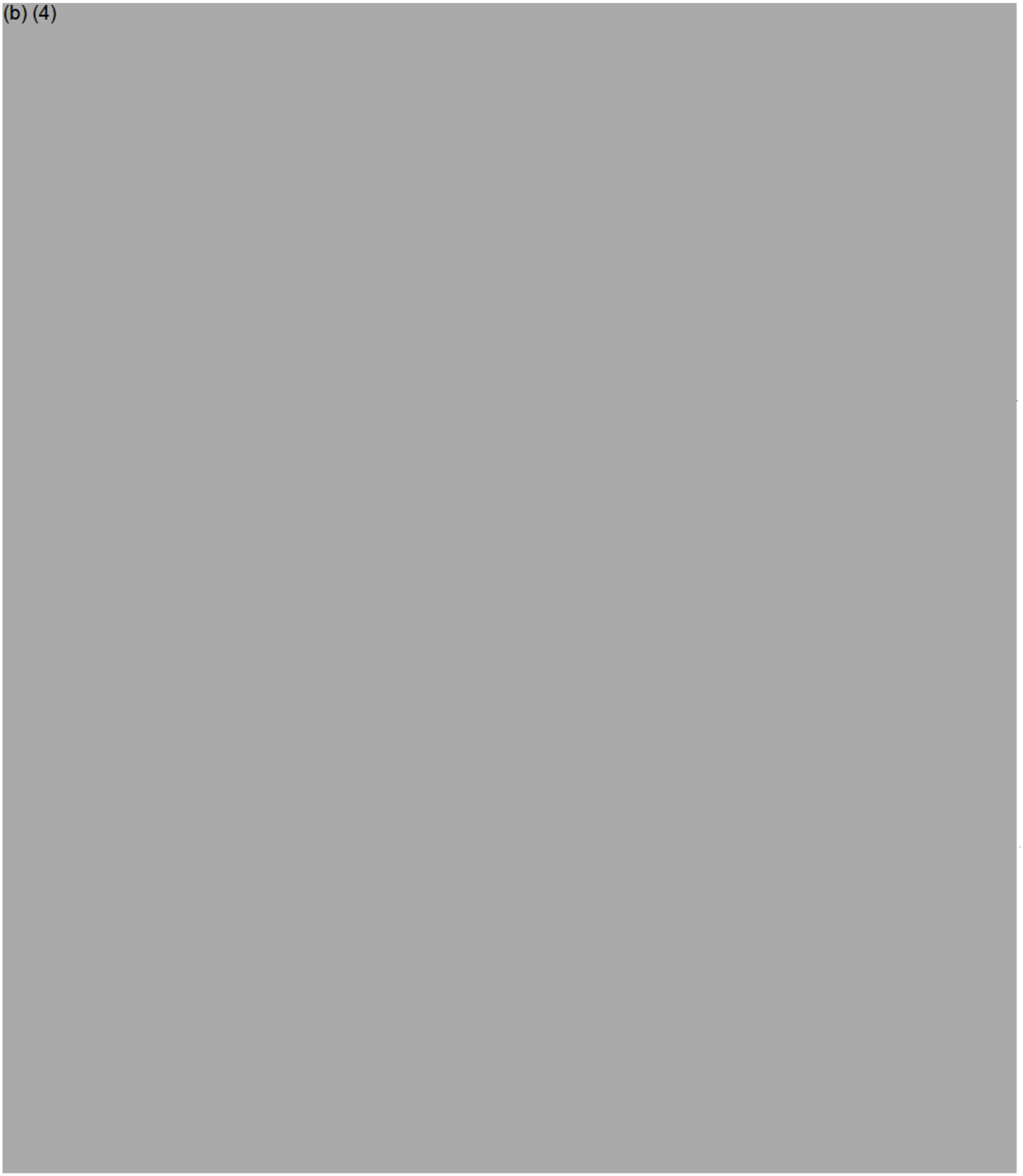
(b) (4)



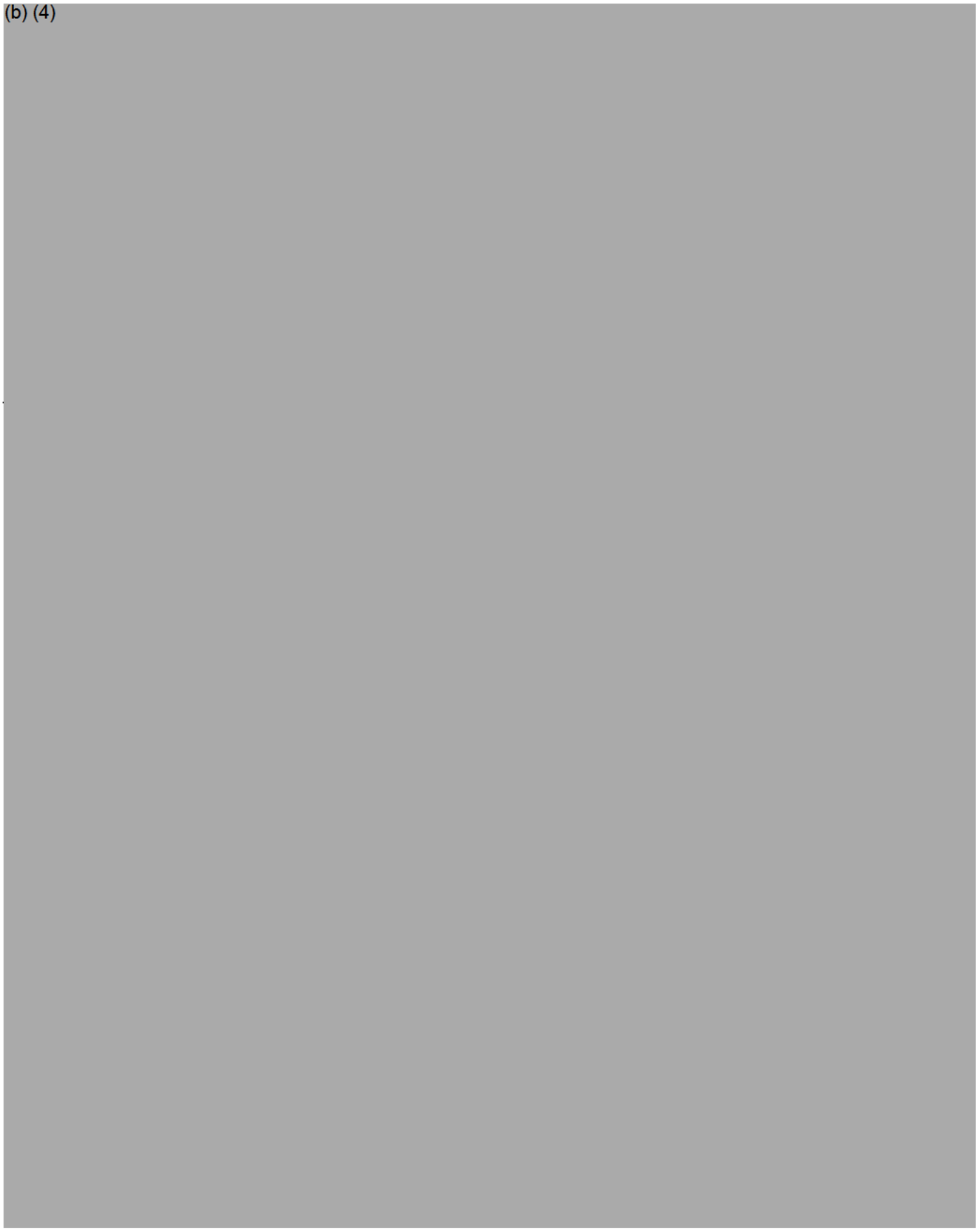
(b) (4)



(b) (4)



(b) (4)



(b) (4)

III. BIOCOMPATIBILITY

Since only rectal catheter with balloon has material change and directly contacts mucosal tissue of patients, this component of the system is subject for biocompatibility evaluation. Although the catheter only has limited contact duration during each intended use, long-term repeatedly use of this system is common. The labeling indicates that although the rectal catheter is for single use, the other components can be reused for 15 or 90 times (equal to irrigating every other day for 1 or 6 months). Therefore, from biocompatibility perspective, this device can be considered as a mucosal contact surface device with permanent contact. According to ISO 10993-1:2009 and FDA bluebook memo G95-1, evaluation cytotoxicity, sensitization, irritation, subacute/subchronic toxicity, genotoxicity, and implantation (optional) of the revised rectal catheter are recommended.

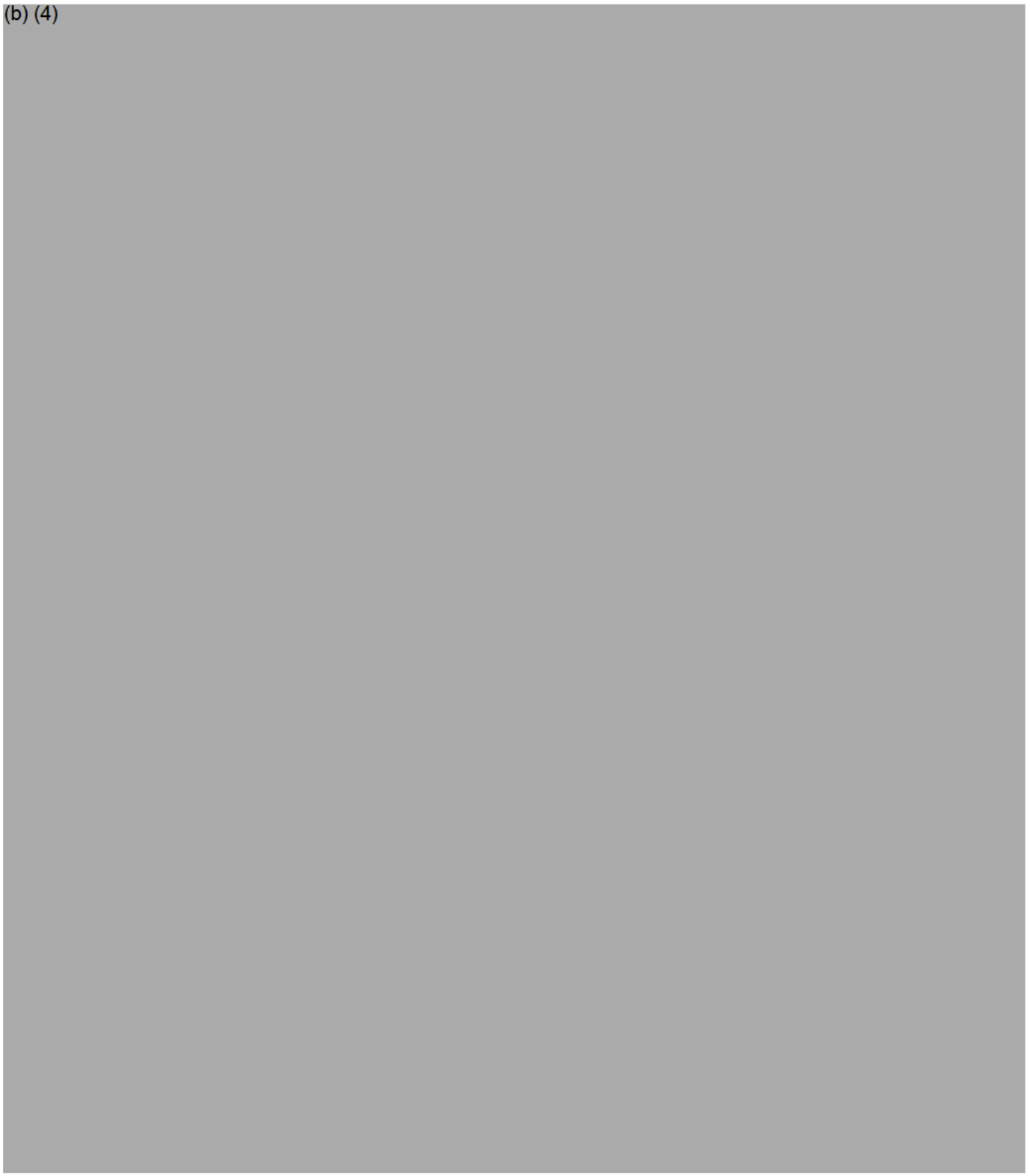
The evaluations provided by the sponsor are summarized in the following table. The responses to the deficiencies from previous review are review below.

Test article	Test and method	Report # and page info	*Review Summary*
Anal irrigation balloon catheter (prototype)	(b) (4)		
Monaco anal irrigation catheter prototype			
Peristeen rectal catheter (Monaco), 29123; Lot#23-05-2011, described to be consisted of blue molded plastic, grey rubber, and a clear balloon.			

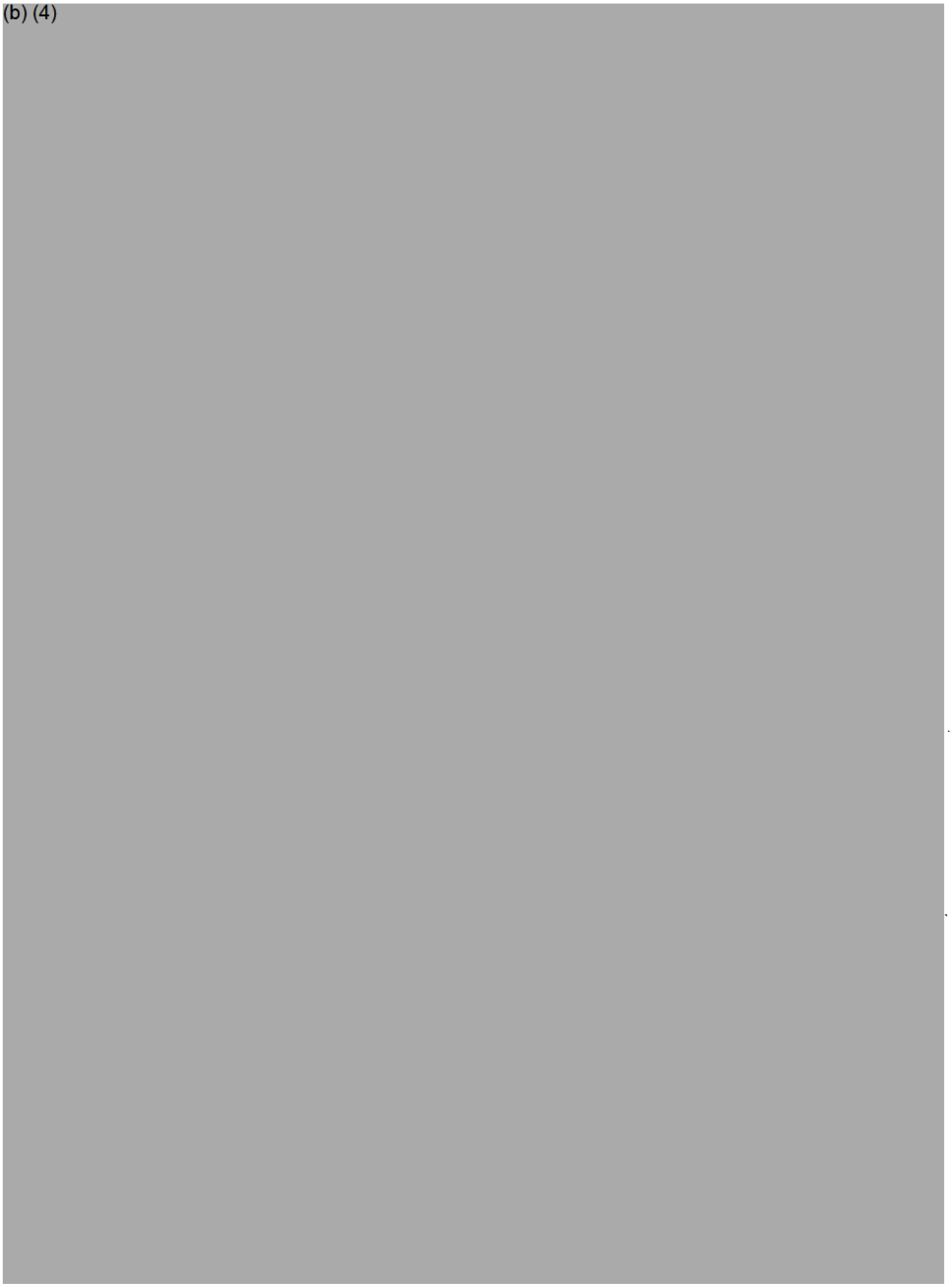
Test article	Test and method	Report # and page info	*Review Summary*
	(b) (4)		
Peristeen rectal catheter (Monaco), 29123, Lot#23-05-2011,			

(b) (4)

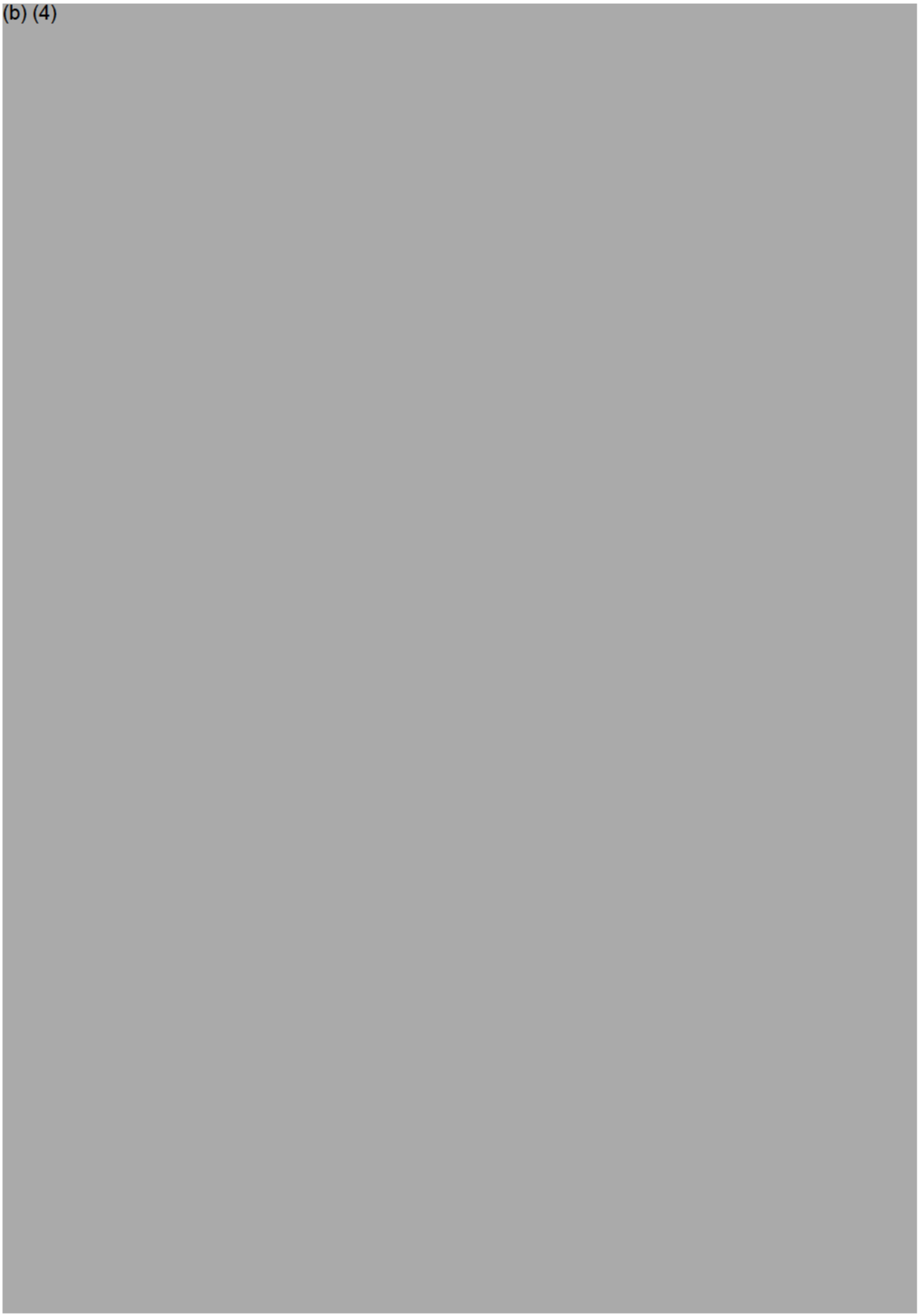
(b) (4)



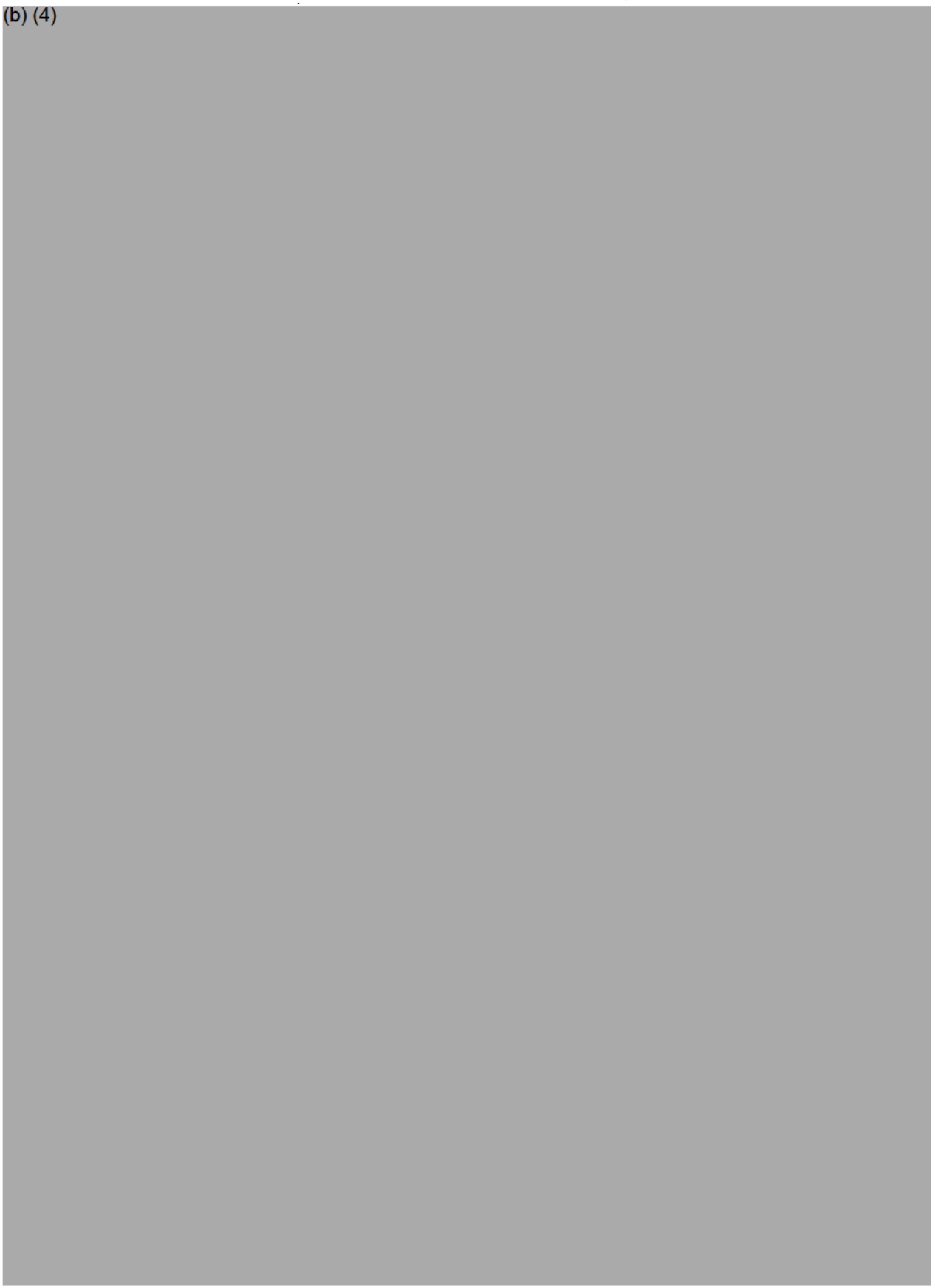
(b) (4)



(b) (4)



(b) (4)



(b) (4)

IV. RECOMMENDATION

As discussed above, the responses to the deficiencies identified in previous review are acceptable. There is no remaining biocompatibility concern with the proposed device.

Xin Fu, Ph.D., D.A.B.T.

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Martin Golding

Subject: 510(k) Number K112860 | 31

To: The Record

Please list CTS decision code AI

☐ 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 (select code below), Withdrawn, etc.).

Not Substantially Equivalent (NSE) Codes

☐	NO	NSE for lack of predicate
☐	NI	NSE for new intended use
☐	NQ	NSE for new technology that raises new questions of safety and effectiveness
☐	NP	NSE for lack of performance data
☐	NM	NSE requires PMA
☐	NS	NSE no response
☐	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			

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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			
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**

(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: Carolyn Y Newland (Branch Chief) GRDB (Branch Code) 2/15/12 (Date)

Final Review: (Division Director) (Date)

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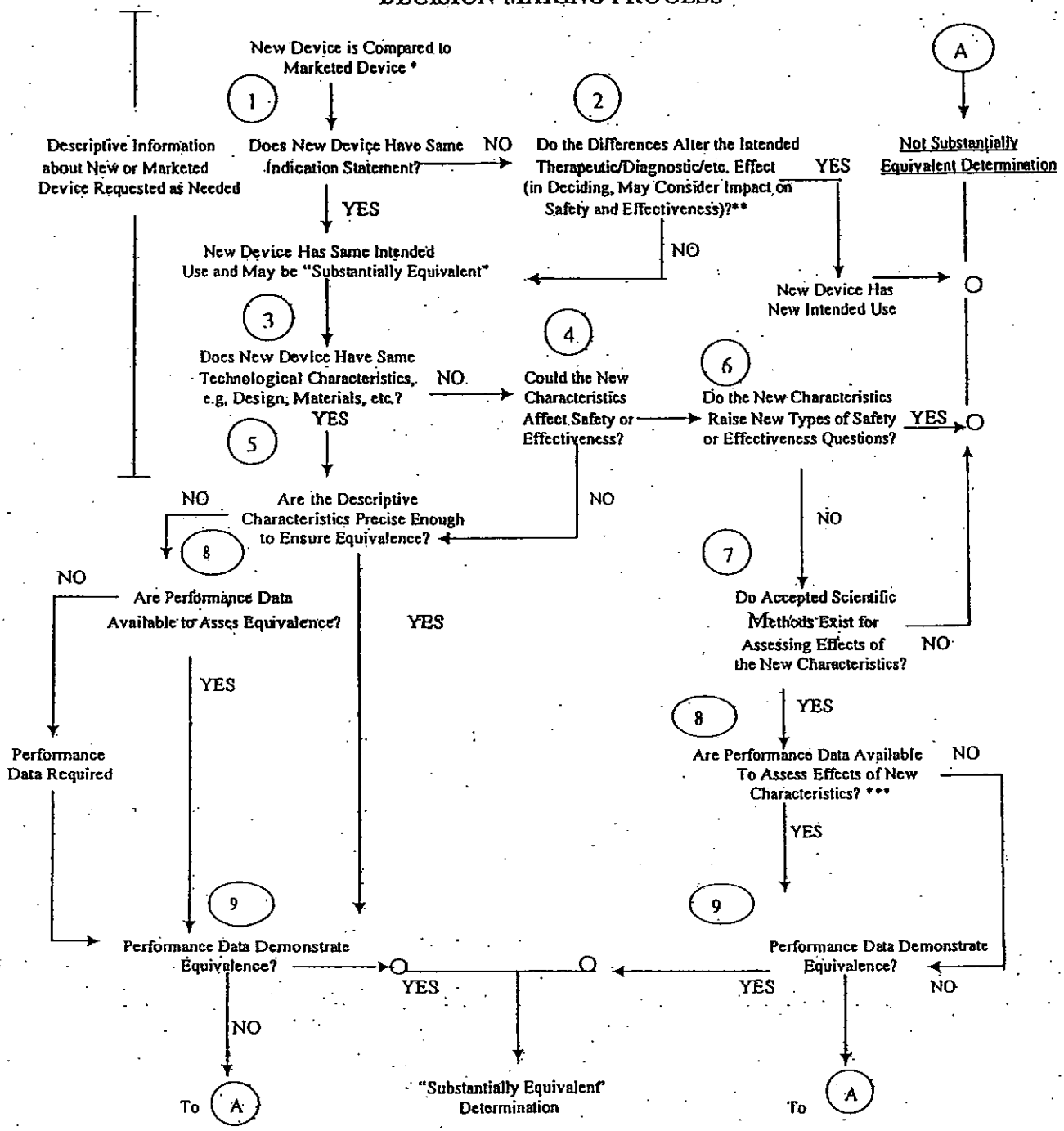
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K112860 Supplement S001

Date: 2/3/2012
To: The Record
From: Martin Golding, M.D.

Office: ODE
Division: DRGUD
Branch: GRDB

510(k) Holder: Coloplast A/S
Device Name: Peristeen™ Anal Irrigation (PAI) System
Contact: Brian Schmidt, Regulatory Affairs Manager
Address: 1601 West River Road
Minneapolis, MN 55411
Phone: (612) 302-4987
Fax: (612) 287-4138
Email: usbes@coloplast.com

I. Purpose and Submission Summary

The 510(k) holder has modified the Peristeen™ Anal Irrigation (PAI) System (K083770) by removing a complication, 'during the spinal shock phase'. The sponsor also changed the device's materials and deleted a contraindication. This is my second review of this traditional 510(k). My first review resulted in the sponsor being sent an Additional Information (AI) letter. The proposed device is the Peristeen™ Anal Irrigation (PAI) System manufactured by Coloplast A/S ("the sponsor"). The device is regulated under **21 CFR §876.5980** Gastrointestinal tube and accessories, and is a **Class II** device. The product codes for this device are **KNT and FCE.**

II. Indications for Use

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Predicate Indication (K083770, K103254)
The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter — which incorporates an inflatable balloon — inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - < 21 years old) and adult spinal cord injury patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

The Indications for Use have not changed from the predicate to current device; however, the contraindications have changed.

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Contraindications

Added "Complex diverticular disease"
Added "Abdominal or anal surgery within the last 3 months"
Removed "During the spinal shock phase" (which is now a precaution)

The change in contraindications does not change the intended use of the device in patients with neurogenic bowel dysfunction. This device is intended to be used in the same patients which the Class I enema kits, Product Code FCE, are used in for similar purposes.

Other contraindications include:

- Known obstruction of the large bowel
- Acute inflammatory bowel disease
- Diverticulitis
- Pregnancy (and have never used anal irrigation before)

III. 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 #3654 http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf			x
Clinical Trials Form http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf			x

III. Device Description

The Peristeen™ Anal Irrigation system is a Class II device, consisting of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times.

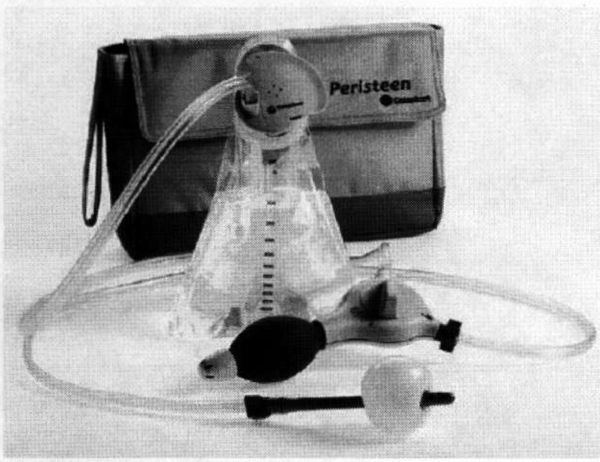

Figure 1: Peristeen Anal Irrigation System

The Peristeen Anal Irrigation (PAI) System (see Figure 1) is intended for intermittent use to allow the flow of water into the colon that facilitates emptying of the colon/bowel in spinal cord injury patients with neurogenic bowel dysfunction. The PAI System consists of a single-use irrigation catheter (see Figure 2) that incorporates an inflatable balloon to keep the catheter in place during the procedure and retain the water that flows into the colon, preventing leakage while irrigating. The rectal catheter is non-sterile, intended for single-use.

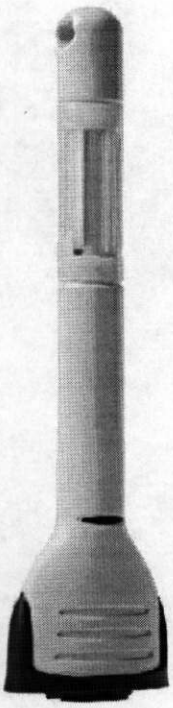

Figure 2: Proposed Peristeen Catheter

The control unit (see Figure 3) is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake. The control unit housing has a manually operated knob that has the four positions indicated in Figure 3:

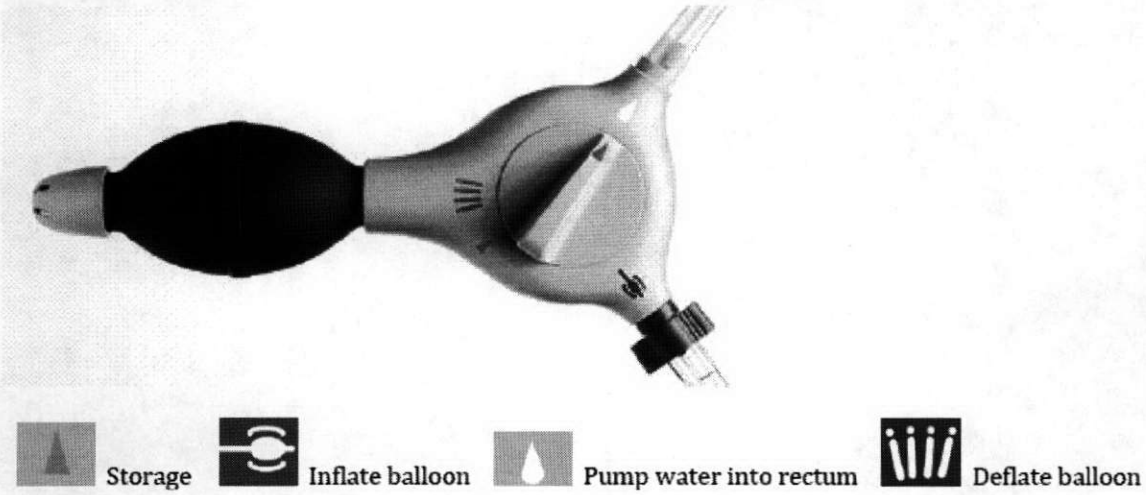

Figure 3: Peristeen Anal Irrigation System Control Unit

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	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)? Are validated "cleaning" instructions included for the end user?	x*		

*All components are reusable for a specified number of times except for the rectal catheters which are labeled as single use only. The end user is instructed to clean the reusable components with soap and water

IV. Device Comparison

The design of the proposed Peristeen catheter is in principle similar to the predicate Peristeen catheter except for the choice of materials and changes in some of the production processes. The catheter and balloon materials are changing for polyvinyl chloride (PVC) and chloroprene to (b) (4) dicate catheter, and the balloon is welded to the new catheter instead of glued as in the existing catheter. The coating and packaging processes will remain unchanged.

Table 1. Materials

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Material	PVC (polyvinyl chloride)	(b) (4)
Balloon Material	Chloroprene	
Lubricious coating: - Top coating - Base coating	(b) (4)	

Table 2: Production Processes

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Balloon material	Dip molded	(b) (4)
Rectal Catheter	Dip molded	
Balloon to Catheter attachment	Glued	

Table 3: Other Device Characteristics

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Length	5.52 in	(b) (4)
Sterility	Non Sterile	
Packaging	Plastic Pouch	
Shelf Life	1.5 years	

5.7

V. Labeling/User Guide

The sponsor has provided the following comparison between the proposed and predicate labeling in an email attachment provided on October 20, 2011.

Table 4: Changes to Contraindications

New User Guide	Predicate User Guide
Anal irrigation procedure should always be carried out with care. Bowel perforation is an extremely rare, **but serious and potentially lethal complication** to anal irrigation and will require immediate admission to a hospital, **often requiring surgery**	Anal irrigation should always be carried out with care. Although bowel perforation is extremely rare, it is a potential complication to anal irrigation and will require immediate admission to hospital.
Severe and sustained abdominal pain or back pain, **especially if combined with fever**	Severe and sustained abdominal pain or back pain, with or without fever
Sustained anal bleeding	Severe anal bleeding
During the spinal shock phase	During the spinal shock phase
Known obstruction of the large bowel due to strictures or tumors	Known obstruction of the large bowel
Diverticulitis	Diverticulitis
Acute inflammatory bowel disease	Acute inflammatory bowel disease
ADDED-Abdominal or anal surgery within the last 3 months	Was not a previous contraindication
If you are pregnant and have never used anal irrigation before, you should not start up the irrigation procedure during pregnancy	If you are pregnant and have never used anal irrigation before, you should not start up the irrigation procedure during pregnancy

Table 5: Changes to Precautions

New User Guide	Predicate User Guide
ADDED-If you are heavily constipated an initial and thorough clean-out of your bowels is advisable before starting up the irrigation procedure.	This statement was not in the predicate guide.
Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)	Suffer from an Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
Ischemic colitis	Was not a previous precaution
Any Anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids **(third or fourth degree hemorrhoids)**	Any Anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids
Irradiation therapy in the abdominal or pelvic region	Have had Irradiation therapy in the abdominal or pelvic region
Diverticular disease	Was not a previous precaution
Previous abdominal or anal surgery	Have had recent abdominal or anal surgery
Recent colonic biopsy or polypectomy	Was not a previous precaution
~~**Spinal Cord Shock Phase**~~	Was previously a contraindication
Autonomic dysreflexia	Suffer from Autonomic dystreflexia
Cancer in the abdominal or pelvic region	Was not a previous precaution
Fecal impaction	Was not a previous precaution
Long term steroid therapy	Was not a previous precaution
Anticoagulant therapy or bleeding disorder	Have a regular intake of anticoagulant medication with vitamin K antagonists, as normally small and harmless rectal bleeding may be difficult to stop
Change stool pattern like sudden diarrhea of unknown origin. The cause for diarrhea must be identified	Have diarrhea, as the cause of the diarrhea must be identified.

New User Guide	Predicate User Guide
Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.	Use Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.
Severe cognitive impairment (unless caregiver is available to supervise/administer)	Was not a previous precaution
Children under 2 years of age	Was not a previous precaution
REMOVED	Are pregnant and have previous experience with anal irrigation, please consult your doctor to carefully evaluate if you may continue irrigating.

Table 6: Changes to Instructions

New User Guide	Predicate User Guide
The water must be lukewarm **(96-100°F).** If it is too hot, it may harm the delicate lining of the **bowel**; if it is too cold, **stomach** cramps may occur.	The water must be lukewarm (36-38°C). If it is too hot, it may harm the delicate lining of the rectum; if it is too cold, cramps may occur.
If you feel the need for a break, turn the knob on the control unit to the balloon symbol. When you are ready, turn the knob back to the water symbol and resume pumping.	In case of discomfort and you feel the need for a break, stop the water flow and wait until it subsides. When you are ready, resume pumping. If the discomfort does not disappear, contact your health care professional immediately.
Try one or more of the following: sitting in the brace position (leaning/bending forward), coughing, standing up, abdominal massage. If water is still not expelled, then you may be heavily constipated and a clean-out of the bowel might be necessary. You might also be dehydrated, so remember to drink plenty of water and repeat the irrigation again the day after. Contact your health care professional for assistance.	You may be heavily constipated and a clean-out of the bowel is necessary. Contact your health care professional for assistance. The reason could also be that you have not had enough to drink and are dehydrated, so the bowel has absorbed the irrigation water. Try irrigating once more using the normal amount of water and remember to drink more water. If another attempt at irrigation does not help, contact your doctor or nurse.
The system and the rectal catheter should be stored at room temperature (maximum 77° F) and out of direct sunlight. When storing the system, ensure that you turn the knob on the control unit to the finish symbol. Also ensure that tubes are not kinked and that the system is kept away from sharp objects.	The system and the rectal catheters should be stored at a temperature of between 2° and 25° Celsius and away from direct sunlight. Ensure the tubing is not kinked when stored.

Comment:
Changes in user guide represent clarifications and do not affect the safety or efficacy of the device.

Labeling changes include change in contraindications as noted in the indications for use section, and the precautions listed below.

Precautions

Added "Ischemic colitis"
Added "Recent colonic biopsy or polypectomy"
Added "Diverticular disease"
~~Added "Spinal Cord Shock phase"~~
Added "Cancer in the abdominal or pelvic region"
Added "Fecal impaction"
Added "Long Term steroid therapy"
Added "Children under 2 years of age"
Added "Severe cognitive impairment (unless caregiver is available to supervise/administer)

Comment:
The labeling adequately describes the usage of the device
The sponsor initially removed the contraindication for patients with acute spinal cord injury, and this has been included again as a contraindication in Supplement 1.
The device is provided non-sterile. The main unit is re-usable while the rectal catheter is for single use only.
There are symbols on the device that are well documented in the user guide.
There are adequate instructions for use.
There are the same contraindications, warnings and precautions as the predicate devices.
No additional contraindications are warranted.

VI. Sterilization/Shelf Life/Reuse

The rectal catheter is supplied non-sterile and is non-reusable. The remainder of the device is non-sterile and reusable.

The shelf life has not changed

VII. Materials

The design of the proposed Peristeen catheter is in principle similar to the predicate Peristeen catheter except for the choice of materials and changes in some of the production processes. The catheter and balloon materials are changing for polyvinyl chloride (PVC) and chloroprene to (b) (4) [redacted]. The coating and packaging processes will remain unchanged.

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Material	PVC (polyvinyl chloride)	(b) (4) [redacted]
Balloon Material	Chloroprene	
Lubricious coating: - Top coating - Base coating	(b) (4) [redacted]	

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Change Made/Date	Reason	Justification for Change
Production of the double lumen tube is transferred from Coloplast A/S (Denmark) to Contract Manufacturer Prozup (Taiwan)	Switch from in-house production to contract manufacturer	Change Control no. LQUG-7LXDFE
Production of the water bag is transferred from Duoplast A/S (Denmark) to Coloplast A/S (Hungary)	Switch from contract manufacturer to in house production	Change Control no. RCHN-7NQC3T
Change in excess pressure valve and lid assembly	This minor adjustment in the specification limits reflects a slight decrease in pressure over time. This small decrease is acceptable because it cannot be detected by the patient and it does not affect the function of the device.	Change Control no. LLAN-7NWBYH LLAN-7NWCFY LLAN-7P5G6B LLAN-7P5GM5
Change in material of the hand pump	The PVC blend used for the hand pump black ball on the PAI control unit will be changed due to material discontinuation at the supplier. (b) (4) [redacted] (b) (4) [redacted]	Change Control no. TTOP-84GCK3

VIII. Biocompatibility

Data regarding biocompatibility results were requested from the sponsor in our first Additional Information (AI) letter, and Dr. Xin Fu has reviewed the information provided by the sponsor in Supplement 1. Dr. Fu has raised a number of biocompatibility concerns in her review (see biocompatibility consult).

IX. Software

Not Applicable.

XI. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable

XII. Performance Testing – Bench

Bench testing was reviewed by (b) (4) [redacted] He considers the bench performance testing provided by the sponsor in Supplement 1 to be acceptable.

XIII. Performance Testing – Animal

Not applicable

XIV. Performance Testing – Clinical

Not applicable

XV. Postmarket Surveillance Information

Not reviewed

XVI. Substantial Equivalence Discussion

Not Applicable

XVII. Deficiencies

(b) (4)

(b) (4)

[redacted]

(b) (4)

[redacted]

XVIII. Contact History

On Wednesday, October 12th the sponsor's representative Brian Schmidt was notified that their 510(k) submission was being converted to a traditional 510(k). On Thursday, October 20th the sponsor was contacted regarding further clarification of the physician IFU and User Guide. The sponsor responded with information on the same day.

XIX. Recommendation

There is inadequate information to determine substantial equivalence. Additional information is requested via additional information letter.

Martin I. Golding, M.D. — 2/15/12 — Date

Carolyn Neuland, Ph.D. — 2/15/12 — Date

6.4

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
OFFICE OF DEVICE EVALUATION

Memorandum

DATE: FEBRUARY 1, 2012

FROM: David Pudwill, Biomedical Engineer
Gastroenterology and Renal Devices Branch/DRGUD/ODE

TO: Martin Golding, M.D., Lead Reviewer and Medical Officer
Gastroenterology and Renal Devices Branch/DRGUD/ODE

THROUGH: Carolyn Neuland, Ph.D., Branch Chief
Gastroenterology and Renal Devices Branch/DRGUD/ODE

CyN 2/15/12

SUBJECT: Engineering Review for K112860/S001
Peristeen™ Anal Irrigation (PAI) System
Coloplast A/S (aka "the sponsor")

BACKGROUND

The 510(k) holder has modified the Peristeen™ Anal Irrigation (PAI) System (K083770) by removing a complication, 'during the spinal shock phase'. The sponsor also changed the device's materials and deleted a contraindication. I provided a deficiency related to the performance testing in the original submission. Dr. Martin Golding has asked me to provide a consulting review of the performance testing provided in Supplement 1.

INDICATIONS FOR USE

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

DEVICE DESCRIPTION

The Peristeen™ Anal Irrigation system is a Class II device, consisting of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times.

65

The Peristeen Anal Irrigation (PAI) System (see Figure 1) is intended for intermittent use to allow the flow of water into the colon that facilitates emptying of the colon/bowel in spinal cord injury patients with neurogenic bowel dysfunction.
The control unit (see Figure 2) is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake. The control unit housing has a manually operated knob that has the four positions indicated in Figure 2:

The PAI System includes a single-use irrigation catheter (see Figure 3) that incorporates an inflatable balloon to keep the catheter in place during the procedure and retain the water that flows into the colon, preventing leakage while irrigating. The rectal catheter is non-sterile, intended for single-use.

Figure 1: Peristeen Anal Irrigation (PAI) System

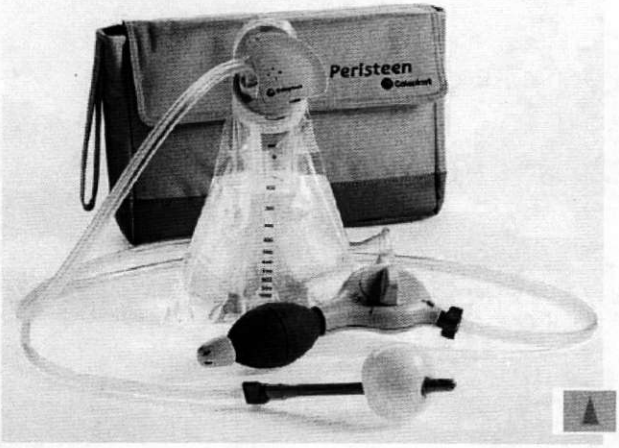


Figure 2: PAI System Control Unit

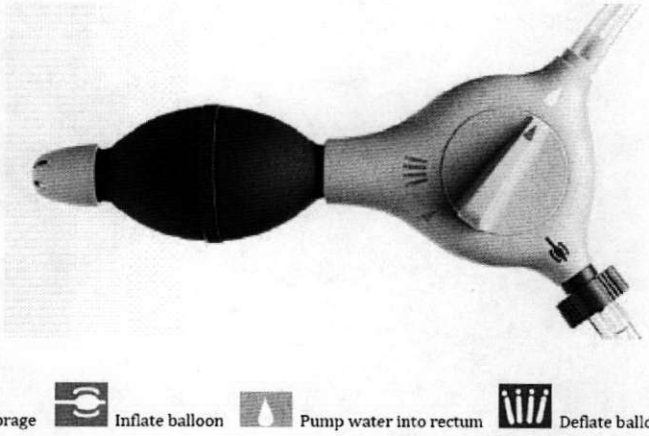


Figure 2: Proposed Rectal Catheter

BENCH PERFORMANCE TESTING

(b) (4)

PREVIOUS DEFICIENCY

(b) (4)

(b) (4)

(b) (4)

[redacted]

RECOMMENDATION: SE

I recommend that the proposed device can be considered substantially equivalent (SE). This recommendation is based on my review of the performance testing alone, and there could be other issues (e.g., biocompatibility) that should be addressed by the lead or other consulting reviewer.

David A. Pudwill — Date: 02/01/12

Carolyn Y. Neuland, Ph.D. — Date: 2/15/12

CJW 2/15/12

Memo to Record

Date: February 1, 2012
From: Xin Fu, Ph.D., D.A.B.T., DRGUD/ULDB
To: Martin Golding, M.D., DRGUD/GRDB
Subject: Biocompatibility Review for K112860/S001, a special 510(k)
Company: Coloplast A/S

This consult is provided to Dr. Golding in response to his request for review of biocompatibility review of device, **Peristeen™ Anal Irrigation System,** from Coloplast.

Product code KNT, Class II 21CFR 876.5980, gastrointestinal tube & accessories; Class I 21CFR876.5210 Enema kit

I. INTENDED USE

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter -which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

II. DEVICE DESCRIPTION

The Peristeen™ Anal Irrigation (PAI) system consists of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times.

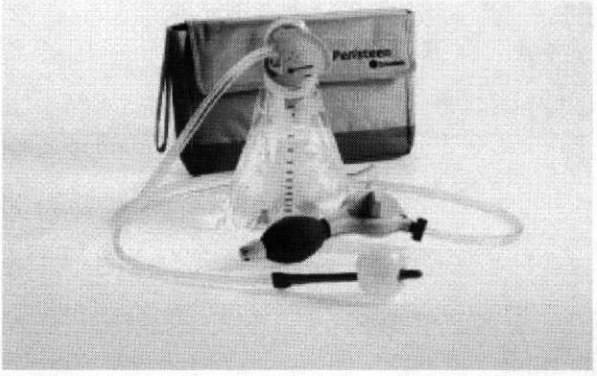
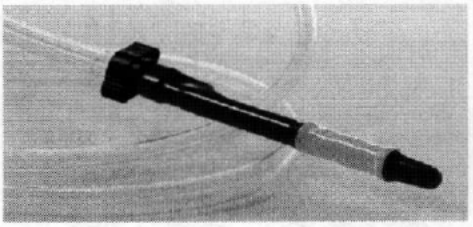


Figure 1: Peristeen Anal Irrigation (PAI) System

The proposed device is modified from the Peristeen device that was previously cleared under K083770 and K103254. The modifications include change in design and materials of the regular rectal catheter and update of the instructions for use. The differences are illustrated in the following picture (left, current Peristeen catheter; right, proposed Peristeen catheter) and described in the following tables.



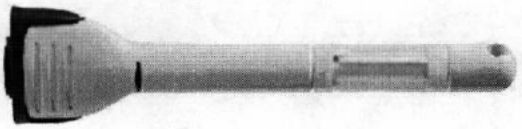


Table 1. Materials

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Material	PVC (polyvinyl chloride)	(b) (4)
Balloon Material	Chloroprene	
Lubricious coating: - Top coating - Base coating	(b) (4) (b) (4)	

Table 2: Production Processes

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Balloon material	(b) (4)	
Rectal Catheter		
Balloon to Catheter attachment		

Table 3: Other Device Characteristics

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Length	5.52 in	4.96 in
Sterility	Non Sterile	*Same*
Packaging	Plastic Pouch	*Same*
Shelf Life	1.5 years	Currently 1 year (to be extended via stability protocol)

Other changes include:

- Manufacturers are change for production of double lumen tube and water bag
- Change in excess pressure valve and lid assembly – a slight decrease in pressure over time.
- Change in material of the hand pump – The PVC blend used for the hand pump black ball on the PAI control unit will be changed due to material discontinuation

(b) (4)

III. BIOCOMPATIBILITY

Since only rectal catheter with balloon has material change and directly contacts mucosal tissue of patients, this component of the system is subject for biocompatibility evaluation. Although the catheter only has limited contact duration during each intended use, long-term repeatedly use of this system is common. The labeling indicates that although the rectal catheter is for single use, the other components can be reused for 15 or 90 times (equal to irrigating every other day for 1 or 6 months). Therefore, from biocompatibility perspective, this device can be considered as a mucosal contact surface device with permanent contact. According to ISO 10993-1:2009 and FDA bluebook memo G95-1, evaluation cytotoxicity, sensitization, irritation, subacute/subchronic toxicity, genotoxicity, and implantation (optional) of the revised rectal catheter are recommended.

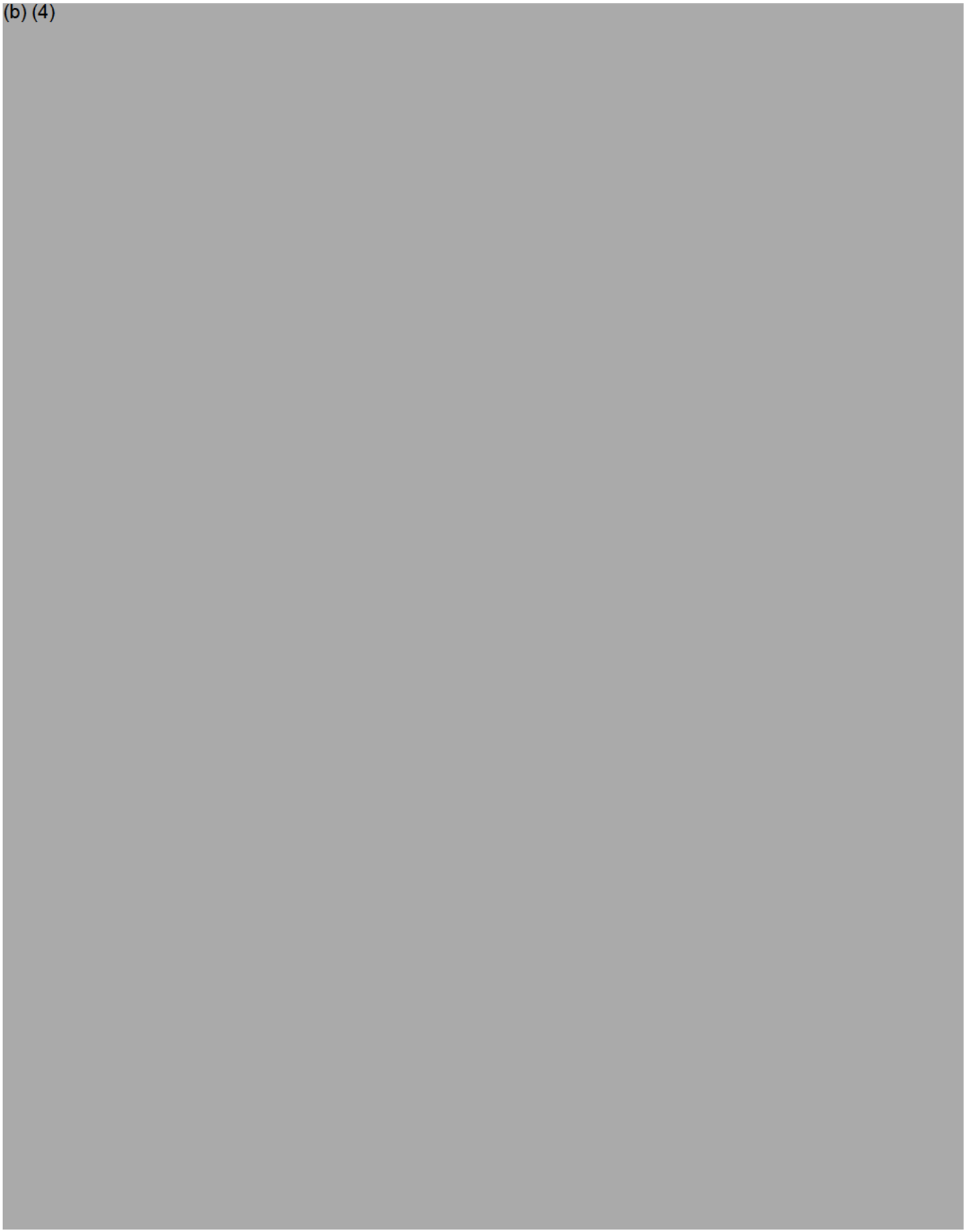
In this supplement, the evaluations provided by the sponsor are summarized in the following table. Detailed review of each test is documented below or the attached review templates for cytotoxicity, sensitization, intracutaneous reactivity, acute systemic toxicity, which are provided by biocompatibility quality review program.

Test article	Test and method	Report # and page info	*Review Summary*
Anal irrigation balloon catheter (prototype)	(b) (4)		
Monaco anal irrigation catheter prototype			
Peristeen rectal catheter (Monaco), 29123, Lot#23-05-2011, described to be consisted of blue molded plastic, grey			

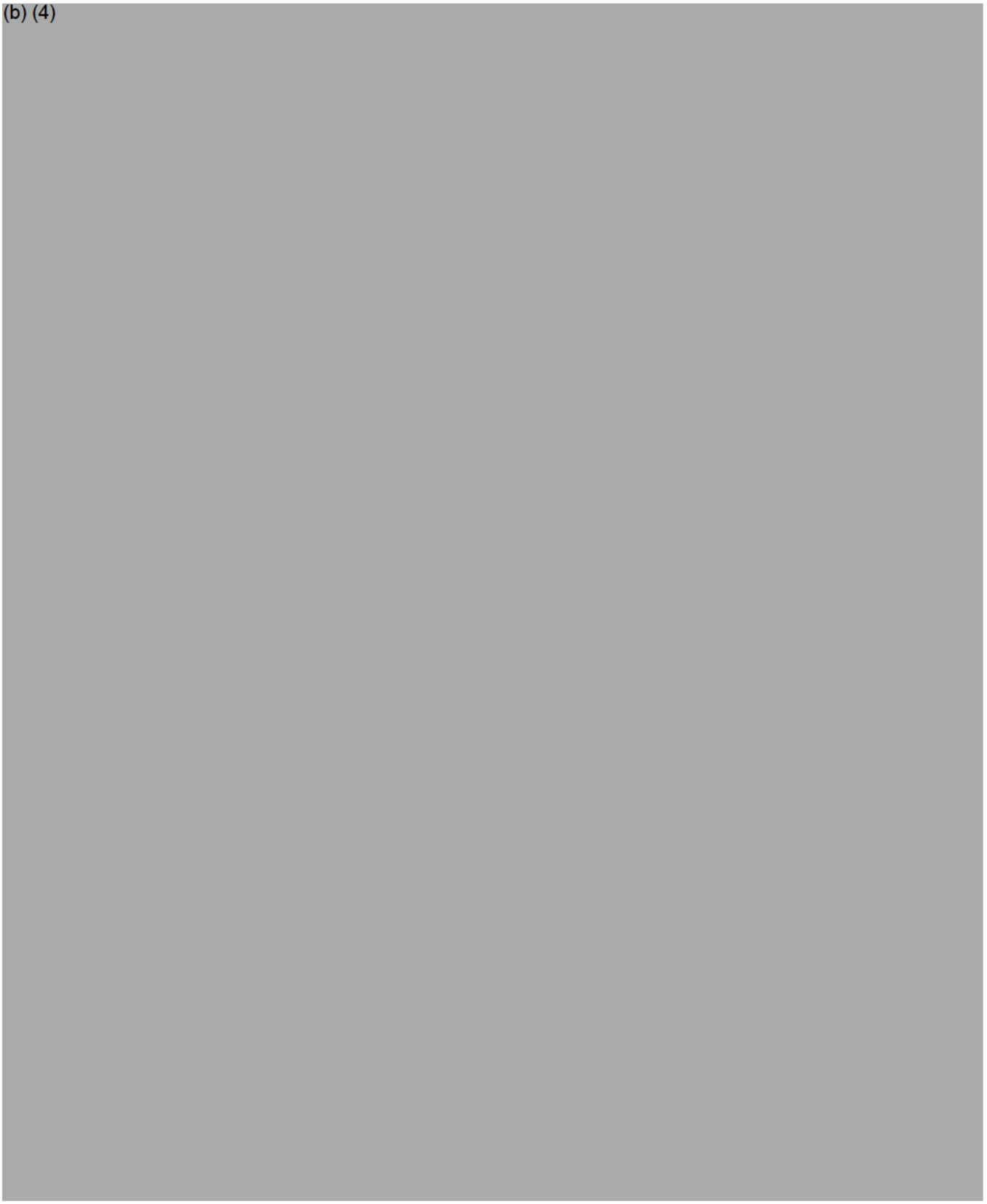
Test article	Test and method	Report # and page info	*Review Summary*
rubber, and a clear balloon. *Need to further clarify whether it was the same device proposed in this submission.*	(b) (4)		

(b) (4)

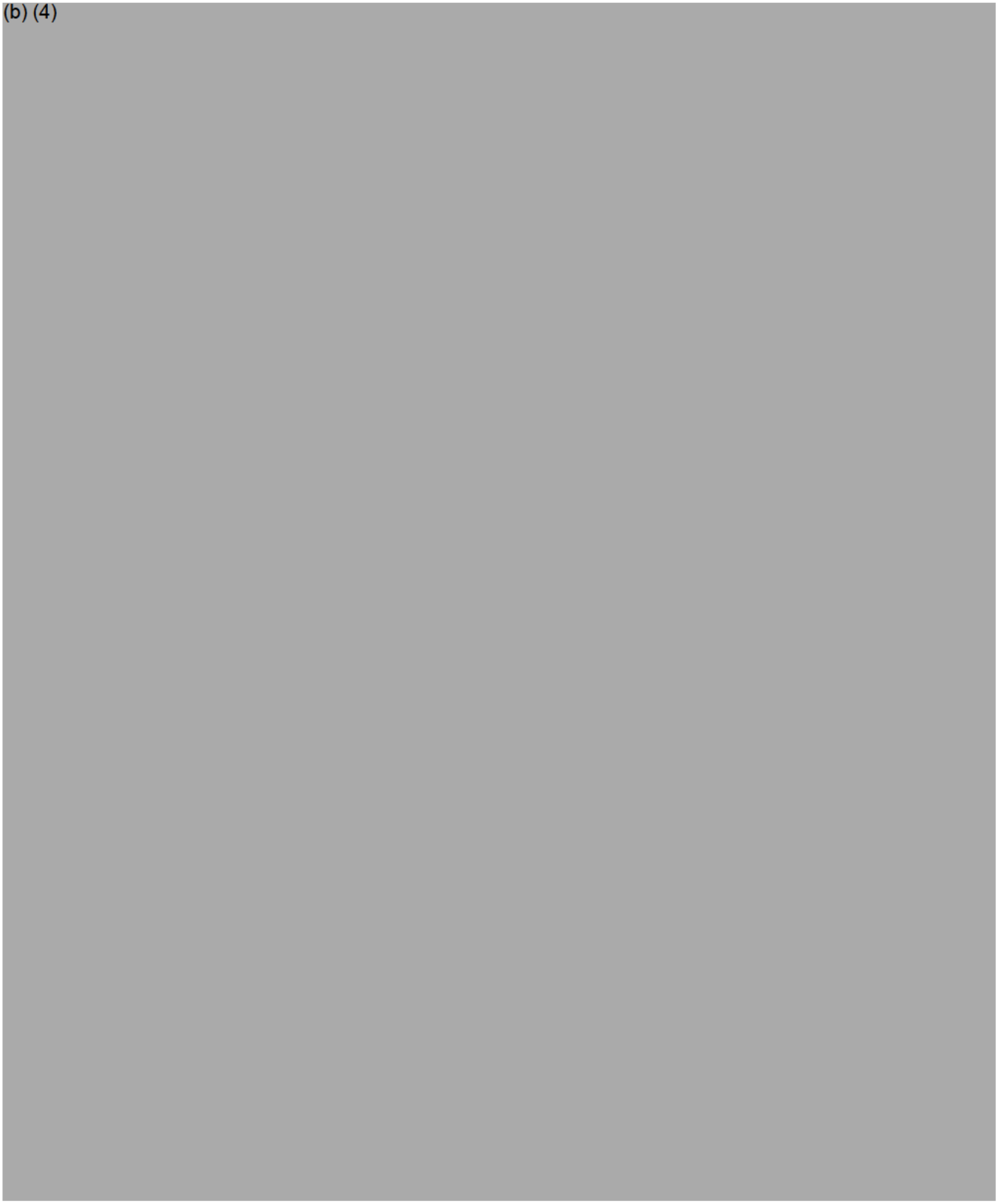
(b) (4)



(b) (4)



(b) (4)



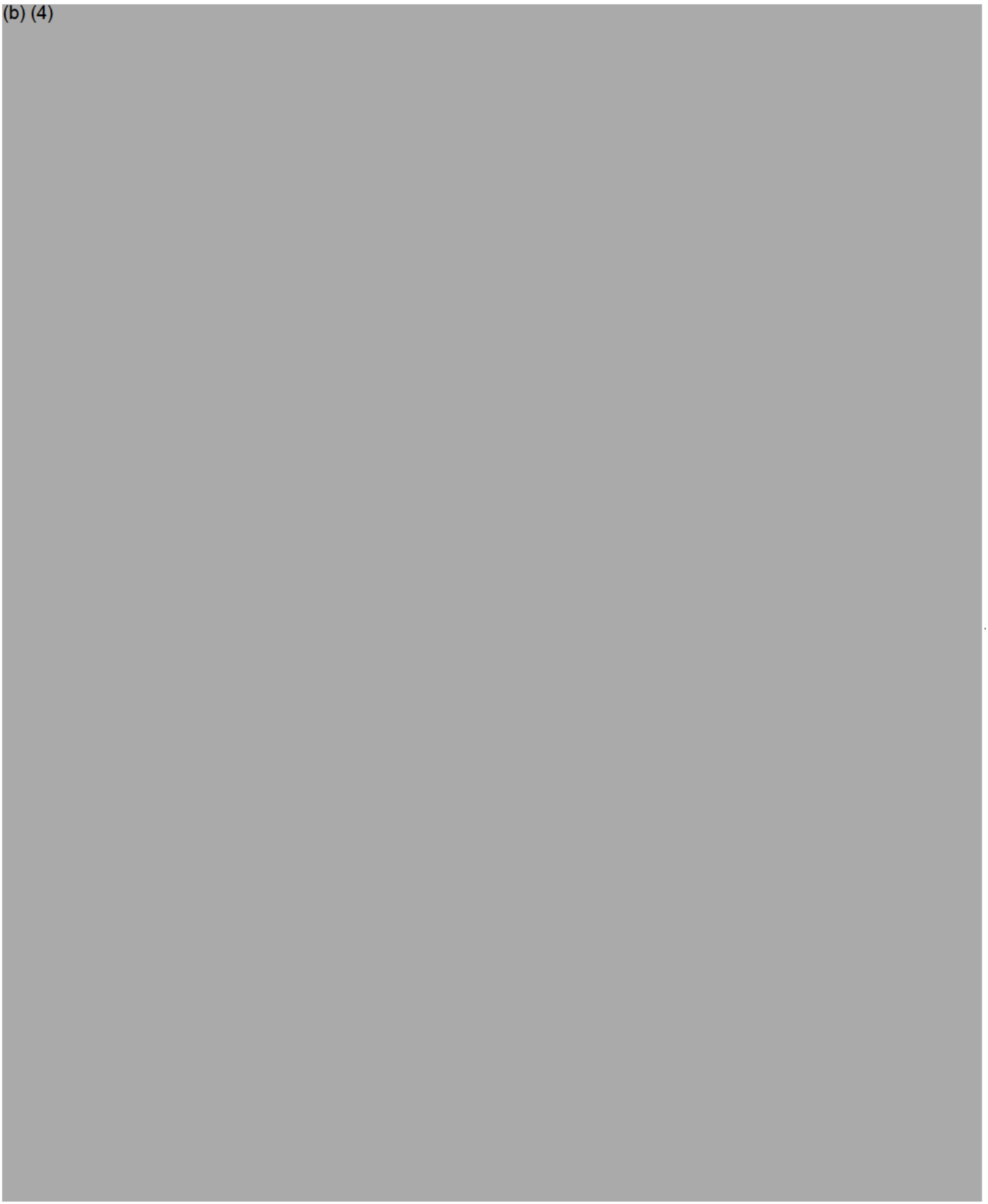
Review Comment

(b) (4)

IV. RECOMMENDATION

(b) (4)

(b) (4)

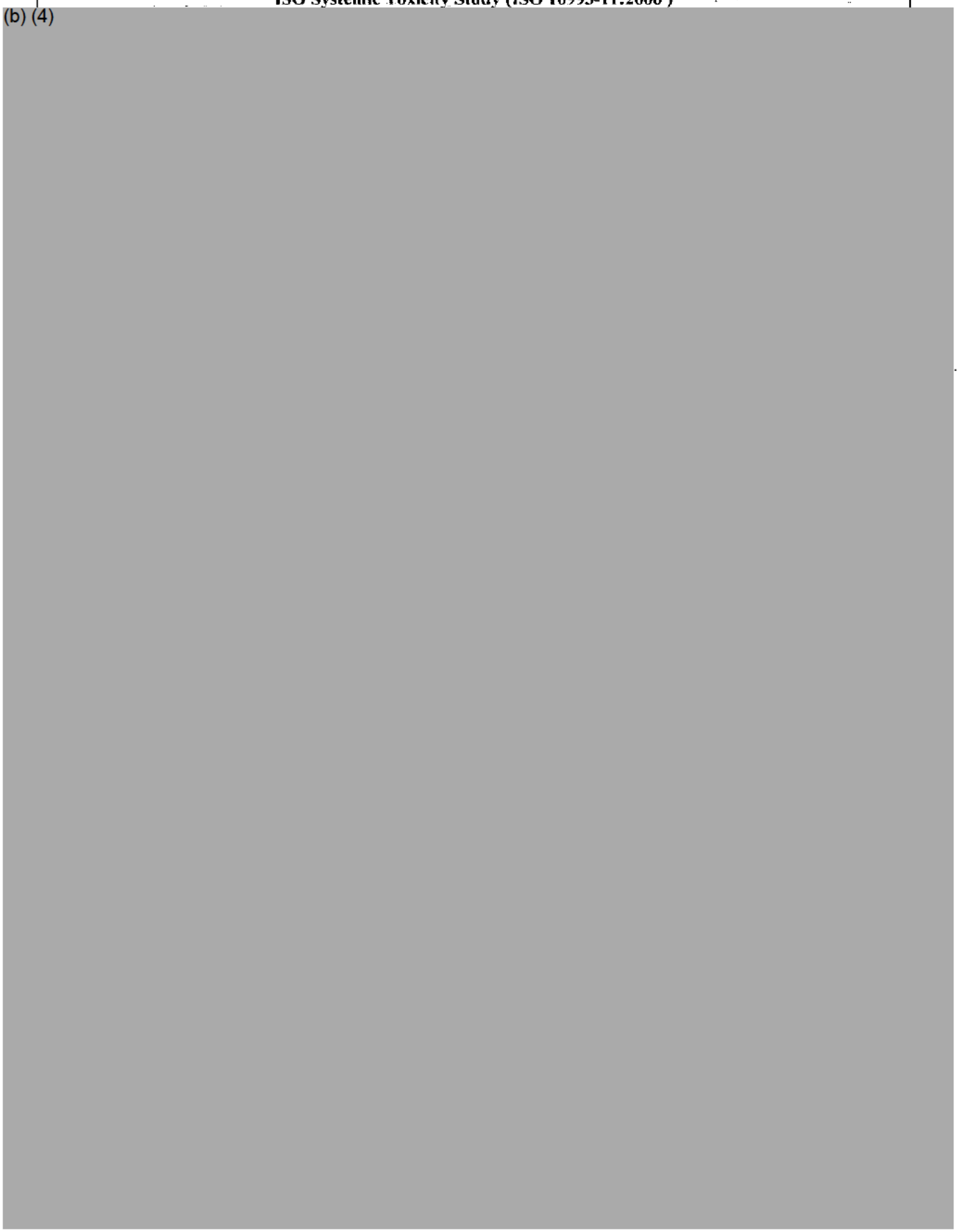


(b) (4)

Xin Fu, Ph.D., D.A.B.T.

ISO Systemic Toxicity Study (ISO 10993-11:2006)

(b) (4)



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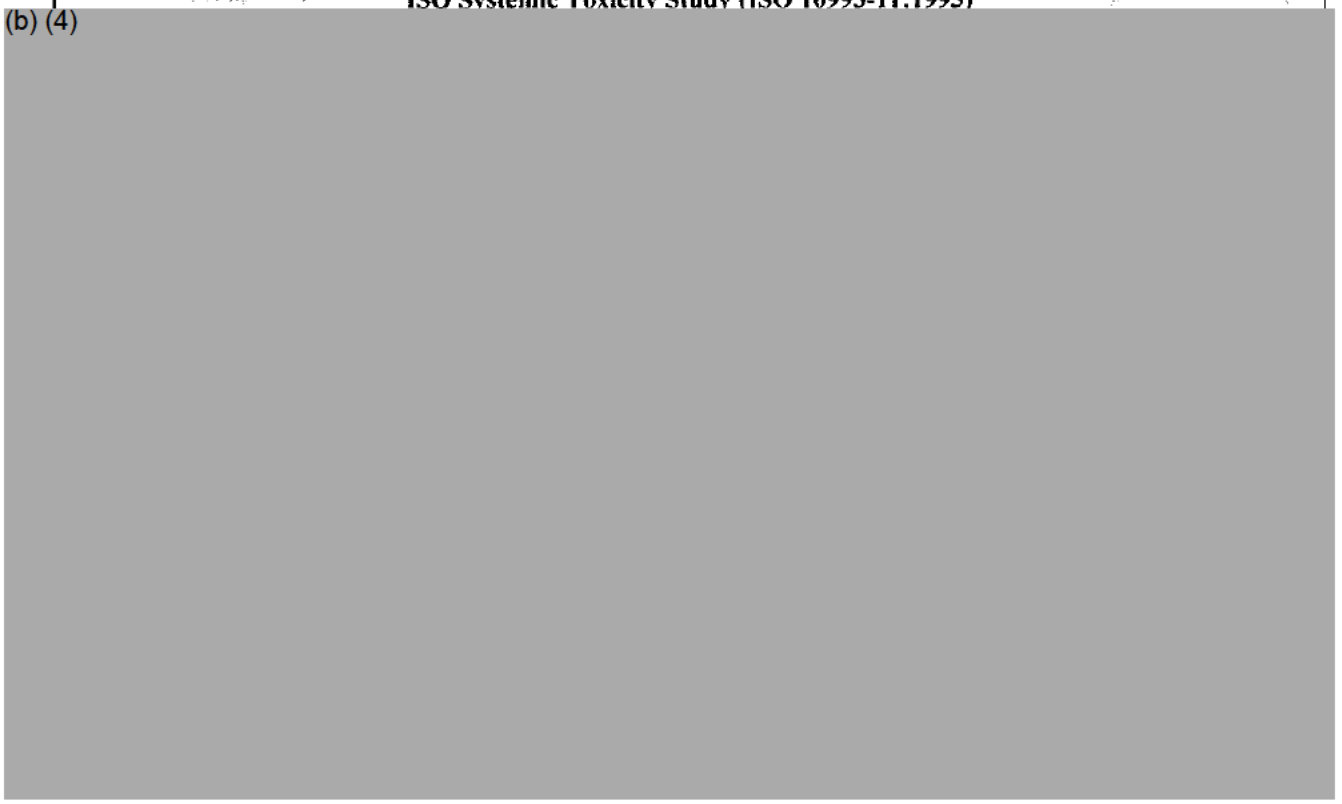
(b) (4)

ISO Systemic Toxicity Study (ISO 10993-11:1993)

(b) (4)



ISO In Vitro Cytotoxicity Study (ISO 10993-5:2002) - Extract

(b) (4)

ISO In Vitro Cytotoxicity Study (ISO 10993-5:2002) – Extract (Qualitative and Quantitative Test)

(b) (4)

[redacted]

ISO In Vitro Cytotoxicity Study (ISO 10993-5:2002) – Extract (Qualitative and Quantitative Test)

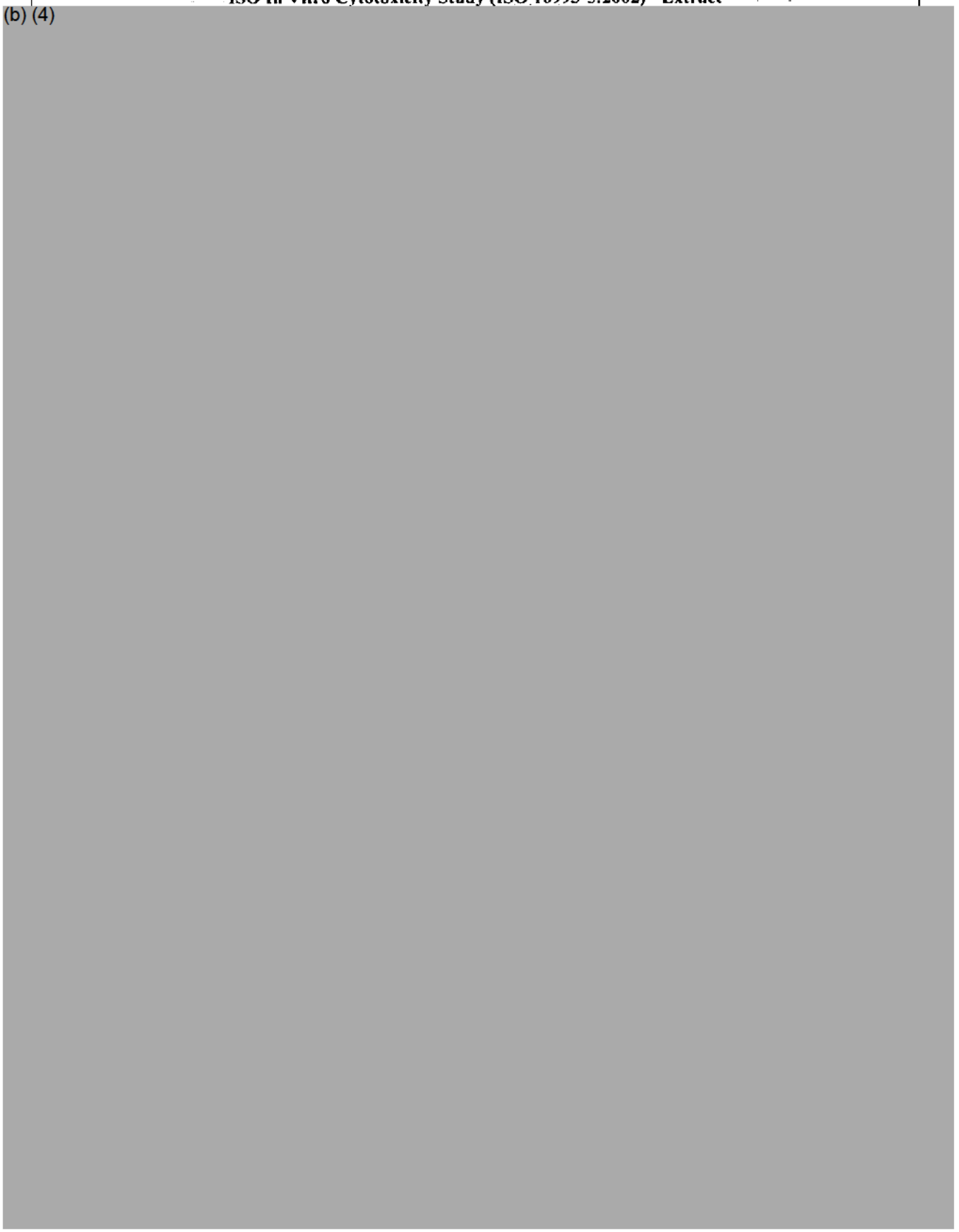
(b) (4)

Revised: ESM 10-25-07; RKP 11/26/07

85

ISO In Vitro Cytotoxicity Study (ISO 10993-5:2002) - Extract

(b) (4)



ISO In Vitro Cytotoxicity Study (ISO 10993-5:2002) – Extract (Qualitative and Quantitative Test)

(b) (4)

ISO In Vitro Cytotoxicity Study (ISO 10993-5:2002) – Extract (Qualitative and Quantitative Test)

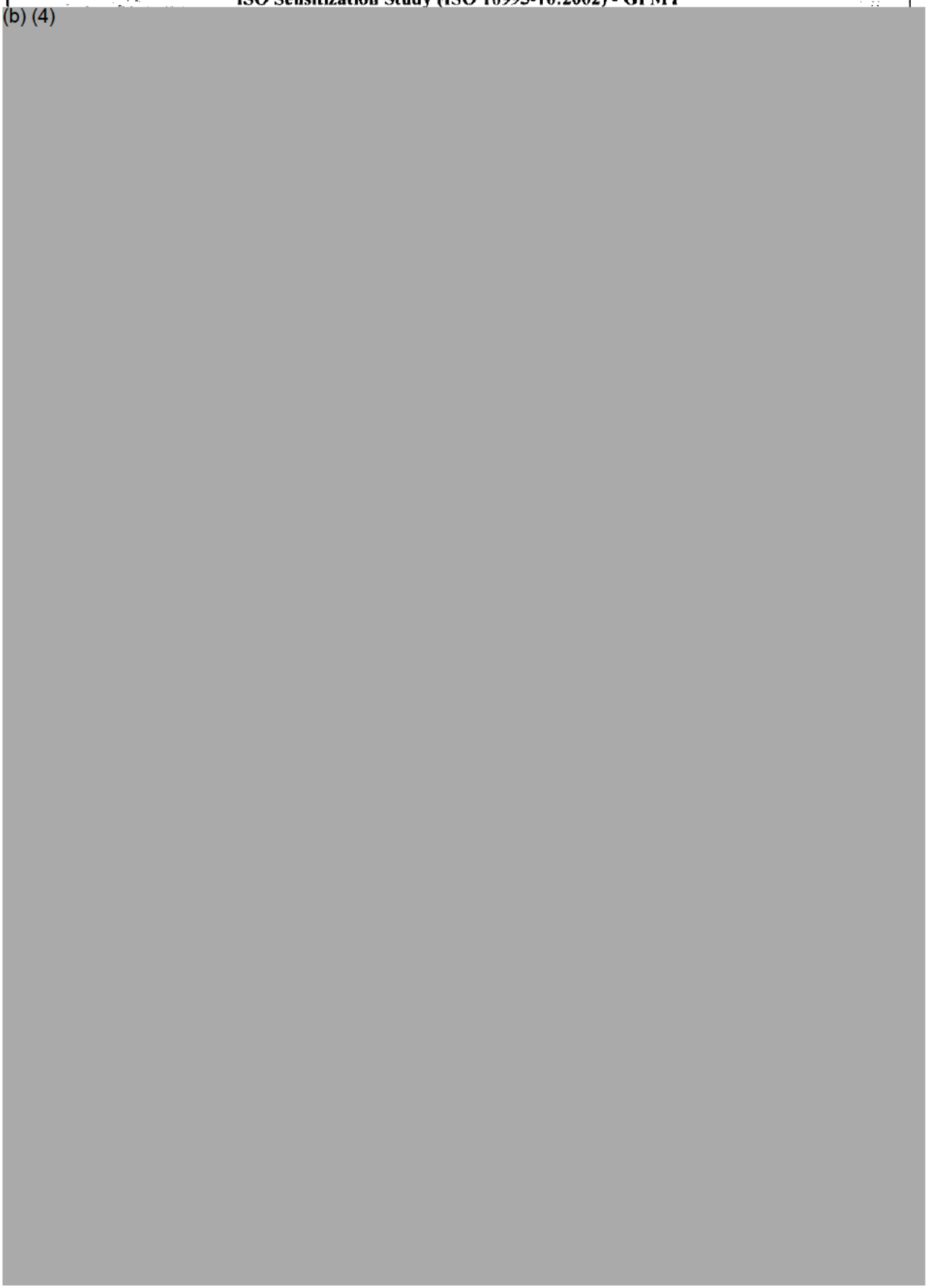
(b) (4)

(b) (4)

(b) (4)

ISO Sensitization Study (ISO 10993-10:2002)- GPMT

(b) (4)



ISO Sensitization Study (ISO 10993-10:2002) - GPMT

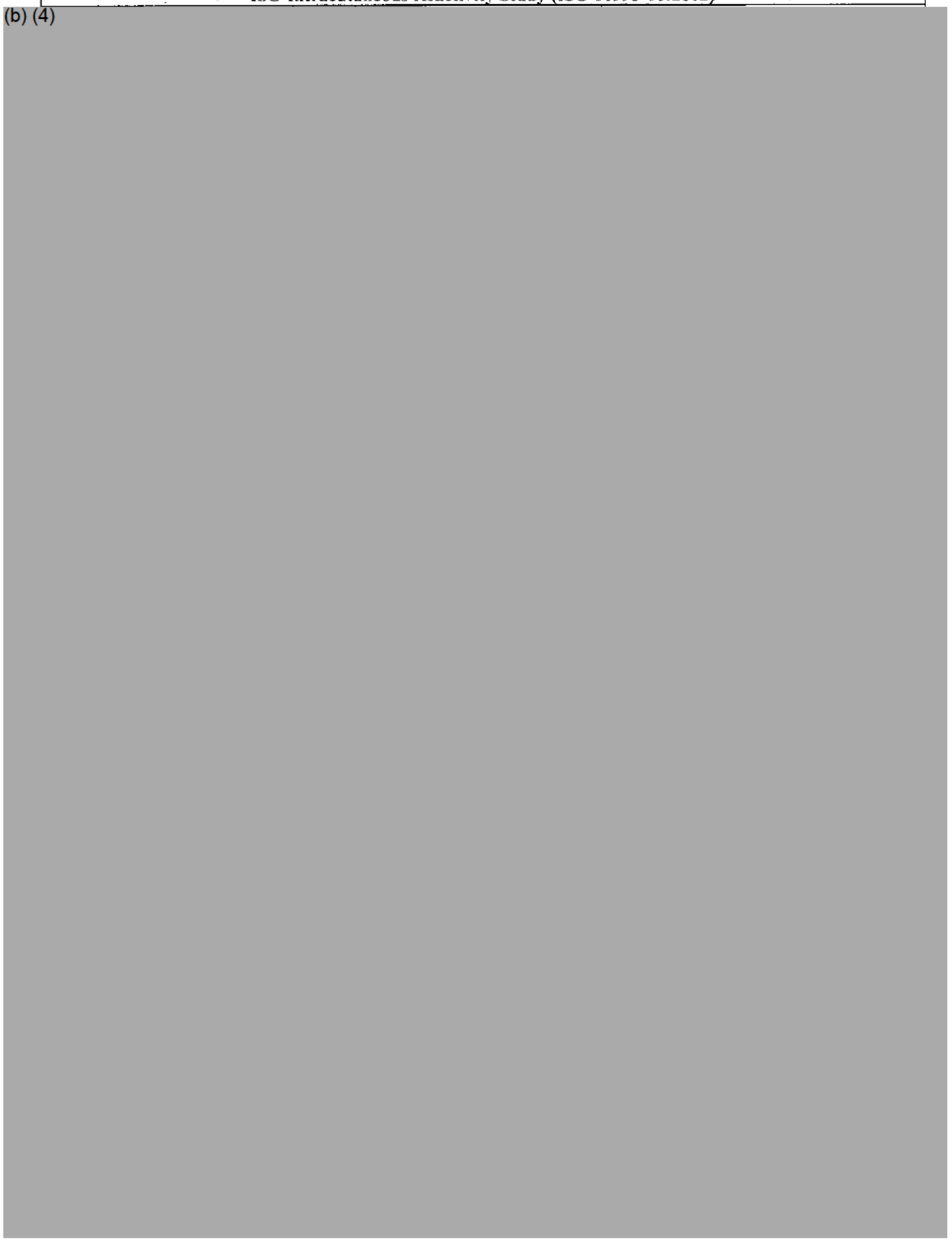
(b) (4)

ISO Intracutaneous Reactivity Study (ISO 10993-10:2002)

(b) (4)

ISO Intracutaneous Reactivity Study (ISO 10993-10:2002)

(b) (4)



ISO Intracutaneous Reactivity Study (ISO 10993-10:2002)

(b) (4)

ISO Intracutaneous Reactivity Study (ISO 10993-10:2002)

(b) (4)

Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name Martin Golding

Subject: 510(k) Number K112860

To: The Record

Please list CTS decision code AF

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 N, 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			

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			
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**

(*If unclassified, see 510(k) Staff)

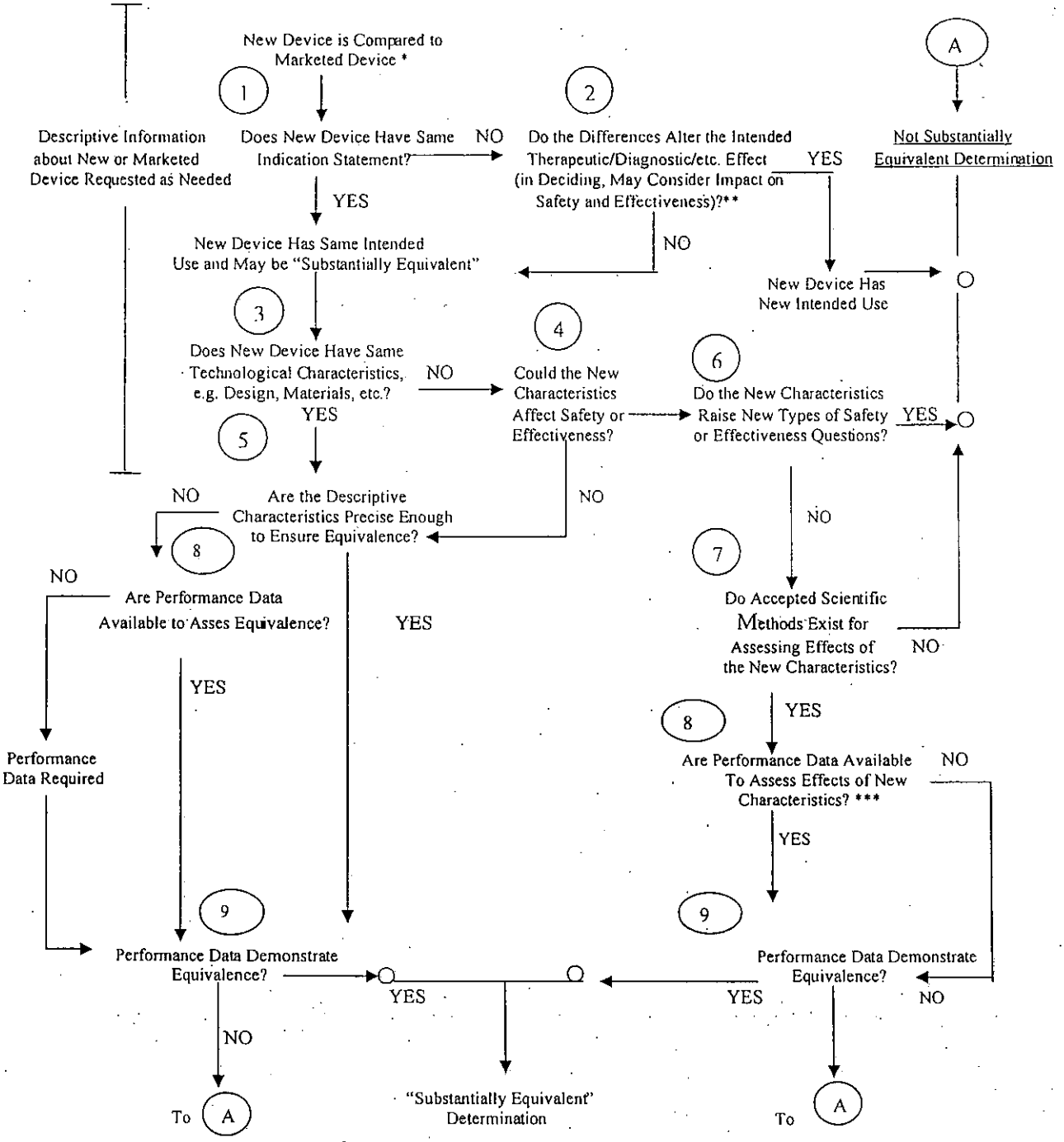
Additional Product Codes: _____

Review: Carolyn Y Neuland (Branch Chief) GRDB (Branch Code) 11/4/11 (Date)

Final Review: _____ (Division Director) (Date)

110

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
10903 New Hampshire Ave
Silver Spring, MD 20993

Premarket Notification [510(k)] Review
Traditional

K112860

Date: 10/12/2011
To: The Record
From: Martin Golding, M.D.

Office: ODE
Division: DRGUD
Branch: GRDB

510(k) Holder: Coloplast A/S
Device Name: Peristeen™ Anal Irrigation (PAI) System
Contact: Brian Schmidt, Regulatory Affairs Manager
Address: 1601 West River Road
Minneapolis, MN 55411
Phone: (612) 302-4987
Fax: (612) 287-4138
Email: usbes@coloplast.com

I. Purpose and Submission Summary

The 510(k) holder has modified the Peristeen™ Anal Irrigation (PAI) System (K083770) by removing a complication, 'during the spinal shock phase'. The sponsor also changed the device's materials and deleted a contraindication. This is my first review of this traditional 510(k). The proposed device is the Peristeen™ Anal Irrigation (PAI) System manufactured by Coloplast A/S ("the sponsor"). The device is regulated under **21 CFR §876.5980** Gastrointestinal tube and accessories, and is a **Class II** device. The product codes for this device are **KNT and FCE.**

II. Indications for Use

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Predicate Indication (K083770, K103254)
The Peristeen™ Anal Irrigation (PAI) System is intended to instill water into the colon through a rectal catheter — which incorporates an inflatable balloon — inserted into the rectum to promote evacuation of the contents of the lower colon. The PAI System is indicated for use by Children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - < 21 years old) and adult spinal cord injury patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

The Indications for Use have not changed from the predicate to current device; however, the contraindications have changed.

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Contraindications

Added "Complex diverticular disease"
Added "Abdominal or anal surgery within the last 3 months"
Removed "During the spinal shock phase" (which is now a precaution)

The change in contraindications does not change the intended use of the device in patients with neurogenic bowel dysfunction. This device is intended to be used in the same patients which the Class I enema kits, Product Code FCE, are used in for similar purposes.

Other contraindications include:

- Known obstruction of the large bowel
- Acute inflammatory bowel disease
- Diverticulitis
- Pregnancy (and have never used anal irrigation before)

III. 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 #3654 http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf			x
Clinical Trials Form http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf			x

III. Device Description

The Peristeen™ Anal Irrigation system is a Class II device, consisting of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times.

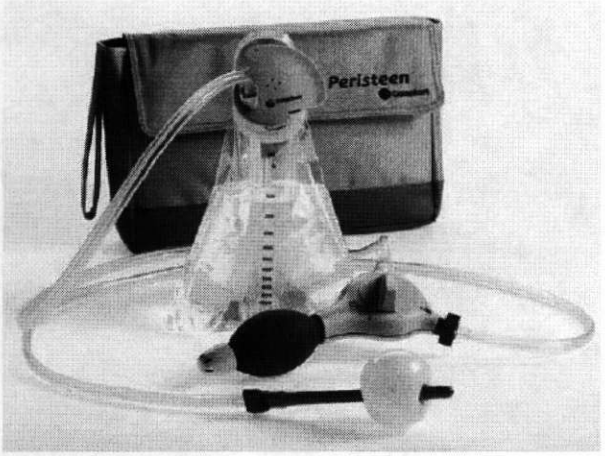

Figure 1: Peristeen Anal Irrigation System

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The Peristeen Anal Irrigation (PAI) System (see Figure 1) is intended for intermittent use to allow the flow of water into the colon that facilitates emptying of the colon/bowel in spinal cord injury patients with neurogenic bowel dysfunction. The PAI System consists of a single-use irrigation catheter (see Figure 2) that incorporates an inflatable balloon to keep the catheter in place during the procedure and retain the water that flows into the colon, preventing leakage while irrigating. The rectal catheter is non-sterile, intended for single-use.

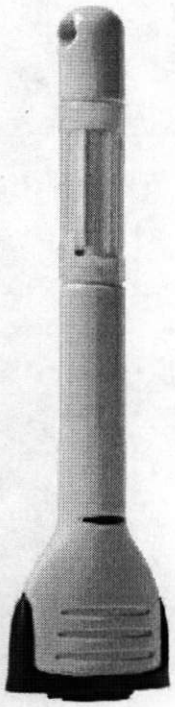

Figure 2: Proposed Peristeen Catheter

The control unit (see Figure 3) is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake. The control unit housing has a manually operated knob that has the four positions indicated in Figure 3:

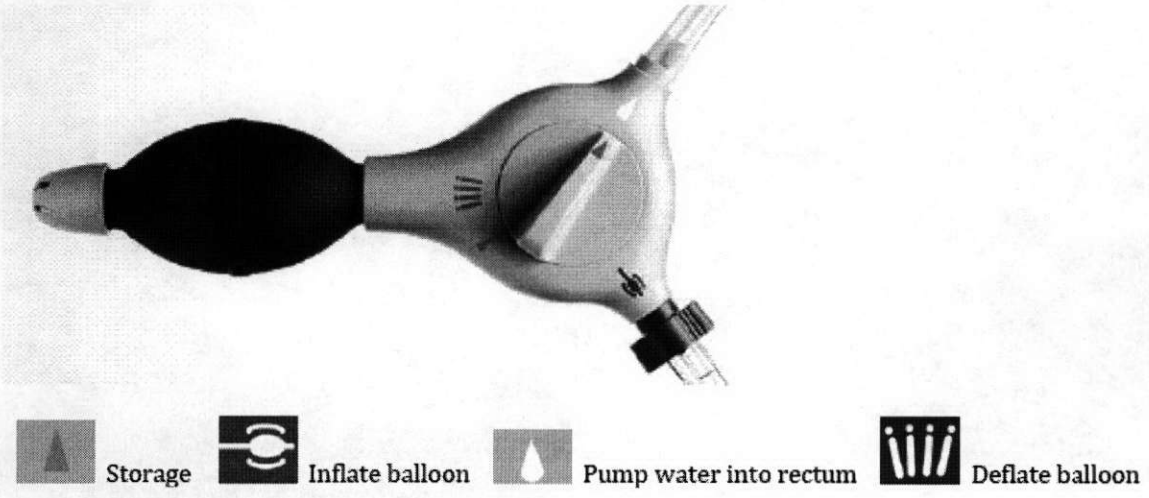

Figure 3: Peristeen Anal Irrigation System Control Unit

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	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)? Are validated "cleaning" instructions included for the end user?	x*		

*All components are reusable for a specified number of times except for the rectal catheters which are labeled as single use only. The end user is instructed to clean the reusable components with soap and water

IV. Device Comparison

The design of the proposed Peristeen catheter is in principle similar to the predicate Peristeen catheter except for the choice of materials and changes in some of the production processes. The catheter and balloon materials are changing for polyvinyl chloride (PVC) and chloroprene to (b) (4) [redacted] The coating and packaging processes will remain unchanged.

Table 1. Materials

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Material	PVC (polyvinyl chloride)	(b) (4) [redacted]
Balloon Material	Chloroprene	
Lubricious coating: - Top coating - Base coating	(b) (4) [redacted]	

Table 2: Production Processes

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Balloon material	(b) (4) [redacted]	
Rectal Catheter		
Balloon to Catheter attachment		

Table 3: Other Device Characteristics

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Length	5.52 in	4.96 in
Sterility	Non Sterile	*Same*
Packaging	Plastic Pouch	*Same*
Shelf Life	1.5 years	Currently 1 year (to be extended via stability protocol)

U5

V. Labeling/User Guide

The sponsor has provided the following comparison between the proposed and predicate labeling in an email attachment provided on October 20, 2011.

Table 4: Changes to Contraindications

New User Guide	Predicate User Guide
Anal irrigation procedure should always be carried out with care. Bowel perforation is an extremely rare, **but serious and potentially lethal complication** to anal irrigation and will require immediate admission to a hospital, **often requiring surgery**	Anal irrigation should always be carried out with care. Although bowel perforation is extremely rare, it is a potential complication to anal irrigation and will require immediate admission to hospital.
Severe and sustained abdominal pain or back pain, **especially if combined with fever**	Severe and sustained abdominal pain or back pain, with or without fever
Sustained anal bleeding	Severe anal bleeding
REMOVED	During the spinal shock phase
Known obstruction of the large bowel due to strictures or tumors	Known obstruction of the large bowel
Diverticulitis	Diverticulitis
Acute inflammatory bowel disease	Acute inflammatory bowel disease
ADDED-Abdominal or anal surgery within the last 3 months	Was not a previous contraindication
If you are pregnant and have never used anal irrigation before, you should not start up the irrigation procedure during pregnancy	If you are pregnant and have never used anal irrigation before, you should not start up the irrigation procedure during pregnancy

Table 5: Changes to Precautions

New User Guide	Predicate User Guide
ADDED-If you are heavily constipated an initial and thorough clean-out of your bowels is advisable before starting up the irrigation procedure.	This statement was not in the predicate guide.
Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)	Suffer from an Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
Ischemic colitis	Was not a previous precaution
Any Anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids **(third or fourth degree hemorrhoids)**	Any Anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids
Irradiation therapy in the abdominal or pelvic region	Have had Irradiation therapy in the abdominal or pelvic region
Diverticular disease	Was not a previous precaution
Previous abdominal or anal surgery	Have had recent abdominal or anal surgery
Recent colonic biopsy or polypectomy	Was not a previous precaution
Spinal Cord Shock Phase	Was previously a contraindication
Autonomic dysreflexia	Suffer from Autonomic dystreflexia
Cancer in the abdominal or pelvic region	Was not a previous precaution
Fecal impaction	Was not a previous precaution
Long term steroid therapy	Was not a previous precaution
Anticoagulant therapy or bleeding disorder	Have a regular intake of anticoagulant medication with vitamin K antagonists, as normally small and harmless rectal bleeding may be difficult to stop
Change stool pattern like sudden diarrhea of unknown origin. The cause for diarrhea must be identified	Have diarrhea, as the cause of the diarrhea must be identified.

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New User Guide	Predicate User Guide
Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.	Use Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.
Severe cognitive impairment (unless caregiver is available to supervise/administer)	Was not a previous precaution
Children under 2 years of age	Was not a previous precaution
REMOVED	Are pregnant and have previous experience with anal irrigation, please consult your doctor to carefully evaluate if you may continue irrigating.

Table 6: Changes to Instructions

New User Guide	Predicate User Guide
The water must be lukewarm **(96-100°F).** If it is too hot, it may harm the delicate lining of the **bowel**; if it is too cold, **stomach** cramps may occur.	The water must be lukewarm (36-38°C). If it is too hot, it may harm the delicate lining of the rectum; if it is too cold, cramps may occur.
If you feel the need for a break, turn the knob on the control unit to the balloon symbol  . When you are ready, turn the knob back to the water symbol and resume pumping.	In case of discomfort and you feel the need for a break, stop the water flow and wait until it subsides. When you are ready, resume pumping. If the discomfort does not disappear, contact your health care professional immediately.
Try one or more of the following: sitting in the brace position (leaning/bending forward), coughing, standing up, abdominal massage. If water is still not expelled, then you may be heavily constipated and a clean-out of the bowel might be necessary. You might also be dehydrated, so remember to drink plenty of water and repeat the irrigation again the day after. Contact your health care professional for assistance.	You may be heavily constipated and a clean-out of the bowel is necessary. Contact your health care professional for assistance. The reason could also be that you have not had enough to drink and are dehydrated, so the bowel has absorbed the irrigation water. Try irrigating once more using the normal amount of water and remember to drink more water. If another attempt at irrigation does not help, contact your doctor or nurse.
The system and the rectal catheter should be stored at room temperature (maximum 77° F) and out of direct sunlight. When storing the system, ensure that you turn the knob on the control unit to the finish symbol  . Also ensure that tubes are not kinked and that the system is kept away from sharp objects.	The system and the rectal catheters should be stored at a temperature of between 2° and 25° Celsius and away from direct sunlight. Ensure the tubing is not kinked when stored.

Comment:
Changes in user guide represent clarifications and do not affect the safety or efficacy of the device.

Labeling changes include change in contraindications as noted in the indications for use section, and the precautions listed below.

C.07

Precautions

Added "Ischemic colitis"
Added "Recent colonic biopsy or polypectomy"
Added "Diverticular disease"
Added "Spinal Cord Shock phase"
Added "Cancer in the abdominal or pelvic region"
Added "Fecal impaction"
Added "Long Term steroid therapy"
Added "Children under 2 years of age"
Added "Severe cognitive impairment (unless caregiver is available to supervise/administer)

Comment:
The labeling adequately describes the usage of the device
The new device now claims to not be contraindicated in patients with acute spinal cord injury
The device is provided non-sterile. The main unit is re-usable while the rectal catheter is for single use only.
There are symbols on the device that are well documented in the user guide.
There are adequate instructions for use.
There are the same contraindications, warnings and precautions as the predicate devices.
No additional contraindications are warranted.

VI. Sterilization/Shelf Life/Reuse

The rectal catheter is supplied non-sterile and is non-reusable. The remainder of the device is non-sterile and reusable.

The shelf life has not changed

VII. Materials

The design of the proposed Peristeen catheter is in principle similar to the predicate Peristeen catheter except for the choice of materials and changes in some of the production processes. The catheter and balloon materials are changing for polyvinyl chloride (PVC) and chloroprene to (b) (4)

(b) (4) The coating and packaging processes will remain unchanged.

	Peristeen Anal Irrigation System 510(k) K083770 and K103254	Modified Peristeen This 510(k)
Catheter Material	PVC (polyvinyl chloride)	(b) (4)
Balloon Material	Chloroprene	
Lubricious coating: - Top coating - Base coating	 (b) (4) (b) (4)	

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Change Made/Date	Reason	Justification for Change
Production of the double lumen tube is transferred from Coloplast A/S (Denmark) to Contract Manufacturer Prozup (Taiwan)	Switch from in-house production to contract manufacturer	Change Control no. LQUG-7LXDFE
Production of the water bag is transferred from Duoplast A/S (Denmark) to Coloplast A/S (Hungary)	Switch from contract manufacturer to in house production	Change Control no. RCHN-7NQC3T
Change in excess pressure valve and lid assembly	This minor adjustment in the specification limits reflects a slight decrease in pressure over time. This small decrease is acceptable because it cannot be detected by the patient and it does not affect the function of the device.	Change Control no. LLAN-7NWBYH LLAN-7NWCFY LLAN-7P5G6B LLAN-7P5GM5
Change in material of the hand pump	The PVC blend used for the hand pump black ball on the PAI control unit will be changed due to material discontinuation at the supplier. (b) (4) (b) (4)	Change Control no. TTOP-84GCK3

VIII. Biocompatibility

Data regarding biocompatibility results will be requested from the sponsor

Significant Requirements	Specifications (Acceptance Criteria)	Verification Method/ Rationale	Verification results (Pass/ Fail) with Average + Stdev
Device must be biocompatible	(b) (4)		

IX. Software

Not Applicable.

XI. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

Not applicable

XII. Performance Testing – Bench

Bench testing data was not provided and will be addressed in the deficiency section.

XIII. Performance Testing – Animal

Not applicable

XIV. Performance Testing – Clinical

Not applicable

XV. Postmarket Surveillance Information

Not reviewed

XVI. Substantial Equivalence Discussion

Not Applicable

XVII. Deficiencies

(b) (4)

[redacted]

XVIII. Contact History

On Wednesday, October 12th the sponsor's representative Brian Schmidt was notified that their 510(k) submission was being converted to a traditional 510(k). On Thursday, October 20th the sponsor was contacted regarding further clarification of the physician IFU and User Guide. The sponsor responded with information on the same day.

XIX. Recommendation

There is inadequate information to determine substantial equivalence. Additional information is requested via additional information letter.

Martin J. Golding, M.D. — Date 11/4/11

Carolyn Neuland, Ph.D. — Date 11/4/11

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Form for Converting a Special 510(k) to a Traditional or Abbreviated 510(k)

Note: Please send this to the 510k Staff in Word. You do not need anyone to sign this in person.

Date: October 6, 2011

Reviewer: Martin Golding, M.D.

510(k) Number: K112860

Device Name: Coloplast, Peristeen Anal Irrigation System

Reason for Conversion: (If change in indications for use please list old and new indications.)

(b) (4)

[redacted]

Division Director Concurrence/Name: (Please obtain before calling or e-mailing POS.)

10/11/11

Date of POS Concurrence: (Please document POS contact (email or memo)):

Date of Phone Conversation with Sponsor: 10-12-11

(The reviewer or Branch Chief must contact the sponsor to let them know of the conversion. At this time the reviewer or Branch Chief may want to ask for additional information that was not submitted in the special.)

Please add this to the file

Golding, Martin

CJN 11/4/11

From: McCabe-Janicki, Margaret
Sent: Wednesday, October 12, 2011 5:17 AM
To: Golding, Martin
Cc: Lerner, Herbert P.; Shulman, Marjorie G.; Johnson, Jismi
Subject: Conversion of K112860 from Special to Traditional

Good morning Marty,

It was good to meet you yesterday.

As you requested, I have converted K112860 from a Special to a Traditional 510(k), because (1) the sponsor is removing a contraindication, which constitutes a change in indication, and (2) a new material is being used in this device and you have never seen this change with this device type before, to the best of your knowledge.

I just realized that I neglected to sign off on the paper form; however, this e-mail constitutes POS concurrence, and I saw on the form that Herb has concurred, so that is all we need from a POS standpoint.

The new (90th day) due date is December 29, 2011.

Please remember to include the form in the file, and let the company know about this conversion.

Please let me know if you have any questions or concerns, or if I can be of further assistance.

Best,
Margaret

Margaret McCabe Janicki, B.S.
Consumer Safety Officer
FDA/CDRH/ODE/POS/Premarket Notification (510(k)) Staff
10903 New Hampshire Ave.
White Oak Building 66, Room 1532
Silver Spring, MD 20993
Office: 301-796-7029
FAX: 301-847-8122

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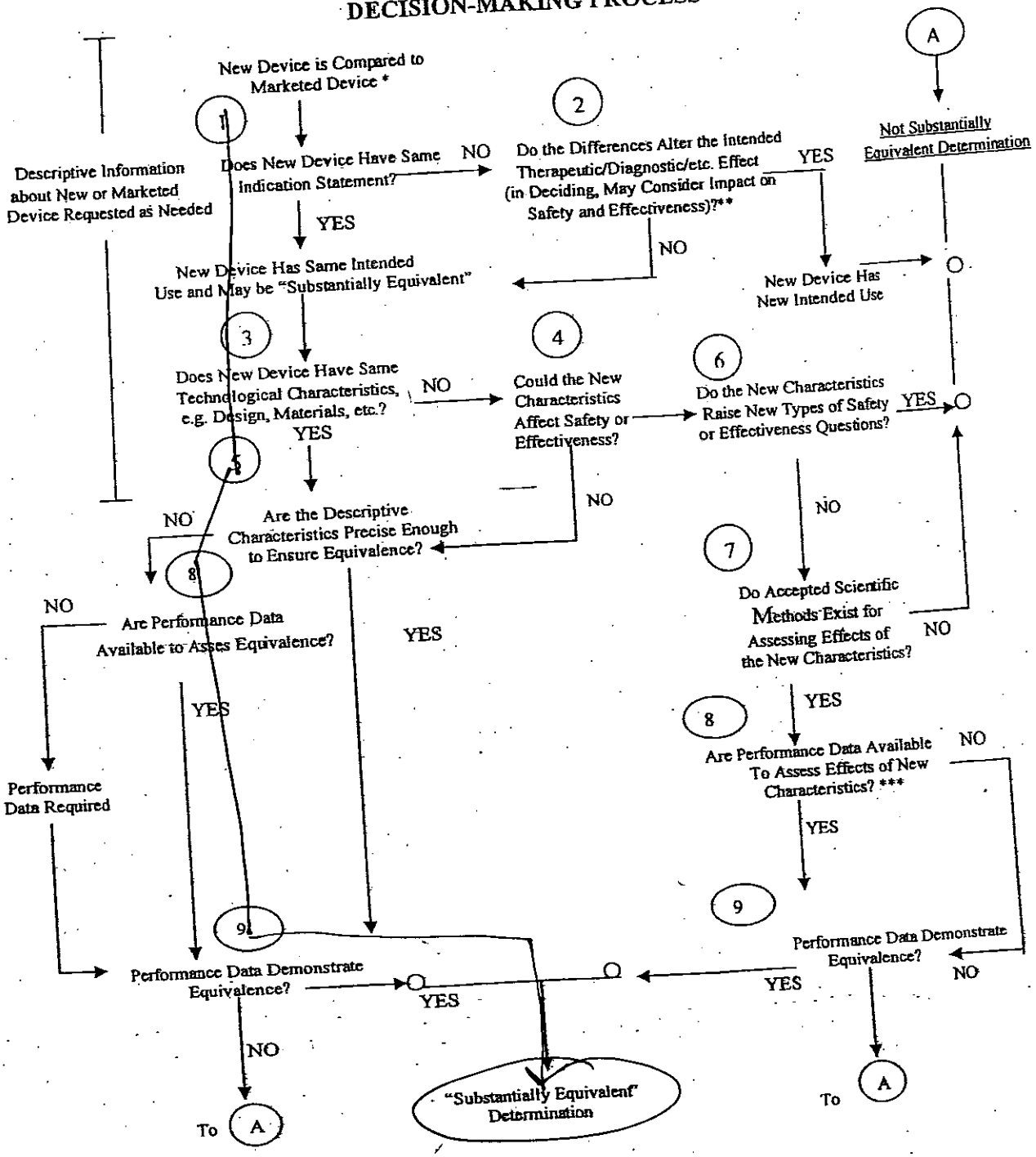
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS



* 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.

6

 K33

Coloplast

Ostomy Care
Urology & Continence Care
Wound & Skin Care

K112860/31
GU/DRGUS

January 06, 2012

Dr. Martin Golding
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) – **K112860**; Peristeen™ Anal Irrigation System

Dear Dr. Golding,

Coloplast A/S hereby submits the additional information to the 510(k) K112860 for the Peristeen™ Anal Irrigation System. This information was requested by FDA in a deficiency letter dated October 4, 2011 (copy of questions attached). The deficiency letter was received by Coloplast on November 7, 2011 so the date stamp on the letter was likely intended to state November 4, 2011 per our email correspondence on November 15, 2011.

This request is provided in duplicate. Coloplast also provides an electronic version copied to CD-ROM. The electronic copy is an exact duplicate of the paper copy.

Coloplast considers the existence and contents of this submission to be confidential and exempt from public disclosure.

Please contact me for questions or if you need further information.

Best regards,

Brian Schmidt
Regulatory Affairs Manager
Phone: 612.302.4987
Fax: 612.287.4138
Email: usbes@coloplast.com

Coloplast

Ostomy Care
Urology & Continence Care
Wound & Skin Care

January 06, 2012

Dr. Martin Golding
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) – **K112860**; Peristeen™ Anal Irrigation System

Dear Dr. Golding,

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Please contact me for questions or if you need further information.

Best regards,

Brian Schmidt
Regulatory Affairs Manager
Phone: 612.302.4987
Fax: 612.287.4138
Email: usbes@coloplast.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Coloplast A/S
% Mr. Brian Schmidt
Regulatory Affairs Manager
Coloplast Corporation
1601 West River Road North
MINNEAPOLIS MN 55411

OCT 0 4 2011

Re: K112860
Trade Name: Peristeen™ Anal Irrigation System
Dated: September 29, 2011
Received: September 30, 2011

Dear Mr. Schmidt:

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 the following additional information.

(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 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

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.

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 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 Dr. Martin Golding at (301) 796-5590. If you need information or assistance concerning the IDE regulations, please 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,

Carolyn Y. Neuland

Carolyn Y. Neuland, Ph.D.
Chief, Gastroenterology and Renal Devices Branch
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

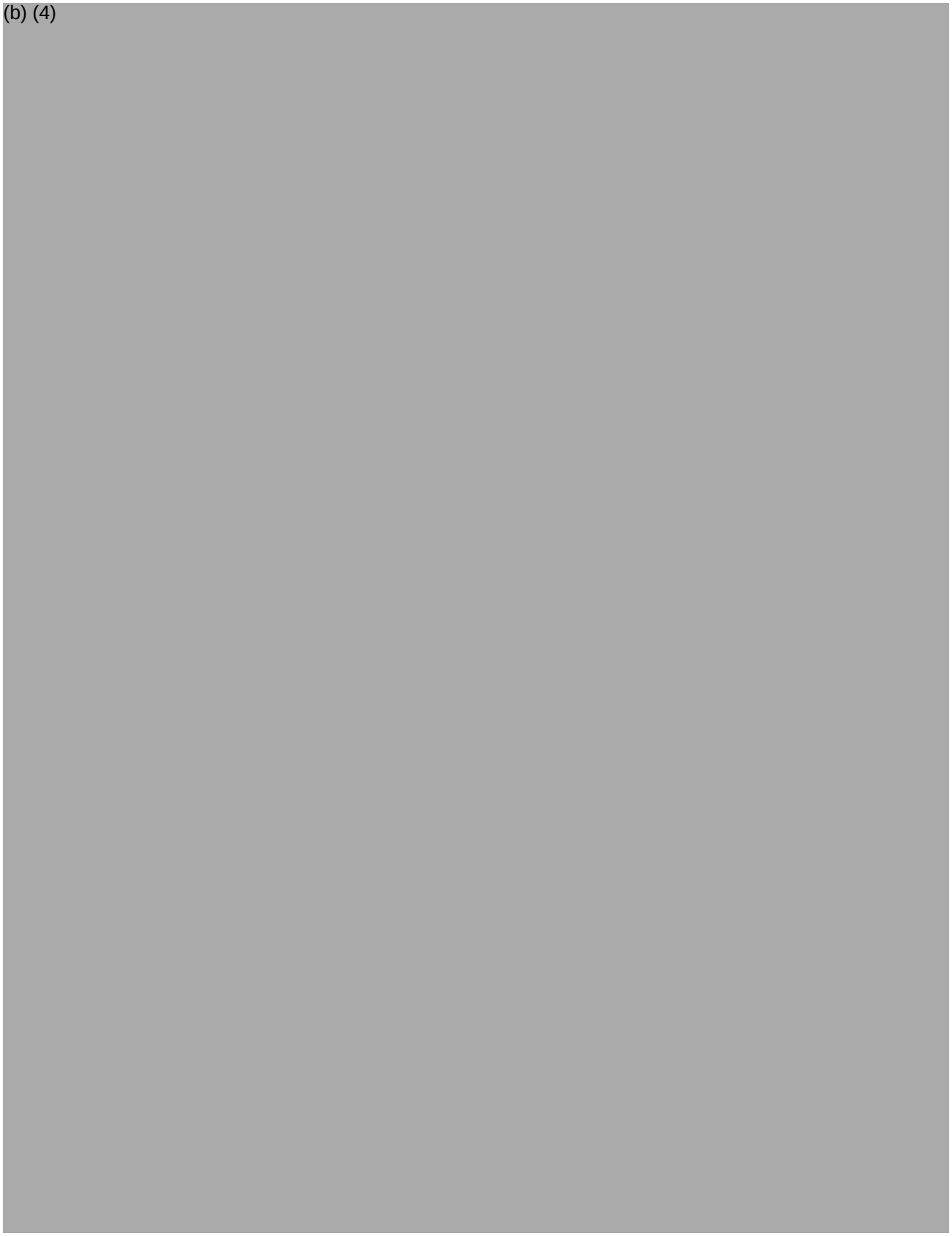
Traditional 510(k) – K112860
Peristeen™ Anal Irrigation System

Coloplast's Response to FDA

Coloplast is providing a response to the deficiencies cited in the K112860 letter from FDA. All items have been addressed. Each FDA recommendation is presented in italics; Coloplast responses are provided in normal type.

(b) (4)

(b) (4)



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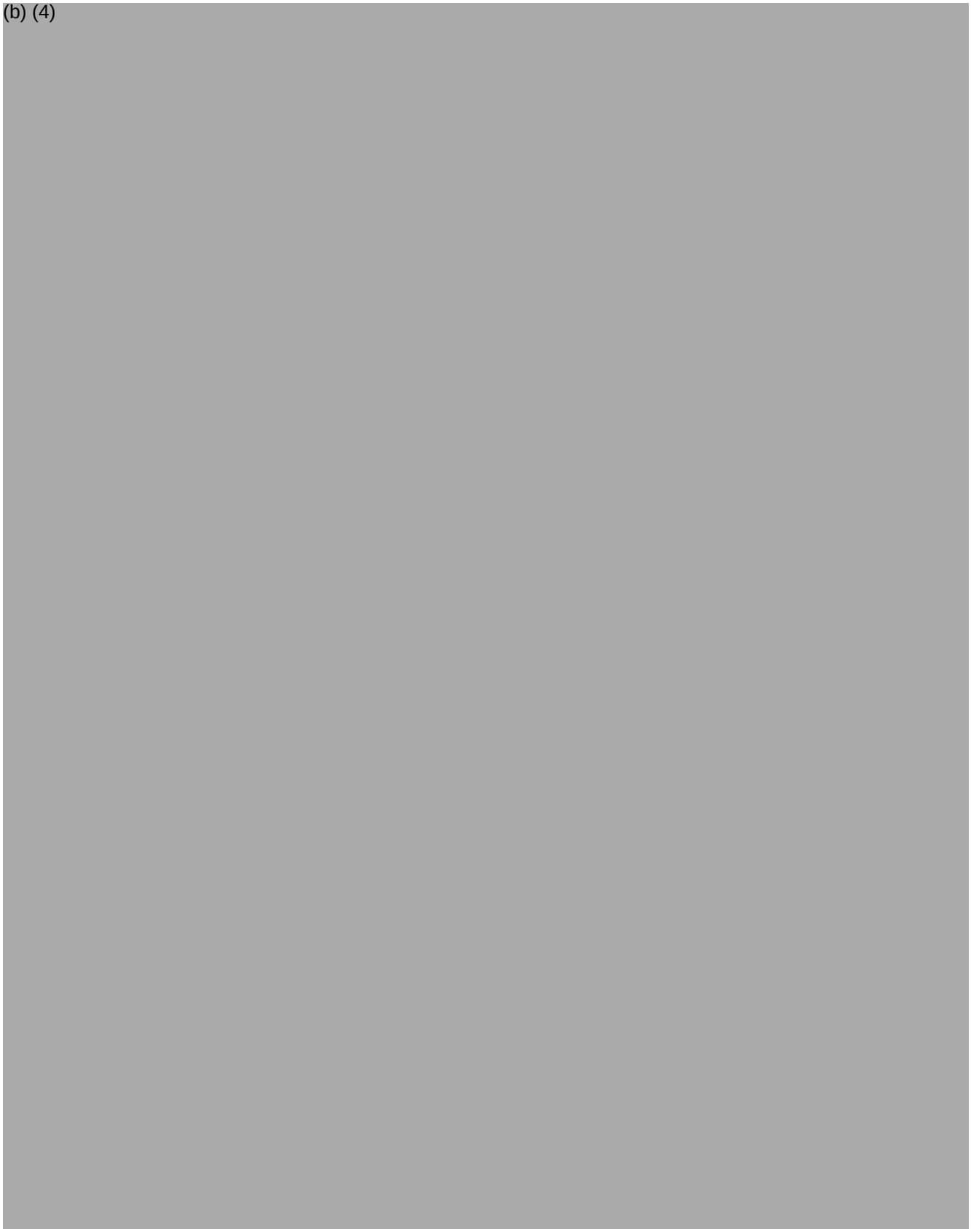

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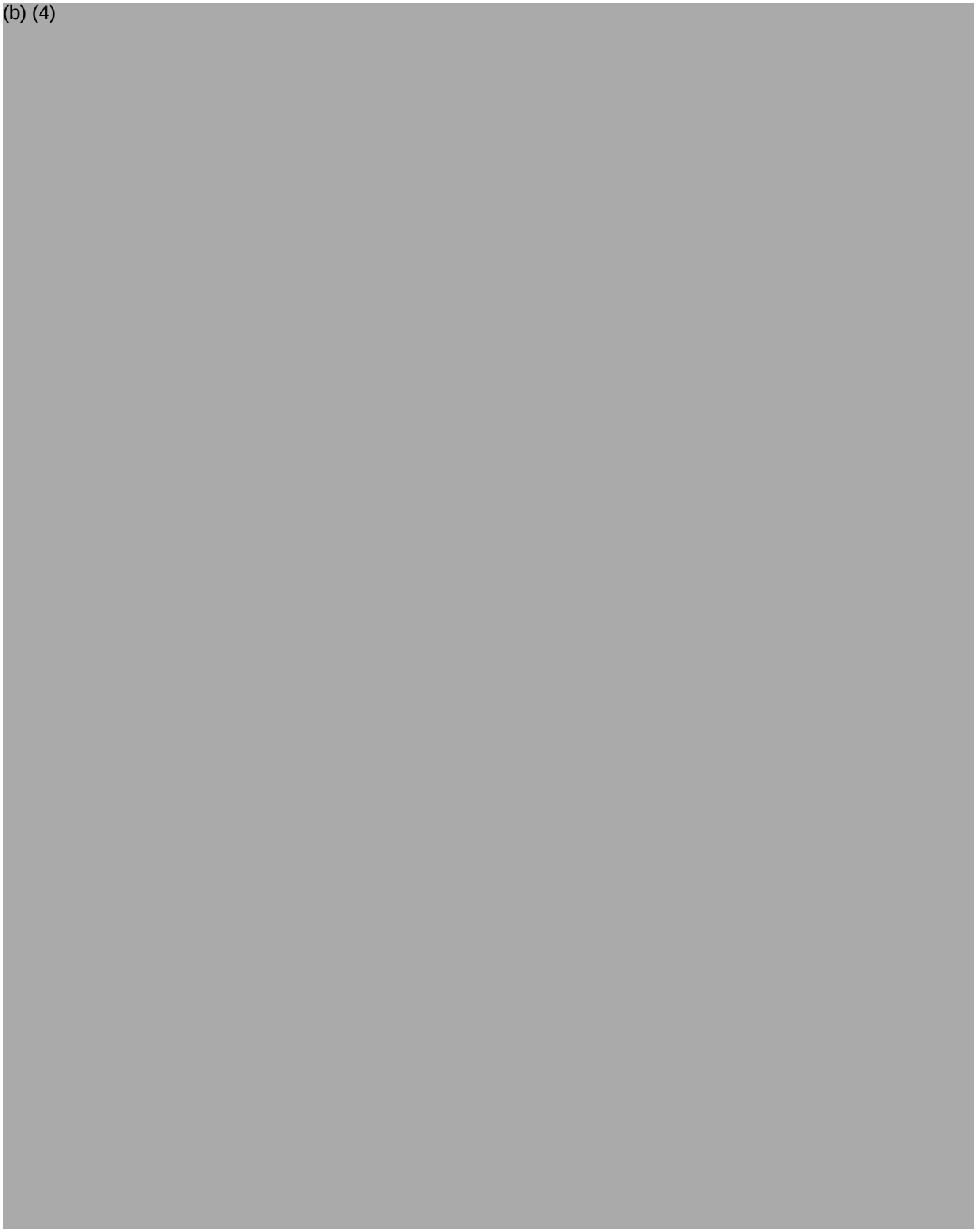


(b) (4)

INSTRUCTIONS FOR USE
PERISTEEN ANAL IRRIGATION SYSTEM

Non-Sterile. Single Patient Use Only. Does not contain natural rubber latex.

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

Intended Use:
The Peristeen Anal Irrigation System is intended to instill water into the colon through a rectal catheter – which incorporates an inflatable balloon – inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen Anal Irrigation System is indicated for use by children (2 years -<12 years old), adolescent (12 years - <18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

For more information on the Peristeen Anal Irrigation System, including complete user instructions, consult the **Peristeen User Guide.**

For a copy of the Peristeen User Guide or a copy of the Peristeen Training for Health Professionals Guide, please call Coloplast customer service at 1-800-258-3476.

Warning
Anal irrigation procedure should always be carried out with care. Bowel perforation is an extremely rare, but serious and potentially lethal complication to anal irrigation and will require immediate admission to a hospital, often requiring surgery.

Contact your doctor immediately, if during or after anal irrigation you experience any of the following:
- **Severe and sustained abdominal pain or back pain, especially if combined with fever**
- **Sustained anal bleeding**

Contraindications

Peristeen Anal Irrigation must **not** be used in the following situations:
- Known obstruction of the large bowel due to strictures or tumors
- During the spinal cord shock phase
- Acute inflammatory bowel disease
- Diverticulitis
- Complex diverticular disease
- Abdominal or anal surgery within the last 3 months
- In patients who are pregnant and have not used the system before*

*If the patient is pregnant and has never used anal irrigation before, they should not start the irrigation procedure during pregnancy.

Precautions
Always consult a physician/health care professional with experience in using Peristeen before starting up the irrigation procedure. If you are heavily constipated an initial and thorough clean-out

of your bowels is advisable before starting up the irrigation procedure. Please consult your health care professional.

Special caution must be shown if you have or have had any of the following:

- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
- Ischemic colitis
- Any Anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids (third or fourth degree hemorrhoids)
- Irradiation therapy in the abdominal or pelvic region
- Diverticular disease
- Previous abdominal or anal surgery
- Recent colonic biopsy or polypectomy
- Autonomic dysreflexia
- Cancer in the abdominal or pelvic region
- Fecal impaction
- Long term steroid therapy
- Anticoagulant therapy or bleeding disorder
- Change stool pattern like sudden diarrhea of unknown origin. The cause for diarrhea must be identified
- Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.
- Severe cognitive impairment (unless caregiver is available to supervise/administer)
- Children under 2 years of age

If any of the above conditions apply to you, anal irrigation must only be initiated after careful investigation and instruction by your health care professional.
When you use anal irrigation you must consult a physician in case of:

- Onset of any of the above mentioned conditions
- Blood in feces, weight loss, abdominal pain
- Changes in the frequency, color and consistency of the stools
- Concurrent use of laxatives or other rectal medications

For hygienic reasons the Peristeen Anal Irrigation system must only be used by the same person. Do not share with others.

Please read the whole instruction including warnings, contraindications and precautions before carrying out the anal irrigation procedure

It is vital for your safety that you consult a physician/health care professional with experience using Peristeen before starting up the irrigation procedure.
We also require that you receive thorough instruction from a health care professional before using this product

Your first irrigation must be supervised by a health care professional.

PERISTEEN ANAL IRRIGATION - DESCRIPTION

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	**RECTAL CATHETER WITH BALLOON**	**RECTAL CATHETER** allows flow of water into lower colon; inflated **BALLOON** keeps water in rectum/colon during irrigation	Use 1 time only, discard after use (single use only) **Note:** Reuse of the single use rectal catheter may create a potential risk to the user.
2.	**CONTROL UNIT & PUMP (see symbol key below)**	The **CONTROL UNIT** allows air or water to go through the system; **The PUMP** inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (equal to irrigating every other day for 6 months)
3.	Two (2) plastic **TUBES** with **CONNECTORS**	1 **TUBE** moves water from the bag into the rectal catheter; 1 **TUBE** allows air to be pumped in or out of the **BALLOON**; the **CONNECTORS** attach the **TUBES** to the **CONTROL UNIT** and the **LID**	Use 90 times (equal to irrigating every other day for 6 months)
4.	Screw-on **LID** with flip-top and suction tube	The **LID** keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (equal to irrigating every other day for 6 months)
5.	**WATER BAG**	The **WATER BAG** holds the water for the irrigation	Use 15 times (equal to irrigating every other day for 1 month)
6.	**STRAP**	The **STRAPs** wrap around your leg and hold the **CONTROL UNIT** and **TUBES** in place	Use 90 times (equal to irrigating every other day for 6 months)
7.	**STORAGE CASE**	The **STORAGE CASE** holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

 = **FINISH**

 = **INFLATE BALLOON**

 = **PUMP WATER**

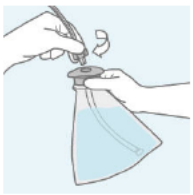
 = **DEFLATE BALLOON/RELEASE AIR**

Preparation

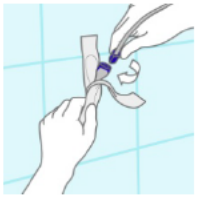
Anal irrigation is most commonly carried out while sitting on the toilet.

1. Open the lid and fill the bag to the top with lukewarm water (96-100 F). As the bag unfolds, the water level will fall and refilling is necessary. Although you need less water for the irrigation, the bag must be filled completely to function properly. Close the lid by clicking it into place.

Note: Use clean tap water. If you do not have access to clean tap water, then we recommend using bottled water. Do not add any additives to the water.



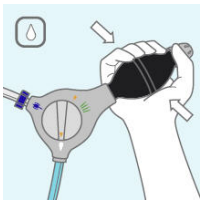
2. Attach the tube with the grey connector to the grey screw top. Lock the connector by turning it (one half turn) 90 clockwise.

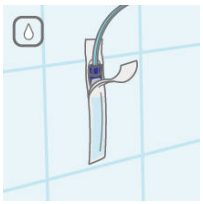


3. Open the catheter packaging about 1 inch but leave the catheter in the packaging.

Attach the tube with the blue connector to the rectal catheter by pushing them together and turn until the connect locks. Lock the connector by turning it one-half turn clockwise.

4. Attach the catheter packaging to a vertical surface by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.



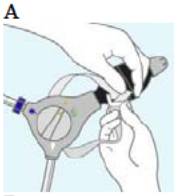


5. Turn the knob on the control unit to the water symbol and pump water into the catheter packaging (2 to 3 pumps) to activate the coating.

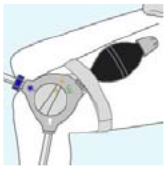
Turn the knob on the control unit to the balloon symbol to prevent any more water from going in the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put into the rectum. Remove the lubricated catheter from the packaging and use it immediately.

Tip: For extra stability when pumping, you can attach the control unit to the thigh by using the strap:

A



B

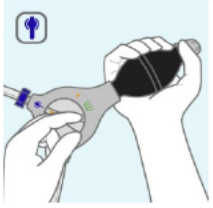


Attach the control unit and tubing to the thigh by using the strap:

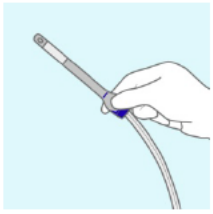
A. Place the strap around the base of the pump. Slide the strap through the buckle and pull tight.

B. Fit the pump to your thigh, adjusting the strap for a comfortable fit.

Insertion of rectal catheter

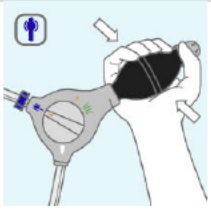


6. Ensure the knob on the control unit is pointing to the balloon symbol . As instructed by your health care professional, insert the rectal catheter carefully into the rectum without using force. The catheter should slide in smoothly.

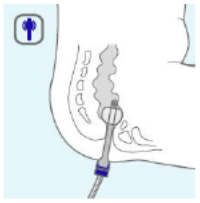


When inserting the catheter, hold it by the finger grip. The finger grip is the widest part of the catheter. Your healthcare professional will instruct you how far to insert the catheter.

Inflation of balloon



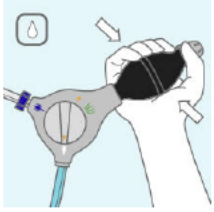
7. Start pumping gently to inflate the balloon. Your health care professional will advise you how many times to pump. A few pumps are usually enough. Your healthcare professional will write down the number of times to pump on the Health Care Notes form they gave you.



Note: Do not overinflate the balloon. The balloon on the small catheter must not be pumped more than twice. The balloon on the regular catheter must not be pumped more than five times.

Note: If you sense that the balloon is too big, turn the knob to the air symbol to deflate it. When ready turn to the balloon symbol to inflate the balloon once again.

Insertion of water



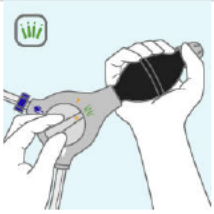
8. Turn the knob on the control unit counter-clockwise to the water symbol . Squeeze the pump slowly-about once per second-until the right amount of water has flowed in. Your healthcare professional will train you on how much water to use and they will write down the number of times to pump on the Health Care Notes form they gave you.

If water leaks, try inflating the balloon further by turning the knob on the control unit clockwise to the balloon symbol and pump one more time. Turn the knob counter-clockwise to the water symbol and resume irrigation.

In case of discomfort, turn the knob of the control unit to the balloon symbol

to stop the water flow and wait until it ceases. When you are ready, turn the knob back to the water symbol and resume pumping. If the discomfort continues, deflate the balloon, remove the catheter and contact your health care professional immediately.

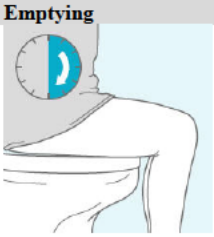
Removal of rectal catheter



9. Turn the knob on the control unit counter-clockwise to the air symbol to deflate the balloon. Often the catheter will slide out by itself; if not, pull the catheter gently.

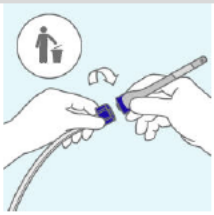
Note: Do not remove the catheter before the balloon is completely deflated
Note: For most efficient result remove the catheter immediately after the balloon has deflated

Emptying



10. Soon the colon will start to empty itself. If nothing happens, try to press, cough or move the upper part of your body to activate the emptying process. The drainage time is individual, but on average it takes thirty minutes.

Conclusion



11. Unlock the connectors from the lid and the catheter. Discard the single use catheter.

Pour excess water out of the bag.

When storing the system, turn the knob on the control unit counter-clockwise to the finish symbol. When the knob is placed in this position, any remaining water in the tubes will run out. Ensure the tubes are not kinked when stored in the storage case and that the system and all its parts are kept away from sharp objects.

The set and the rectal catheter should be stored at room temperature (max. 77 F) and out of direct sunlight.

Frequently Asked Questions:

What should I do if irrigation water and/or feces do not come out (no emptying)?
Try one or more of the following: sitting in the brace position (leaning/bending forward), coughing, standing up, abdominal massage. If water is still not expelled, then you may be heavily constipated and a clean-out of the bowel might be necessary. You might also be dehydrated, so remember to drink plenty of water and repeat the irrigation again the day after. Contact your health care professional for assistance.

Should I use lubricant on the rectal catheter?
No. The rectal catheter is pre-coated with a lubricant, which is activated when water is added to the catheter packaging (see step 5for more details). Adding extra lubricant can damage the balloon.

Why is the temperature of the water important?
The water must be lukewarm (96-100 F). If it is too hot, it may harm the delicate lining of the bowel; if it is too cold, stomach cramps may occur.

Can I stop the irrigation if I want a break?
If you feel the need for a break, turn the knob on the control unit to the balloon symbol. When you are ready, turn the knob back to the water symbol and resume pumping.

Can I re-use the rectal catheter?
The rectal catheter is for single use only and should be disposed of after each irrigation.

What kind of water should I use when traveling?
If you don't have access to clean tap water, then we recommend using bottled water.

How do I change the water bag?
Remove the grey screw top from the bag and screw it onto a replacement bag. Avoid kinking the suction pipe placed on the grey screw top.

How do I clean my Peristeen Anal Irrigation system?
The surface of all the components (not including the single use catheter) can be washed in mild soapy water.

It is possible to replace the tube with the blue connector if it becomes soiled.

How should my Peristeen Anal Irrigation system be stored?
The set and the rectal catheter should be stored at room temperature (max. 77 F) and out of direct sunlight. When storing the system, ensure that you turn the knob on the control unit to the finish symbol  . Also ensure that tubes are not kinked and that the systems is kept away from sharp objects.

Product Evaluation:

Any complications from the use of this device should be brought to our immediate attention by contacting: Quality Assurance, Product Evaluations Department, Coloplast Corp.,1601 West River Road North, Minneapolis, MN 55411
Toll-free telephone (800) 338-7908 in USA; or outside USA: (612) 337-7800

Product Order Information

To order, please contact your local sales representative or Coloplast Customer Service Department at: Coloplast, 1601 West River Road North, Minneapolis, MN 55411; Toll-free telephone: (800) 258-3476.

Distributor:

Coloplast Corp.
Minneapolis
MN 55 411
USA
Tel. 1-800-533-0464
www.us.coloplast.com

Manufacturer:

Coloplast A/S
Holtedam 1
DK-3050 Humlebæk
www.coloplast.com

PERISTEEN™ ANAL IRRIGATION USER GUIDE

TABLE OF CONTENTS

I. DESCRIPTIVE INFORMATION

Non-Sterile. Single Patient Use Only. Does not contain natural rubber latex.
Caution: Federal law restricts this device to sale by or on the order of a physician.

A. Indications for Use

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

B. Description of the device:

Peristeen Anal Irrigation system consists of a single-use rectal catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.

Figure 1: Peristeen Anal Irrigation System

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	Use 1 time only, discard after use (single use only) **Note:** Reuse of the single use rectal catheter may create a potential risk to the user.
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (equal to irrigating every other day for 6 months)
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	Use 90 times (equal to irrigating every other day for 6 months)
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (equal to irrigating every other day for 6 months)
5.	WATER BAG	The WATER BAG holds the water for the irrigation	Use 15 times (equal to irrigating every other day for 1 month)
6.	STRAP	The STRAPs wrap around your leg and hold the CONTROL UNIT and TUBES in place	Use 90 times (equal to irrigating every other day for 6 months)
7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

Peristeen Rectal Catheter

The Peristeen rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is provided non-sterile and is intended for single use only. Photographs of the un-inflated, inflated, and a simulated use model of the catheter are provided in **Figure 2.**

Figure 2: Un-inflated, Inflated, and Simulated Model Peristeen Rectal Balloon Catheter

Peristeen Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake.

The control unit housing has a manually operated knob that has the following four positions:

 Finish  Inflate balloon  Pump water  Deflate balloon

Figure 3: Peristeen Control Unit

The rectal catheter and the water bag are connected to the Control Unit via silicone tubing with color-coded connectors. Water flows through the larger tubes and air flows through the smaller tube. The blue connector attaches to the rectal catheter; the gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.

Peristeen Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.

Figure 4: Peristeen Lid/Connector/Tubing Assembly

Peristeen Lid/Suction Tube

Peristeen Water Bag

The polyethylene bag is designed to hold water for irrigation. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.

Figure 5: Peristeen Water Bag & Tubing

Peristeen System General Information

For ease of use, polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the nylon case provided with the Peristeen System; the storage case also protects the components from exposure to direct sunlight.

The Peristeen Rectal Balloon Catheter is provided non-sterile in a sealed pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Instructions for Use and the User Guide). The catheter is intended for single use only.

The other components of the Peristeen system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.

Figure 6: Peristeen Storage Case, Catheter package

Indications:
The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Warning
Anal irrigation procedure should always be carried out with care. Bowel perforation is an extremely rare, but serious and potentially lethal complication to anal irrigation and will require immediate admission to a hospital, often requiring surgery

Contact your doctor immediately, if during or after anal irrigation you experience any of the following:
- **Severe and sustained abdominal pain or back pain, especially if combined with fever**
- **Sustained anal bleeding**

Contraindications:
Peristeen Anal Irrigation must **not** be used in the following situations:
- Known obstruction of the large bowel due to strictures or tumors
- During the spinal cord shock phase
- Acute inflammatory bowel disease
- Diverticulitis
- Complex diverticular disease
- Abdominal or anal surgery within the last 3 months
- In patients who are pregnant and have not used the system before*

*If the patient is pregnant and has never used anal irrigation before, they should not start the irrigation procedure during pregnancy.

Precautions

Always consult a physician/health care professional with experience in using Peristeen before starting up the irrigation procedure. If you are heavily constipated an initial and thorough clean-out of your bowels is advisable before starting up the irrigation procedure. Please consult your health care professional.

Special caution must be shown if you have or have had any of the following:
- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
- Ischemic colitis
- Any Anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids (third or fourth degree hemorrhoids)
- Irradiation therapy in the abdominal or pelvic region
- Diverticular disease

- Previous abdominal or anal surgery
- Recent colonic biopsy or polypectomy
- Autonomic dysreflexia
- Cancer in the abdominal or pelvic region
- Fecal impaction
- Long term steroid therapy
- Anticoagulant therapy or bleeding disorder
- Change stool pattern like sudden diarrhea of unknown origin. The cause for diarrhea must be identified
- Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.
- Severe cognitive impairment (unless caregiver is available to supervise/administer)
- Children under 2 years of age

If any of the above conditions apply to you, anal irrigation must only be initiated after careful investigation and instruction by your health care professional.
When you use anal irrigation you must consult a physician in case of:

- Onset of any of the above mentioned conditions
- Blood in feces, weight loss, abdominal pain
- Changes in the frequency, color and consistency of the stools
- Concurrent use of laxatives or other rectal medications

For hygienic reasons the Peristeen Anal Irrigation system must only be used by the same person. Do not share with others.

II. OPERATING INFORMATION

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

 = **FINISH**

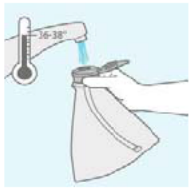
 = **INFLATE BALLOON**

 = **PUMP WATER**

 = **DEFLATE BALLOON/RELEASE AIR**

Preparation

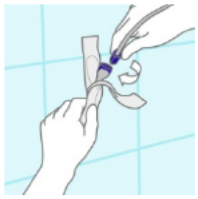
Anal irrigation is most commonly carried out while sitting on the toilet.



1. Open the lid and fill the bag to the top with lukewarm water (96-100 F). As the bag unfolds, the water level will fall and refilling is necessary. Although you need less water for the irrigation, the bag must be filled completely to function properly. Close the lid by clicking it into place.

Note: Use clean tap water. If you do not have access to clean tap water, then we recommend using bottled water. Do not add any additives to the water.

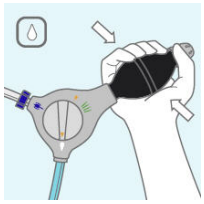
2. Attach the tube with the grey connector to the grey screw top. Lock the connector by turning it (one half turn) 90 clockwise.



3. Open the catheter packaging about 1 inch but leave the catheter in the packaging.

Attach the tube with the blue connector to the rectal catheter by pushing them together and turn until the connect locks. Lock the connector by turning it one-half turn clockwise.

4. Attach the catheter packaging to a vertical surface by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.

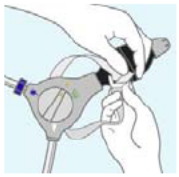


5. Turn the knob on the control unit to the water symbol and pump water into the catheter packaging (2 to 3 pumps) to activate the coating.

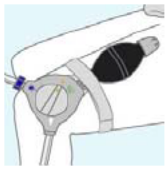
Turn the knob on the control unit to the balloon symbol to prevent any more water from going in the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put into the rectum. Remove the lubricated catheter from the packaging and use it immediately.

Tip: For extra stability when pumping, you can attach the control unit to the thigh by using the strap:

A



B

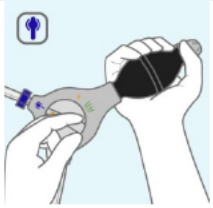


Attach the control unit and tubing to the thigh by using the strap:

A. Place the strap around the base of the pump. Slide the strap through the buckle and pull tight.

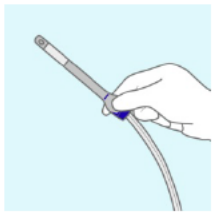
B. Fit the pump to your thigh, adjusting the strap for a comfortable fit.

Insertion of rectal catheter

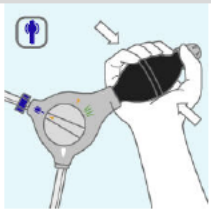


6. Ensure the knob on the control unit is pointing to the balloon symbol . As instructed by your health care professional, insert the rectal catheter carefully into the rectum without using force. The catheter should slide in smoothly.

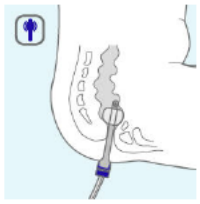
When inserting the catheter, hold it by the finger grip. The finger grip is the widest part of the catheter. Your healthcare professional will instruct you how far to insert the catheter.



Inflation of balloon



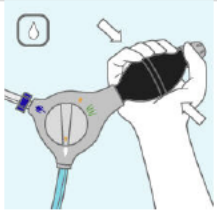
7. Start pumping gently to inflate the balloon. Your health care professional will advise you how many times to pump. A few pumps are usually enough. Your healthcare provider will write down the number of times to pump on the Health Care Notes form they gave you.



Note: Do not overinflate the balloon. The balloon on the small catheter must not be pumped more than twice. The balloon on the regular catheter must not be pumped more than five times.

Note: If you sense that the balloon is too big, turn the knob to the air symbol to deflate it. When ready turn to the balloon symbol to inflate the balloon once again.

Insertion of water



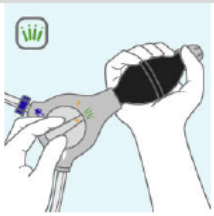
8. Turn the knob on the control unit counter-clockwise to the water symbol . Squeeze the pump slowly-about once per second-until the right amount of water has flowed in. Your healthcare provider will train you on how much water to use and they will write down the number of times to pump on the Health Care Notes form they gave you.

If water leaks, try inflating the balloon further by turning the knob on the control unit clockwise to the balloon symbol and pump one more time. Turn the knob counter-clockwise to the water symbol and resume irrigation.

In case of discomfort, turn the knob of the control unit to the balloon symbol

to stop the water flow and wait until it ceases. When you are ready, turn the knob back to the water symbol and resume pumping. If the discomfort continues, deflate the balloon, remove the catheter and contact your health care professional immediately.

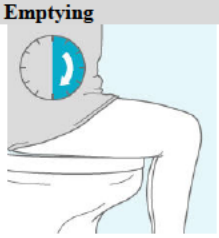
Removal of rectal catheter



9. Turn the knob on the control unit counter-clockwise to the air symbol to deflate the balloon. Often the catheter will slide out by itself; if not, pull the catheter gently.

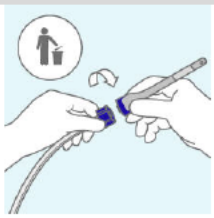
Note: Do not remove the catheter before the balloon is completely deflated
Note: For most efficient result remove the catheter immediately after the balloon has deflated

Emptying



10. Soon the colon will start to empty itself. If nothing happens, try to press, cough or move the upper part of your body to activate the emptying process. The drainage time is individual, but on average it takes thirty minutes.

Conclusion



11. Unlock the connectors from the lid and the catheter. Discard the single use catheter.

Pour excess water out of the bag.

When storing the system, turn the knob on the control unit counter-clockwise to the finish symbol . When the knob is placed in this position, any remaining water in the tubes will run out. Ensure the tubes are not kinked when stored in the storage case and that the system and all its parts are kept away from sharp objects.

The set and the rectal catheter should be stored at room temperature (max. 77 F) and out of direct sunlight.

III. TROUBLESHOOTING INFORMATION:

Who can perform anal irrigation?
Anal irrigation is for people with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation and/or time-consuming bowel management procedures. You must be examined by a health care professional and receive professional instruction before starting the irrigation. After receiving instruction and training, the majority will be able to perform anal irrigation on their own.

How often should I irrigate?
Anal irrigation may be performed every other day or as recommended by your doctor or nurse.

How long does the irrigation take?
The time used for irrigation is individual. When using anal irrigation you approximately use 30-45 minutes on bowel management daily.

How much air and water should I use?

The required amount of air to pump into the balloon and water to pump into the rectum is individual and your doctor or nurse will tell you how much to use. They will write the amounts of air and water to pump on your Health Care Notes form. You should not increase the amount of water uncritically since the bowel may retain it and release it over time in small amounts.

Why is the temperature of the water important?
The water must be lukewarm (96-100°F). If it is too hot, it may harm the delicate lining of the bowel; if it is too cold, stomach cramps may occur.

How quickly should I pump the water?
If the water is pumped too quickly into the bowel, you may experience discomfort such as sweating, dizziness and stomach ache. We recommend one pump per second or as recommended by your doctor or nurse.

Can I stop the irrigation if I want a break?
If you feel the need for a break, turn the knob on the control unit to the balloon symbol  . When you are ready, turn the knob back to the water symbol  and resume pumping.

What should I do if the irrigation water and/or feces do not come out (no emptying)?
Try one or more of the following: sitting in the brace position (leaning/bending forward), coughing, standing up, abdominal massage. If water is still not expelled, then you may be heavily constipated and a clean-out of the bowel might be necessary. You might also be dehydrated, so remember to drink plenty of water and repeat the irrigation again the day after. Contact your health care professional for assistance.

What should I do if water leaks into the toilet?
If water leaks past the balloon and into the toilet there is no need to change the irrigation procedure if the irrigation still works.

You can stop the pumping of water, wait for a while and fill some more water into the bowel. Make sure the catheter is placed in the correct position right above the sphincters. If water still seeps into the toilet, you can fill more air into the balloon and resume pumping water into the bowel.

What if I experience leakages after irrigation?
If you experience leakages after irrigation you might have used too much water. Make sure to use the amount of water recommended by your health care professional. You can also try to stay a little longer at the toilet. Contact your health care professional if you continue experiencing leakages.

What if I experience defecation between irrigations?
If you experience defecation between irrigations, the cause may be insufficient emptying after irrigation owing to constipation or hard stools. Contact your health care professional for different solutions, e.g. frequency of irrigation, amount of water and/or medication.

How should my Peristeen Anal Irrigation system be stored?
The system and the rectal catheter should be stored at room temperature (maximum 77° F) and out of direct sunlight. When storing the system, ensure that you turn the knob on the control unit to the finish symbol  . Also ensure that tubes are not kinked and that the systems is kept away from sharp objects.

How do I clean my Peristeen Anal Irrigation system?

The tube can be cleaned by turning the knob on the control unit to the water symbol and pumping the dirty water out of the tube. You may choose to change the tube with the blue connectors more frequently if you desire. The surface of all the components (excluding the single use catheter) can be washed in mild soapy water, and rinsed thoroughly. Remember to keep the Control Unit knob in the Resting/Storage position when you are not using the Peristeen System.

What do I do when travelling?
The bowels absorb water, so when travelling in countries where it is not safe to drink the water, care should be taken to use distilled or bottled water for irrigation.

Flatulence
Anal irrigation empties the bowel of feces and air. Experience shows that the release of gas from the rectum will be considerably reduced once irrigation is practiced regularly.

Adaptation period
An adaptation period of approx. 10 days may be expected. The procedure must be individually adjusted together with your health care professional regarding the amount of air to pump into the balloon, water to pump into the rectum, as well as recommended frequency of irrigating.

IV. DISEASE AND SELF-CARE INFORMATION

The bowel system
The bowels are part of the digestive system, the primary function of which is to break down the food we eat. The food passes through the stomach and the small bowel (small intestine), where it is broken down and useful components are absorbed into the body. What is left continues to the large bowel (colon and rectum).

The large bowel receives a liquid mixture of digested food and juices from the small bowel. The main function of the large bowel is to absorb water and salts and to store the waste products (feces) before they are transported to the rectum. The large bowel in an average size adult receives about 1,500 ml small bowel content a day and converts this into 150-200 ml of fecal matter. The bowel absorbs the remainder.

On average it takes 1-3 days for food to pass through the entire digestive tract, though this can vary greatly from person to person. The time it takes for food to pass through the digestive system is called the transit time.

The large bowel has two muscles, which make peristaltic movements when contracting. With the aid of peristalsis, the feces are moved onward from the large bowel into the rectum. Peristalsis is affected by a number of factors such as diet, posture and exercise.

Peristalsis is a wavelike muscular contraction that transports digested food through the intestines to the rectum. The two colon muscles; one longitudinal muscle along the colon and one circular muscle around the colon make the contraction.

There are two sphincters in the rectum controlling the defecation process. The internal sphincter is an extension of the colon musculature and is controlled by reflex, i.e. we cannot consciously control it. The external sphincter can be controlled consciously by the brain.

There are two sphincters in the rectum affecting the evacuation – the internal and the external sphincter. The function of the anal sphincters is to maintain continence and prevent leakage.

Once the rectum receives feces from the large bowel, it is registered in a set of nerve endings. These nerve endings send a signal to the brain that the rectum is full and that it is time to go to the toilet. At this point you can choose to wait for a more suitable time. If you wait too long however, the urge will disappear and the feces will be forced back into the large bowel.

When you decide to go to the toilet, you activate the defecation reflex by relaxing the external sphincter. Typically, the presence of approx. 150 ml of feces will result in a reflex relaxation of the internal sphincter. The external sphincter relaxes and the feces are expelled with the aid of gravity and muscle contractions in the rectum.

Causes of bowel dysfunction
There are many causes of bowel dysfunction and reasons for initiating anal irrigation. The most frequent reasons are mentioned below. In order to receive appropriate and effective treatment, a diagnosis from your health care professional is essential.

Neurological disorders
The defecation mechanism, i.e. the nerves that send a signal to your brain telling you when you need to go to the toilet, may be impaired due to a medical condition or disease, such as: a spinal cord injury, spina bifida, multiple sclerosis, Parkinson’s disease, apoplexia, Alzheimer’s disease or brain tumors.

Sensory disorders
The sensory function of the rectal mucosa may be impaired. This can occur after surgery, as a result of colitis, compaction, rectal prolapse or as a result of surgical correction of congenital absence or abnormality of the anal opening (anal atresia).

Muscular disorders
Damage to the sphincter muscle due to external injuries, tumours or their surgical removal, perineal tear from a vaginal birth, straining from constipation or rectal prolapse.

Psychological/psychiatric disorders
Caused by psychoses, depression, depersonalisation or role conflicts (in children and adults) as well as a result of sexual abuse.

Reduced tissue elasticity
Frequent in old age or after multiple births.

The effect of food and exercise
Food plays an important role in managing your bowels. It is important to find the right balance of stool consistency to avoid either constipation or liquid stools, which will increase the risk of fecal incontinence.

Dietary fiber generally soften stool and reduce the passage time. Too much fiber, however, can worsen symptoms of bloating and stomach pain.

It is worth noting that some food and liquids such as coffee and artificial sweeteners have a mild laxative effect. It is always important to drink plenty of fluids.

Finally physical exercise has a mechanical effect on the bowels, which improves bowel movement.

Constipation
Constipation and fecal incontinence are both symptoms of bowel dysfunction and you often experience both fecal incontinence and constipation at the same time.

Bowel function and defecation habits vary from one person to another. Some have daily bowel movements, others every second or third day. Owing to the extensive variation in the normal defecation pattern, it is difficult to offer a clear definition of constipation.

Constipation occurs when the bowel's movements are reduced. This prolongs transit time in the large bowel and more fluid is absorbed from the feces than with normal transit time, resulting in hard and lumpy stools. This will often result in general discomfort and in some cases disturbed bladder-emptying patterns.

Constipation is generally perceived as:

• Fewer than three defecations a week.
• Prolonged lavatory visits with straining and soreness in the rectum.
• Hard, sparse and lumpy stools.

Because of this natural variation, changes in digestive and bowel movement patterns will be perceived differently depending on what one is accustomed to.

Fecal incontinence
Fecal incontinence can be defined as lack of control of bowel evacuation resulting in involuntary defecation. Anal incontinence also includes incontinence for air (flatus).

In many cases, fecal incontinence occurs as the result of insufficient sensation in the rectal region. In other words, you do not register the urge to defecate. At the same time, control of the internal and external sphincters may be entirely or partially lacking.

Chronic constipation, in which the rectum wall is severely over-stretched, may result in fecal incontinence as the normal defecation reflexes are deactivated by the chronic stretch. At the same time, fluid passes around the fecal mass in the bowel. Often the internal sphincter has reduced function because it is expanded and liquid stools mixed with dry and hard stool may pass.

V. USER ASSISTANCE INFORMATION:

Coloplast in brief

Coloplast A/S is a Danish company founded in 1957 with more than 7,000 employees.

Coloplast develops, produce and market products and services that make life easier for people with very personal and private medical conditions. Working closely with the people who use our products, we create solutions that are sensitive to their special needs. Coloplast calls this intimate healthcare. Our business includes:

- Chronic Care refers to our two largest business areas, Ostomy and Continence Care. These are chronic areas because the people who live with an ostomy or who are incontinent will have to use our products on a daily basis – many for the re-minder of their lives.
- Urology Care products for surgical treatment of urological disorders, such as erectile dysfunction, urinary incontinence, weak pelvic muscles, kidney stones and enlarged prostate.
- Wound Care products for wound healing and skin care. Coloplast specialize in moist wound healing.
- Skin care products improve comfort and prevent skin conditions for people with injured or at-risk skin e.g. hospital patients and stoma-users.

Coloplast A/S operates globally with sales subsidiaries in our principal markets worldwide.

Coloplast A/S
Holtedam 1
DK-3050 Humlebæk
www.coloplast.com

Device Description:

Peristeen Anal Irrigation system consists of a single-use rectal catheter with a balloon for retention; a control unit with a manual switch to add pressure to the water bag, inflate and deflate the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a storage case. The System and accessories are pictured in **Figure 1**.

Figure 1: Peristeen Anal Irrigation System

The Peristeen Anal Irrigation System is made up of the following parts:

	Part Name	What does it do?	How many times can it be used?*
1.	RECTAL CATHETER WITH BALLOON	RECTAL CATHETER allows flow of water into lower colon; inflated BALLOON keeps water in rectum/colon during irrigation	Use 1 time only, discard after use (single use only) Note: Reuse of the single use rectal catheter may create a potential risk to the user.
2.	CONTROL UNIT & PUMP (see symbol key below)	The CONTROL UNIT allows air or water to go through the system; The PUMP inflates or deflates the balloon & makes the water flow through the catheter	Use 90 times (equal to irrigating every other day for 6 months)
3.	Two (2) plastic TUBES with CONNECTORS	1 TUBE moves water from the bag into the rectal catheter; 1 TUBE allows air to be pumped in or out of the BALLOON; the CONNECTORS attach the TUBES to the CONTROL UNIT and the LID	Use 90 times (equal to irrigating every other day for 6 months)
4.	Screw-on LID with flip-top and suction tube	The LID keeps the water in the bag; it also has openings where connectors for tubes are put in	Use 90 times (equal to irrigating every other day for 6 months)
5.	WATER BAG	The WATER BAG holds the water for the irrigation	Use 15 times (equal to irrigating every other day for 1 month)
6.	STRAP	The STRAPs wrap around your leg and hold the CONTROL UNIT and TUBES in place	Use 90 times (equal to irrigating every other day for 6 months)
7.	STORAGE CASE	The STORAGE CASE holds all the system parts and keeps them from exposure to direct sunlight	As desired

*Parts can be used fewer times if desired; they have been tested to be sure that they will work for the number of times listed

Peristeen Rectal Catheter

The Peristeen rectal catheter is intended to allow the flow of water into the colon; the balloon prevents leakage of the fluid while irrigating. The catheter is provided non-sterile and is intended for single use only. Photographs of the un-inflated, inflated, and a simulated use model of the catheter are provided in **Figure 2.**

Figure 2: Un-inflated, Inflated, and Simulated Model Peristeen Rectal Balloon Catheter

Peristeen System Control Unit/Tubing Assembly

The control unit is used for regulation of air in the balloon and water flowing through the catheter into the rectum. The control unit has an acrylonitrile/
butadiene/styrene (ABS) housing. A PVC hand pump is attached to one port of the control unit; it has an ABS exhaust cap for air intake.

The control unit housing has a manually operated knob that has the following four positions:

 Finish  Inflate balloon  Pump water  Deflate balloon/release air

Figure 3: Peristeen Control Unit

The rectal catheter and the water bag are connected to the Control Unit via silicone tubing with color-coded connectors. Water flows through the larger tubes and air flows through the smaller tube. The blue connector attaches to the rectal catheter; the gray connector attaches to the gray lid for the water bag. The Control Unit is provided non-sterile and can be used up to 90 times before replacement.

Peristeen System Lid/Suction Tube assembly

The gray lid is screwed onto the threaded sleeve of the water bag to secure the water inside; it has a flip-top that can be opened for filling or emptying. There is a two-lumen connection port in the top of the lid for the large-lumen tubing. A suction tube attached to the lid draws the water from the bag into the tubing. The Lid/Suction Tube assembly is provided non-sterile and can be used up to 90 times before replacement.

Figure 4: Peristeen Lid/Connector/Tubing Peristeen Lid/Suction Tube Assembly

Peristeen System Water Bag

The polyethylene bag is designed to hold water for irrigation. Volume indicator markings are labeled on the side of the bag so that the volume used may be tracked. The bag holds 1000 ml of fluid. It is provided non-sterile and may be used up to 15 times before replacement.

Figure 5: Peristeen Water Bag & Tubing

Peristeen System General Information

For ease of use, polyester elastic straps are provided that may be used to fasten the control unit and tubing to the thigh.

All the System components can be stored in the nylon case provided with the Peristeen System; the storage case also protects the components from exposure to direct sunlight.

The Peristeen Rectal Balloon Catheter is provided non-sterile in a sealed pouch. Two adhesive dots on the package (protected by two paper circles) allow the package to be attached to a wall or door so that the catheter may be pre-lubricated prior to its insertion (as described in the Instructions for Use and the Peristeen User Guide). The catheter is intended for single use only.

The other components of the Peristeen system are provided non-sterile in plastic pouches packed in cardboard shelf boxes. The complete System comes with the storage case and two packaged rectal catheters; supplementary component kits are available to allow the user to replace components as necessary; these are also packaged as previously described.

Figure 6: Peristeen System Storage Case, Catheter package

Indications:

The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures.

Warning

Anal irrigation procedure should always be carried out with care. Bowel perforation is an extremely rare, but serious and potentially lethal complication to anal irrigation and will require immediate admission to a hospital, often requiring surgery

Contact your doctor immediately, if during or after anal irrigation you experience any of the following:

- **Severe and sustained abdominal pain or back pain, especially if combined with fever**
- **Sustained anal bleeding**

Contraindications:

Peristeen Anal Irrigation must **not** be used in the following situations:

- Known obstruction of the large bowel due to strictures or tumors
- During the spinal cord shock phase
- Acute inflammatory bowel disease
- Diverticulitis
- Complex diverticular disease
- Abdominal or anal surgery within the last 3 months
- In patients who are pregnant and have not used the system before*

*If the patient is pregnant and has never used anal irrigation before, they should not start the irrigation procedure during pregnancy.

Precautions

Always consult a physician/health care professional with experience in using Peristeen before starting up the irrigation procedure. If you are heavily constipated an initial and thorough clean-out of your bowels is advisable before starting up the irrigation procedure. Please consult your health care professional.

Special caution must be shown if you have or have had any of the following:

- Inflammatory bowel disease (e.g. Crohn's disease or ulcerative colitis)
- Ischemic colitis
- Any Anorectal condition, which may cause pain or bleeding e.g. anal fissure, severe hemorrhoids (third or fourth degree hemorrhoids)
- Irradiation therapy in the abdominal or pelvic region
- Diverticular disease
- Previous abdominal or anal surgery
- Recent colonic biopsy or polypectomy
- Autonomic dysreflexia
- Cancer in the abdominal or pelvic region
- Fecal impaction
- Long term steroid therapy
- Anticoagulant therapy or bleeding disorder
- Change stool pattern like sudden diarrhea of unknown origin. The cause for diarrhea must be identified
- Rectal medication for other diseases. The effect of such medication may be diluted by the anal irrigation.
- Severe cognitive impairment (unless caregiver is available to supervise/administer)
- Children under 2 years of age

If any of the above conditions apply to you, anal irrigation must only be initiated after careful investigation and instruction by your health care professional.
When you use anal irrigation you must consult a physician in case of:

- Onset of any of the above mentioned conditions
- Blood in feces, weight loss, abdominal pain
- Changes in the frequency, color and consistency of the stools
- Concurrent use of laxatives or other rectal medications

For hygienic reasons the Peristeen Anal Irrigation system must only be used by the same person. Do not share with others.

Instructions for Use:

Each patient and/or caregiver should be trained in the following steps and should perform these steps with physician assistance to ensure that all steps are understood and can be accomplished independently.

Operating Information

SPECIAL NOTES

When changing to a new WATER BAG, unscrew the grey LID with attached tube from the bag and put in into the replacement bag. Do not kink the suction tube when storing the WATER BAG in the STORAGE CASE.

The **CONTROL UNIT** has a knob with symbols on it; these symbols are included in the instructions and the key is as follows:

 = **FINISH**

 = **INFLATE BALLOON**

 = **PUMP WATER**

 = **DEFLATE BALLOON/RELEASE AIR**

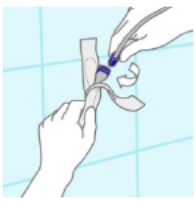
Preparation

Anal irrigation is most commonly carried out while sitting on the toilet.

1. Open the lid and fill the bag to the top with lukewarm water (96-100 °F). As the bag unfolds, the water level will fall and refilling is necessary. Although you need less water for the irrigation, the bag must be filled completely to function properly. Close the lid by clicking it into place.

Note: Use clean tap water. If you do not have access to clean tap water, then we recommend using bottled water. Do not add any additives to the water.

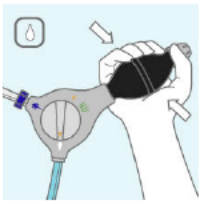
2. Attach the tube with the grey connector to the grey screw top. Lock the connector by turning it (one half turn) 90° clockwise.



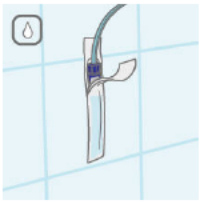
3. Open the catheter packaging about 1 inch but leave the catheter in the packaging.

Attach the tube with the blue connector to the rectal catheter by pushing them together and turn until the connect locks. Lock the connector by turning it one-half turn clockwise.

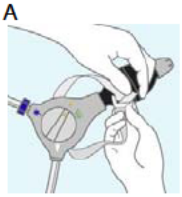
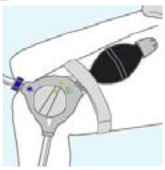
4. Attach the catheter packaging to a vertical surface by removing the paper circles from the catheter package and sticking the adhesive dots on the package to the wall or door.



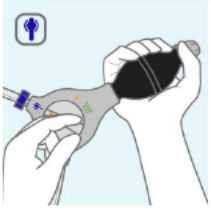
5. Turn the knob on the control unit to the water symbol and pump water into the catheter packaging (2 to 3 pumps) to activate the coating.
Turn the knob on the control unit to the balloon symbol to prevent any more water from going in the package. Wait 30 seconds. This will make the outside of the catheter slippery (lubricated) and it will be easier to put into the rectum. Remove the lubricated catheter from the packaging and use it immediately.



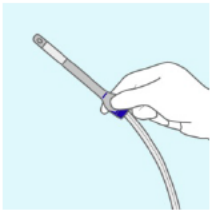
Tip: For extra stability when pumping, you can attach the control unit to the thigh by using the strap:

A 	Attach the control unit and tubing to the thigh by using the strap: A. Place the strap around the base of the pump. Slide the strap through the buckle and pull tight.
B 	B. Fit the pump to your thigh, adjusting the strap for a comfortable fit.

Insertion of rectal catheter

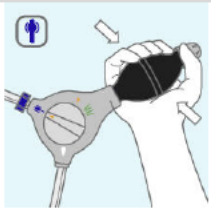


6. Ensure the knob on the control unit is pointing to the balloon symbol . As instructed by your health care professional, insert the rectal catheter carefully into the rectum without using force. The catheter should slide in smoothly.

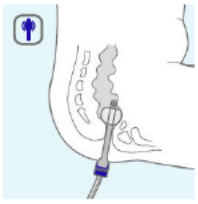


When inserting the catheter, hold it by the finger grip. The finger grip is the widest part of the catheter. Your healthcare professional will instruct you how far to insert the catheter.

Inflation of balloon



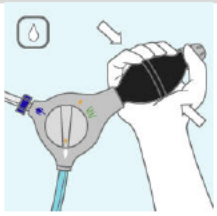
7. Start pumping gently to inflate the balloon. Your health care professional will advise you how many times to pump. A few pumps are usually enough. Your healthcare provider will write down the number of times to pump on the Health Care Notes form they gave you.



Note: Do not overinflate the balloon. The balloon on the small catheter must not be pumped more than twice. The balloon on the regular catheter must not be pumped more than five times.

Note: If you sense that the balloon is too big, turn the knob to the air symbol to deflate it. When ready turn to the balloon symbol to inflate the balloon once again.

Insertion of water

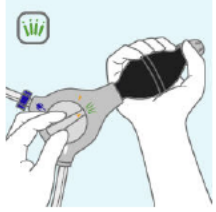


8. Turn the knob on the control unit counter-clockwise to the water symbol . Squeeze the pump slowly-about once per second-until the right amount of water has flowed in. Your healthcare provider will train you on how much water to use and they will write down the number of times to pump on the Health Care Notes form they gave you.

If water leaks, try inflating the balloon further by turning the knob on the control unit clockwise to the balloon symbol and pump one more time. Turn the knob counter-clockwise to the water symbol and resume irrigation.

In case of discomfort, turn the knob of the control unit to the balloon symbol to stop the water flow and wait until it ceases. When you are ready, turn the knob back to the water symbol and resume pumping. If the discomfort continues, deflate the balloon, remove the catheter and contact your health care professional immediately.

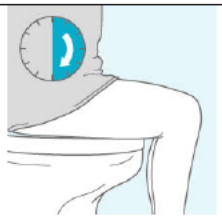
Removal of rectal catheter



9. Turn the knob on the control unit counter-clockwise to the air symbol to deflate the balloon. Often the catheter will slide out by itself; if not, pull the catheter gently.

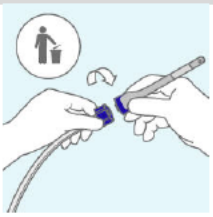
Note: Do not remove the catheter before the balloon is completely deflated
Note: For most efficient result remove the catheter immediately after the balloon has deflated

Emptying



10. Soon the colon will start to empty itself. If nothing happens, try to press, cough or move the upper part of your body to activate the emptying process. The drainage time is individual, but on average it takes thirty minutes.

Conclusion



11. Unlock the connectors from the lid and the catheter. Discard the single use catheter.

Pour excess water out of the bag.

When storing the system, turn the knob on the control unit counter-clockwise to the finish symbol  . When the knob is placed in this position, any remaining water in the tubes will run out. Ensure the tubes are not kinked when stored in the storage case and that the system and all its parts are kept away from sharp objects.

The set and the rectal catheter should be stored at room temperature (max. 77°F) and out of direct sunlight.

Physician Notes:

Peristeen Anal Irrigation is designed to be carried out independently or with the assistance of a caregiver in the user's home. It is important that a healthcare professional supervises the first use of Peristeen Anal Irrigation to help the patient use the system safely, optimally and with confidence. Once a patient and/or caregiver has completed irrigation under supervision, they may try the procedure alone. Sometimes more than one training session is required so each patient should be considered individually in terms of their readiness and capability to do so. Subsequent irrigations should be followed-up by consultations in person or by telephone until the patient and/or caregiver has fully adapted the procedure to meet the individual needs and until they are confident to continue the procedure independently. If a patient is heavily and/or chronically constipated, it may be necessary to thoroughly clean out their bowels before starting Peristeen Anal Irrigation.

Physicians should prescribe irrigation based upon a comprehensive evaluation of the nature of the patient's fecal incontinence and the frequency of either constipation or soiling episodes. Generally, Coloplast recommends that anal irrigation be performed every other day; more or less frequent irrigation may be advised depending upon individual patient needs.

Prior to starting Peristeen Anal Irrigation for the first time, please take time to describe the procedure to your patient, answer any questions, and help manage their expectations. To avoid potential disappointment or concern that anal irrigation does not work for them, explain that an initial period of adjustment is perfectly normal and is required to establish their personalised routine. An anal irrigation bowel diary is a good way of keeping track of progress during this period (see table 1). Peristeen Anal Irrigation can work successfully within a few days but for some individuals it can take 4 to 6 weeks for the treatment to settle down and become routine.

Table 1. Example extract from an anal irrigation bowel diary

Date	Time	Number of balloon pumps	Water volume	Comments
10 June	8.35 am	2 + 1	700 mL	Small amount of water leaked during irrigation. Evacuation after approx 25 minutes
11 June	8.30 am	3	700 mL	No water leakage. Good evacuation
12 June	8.30 am	3	700 mL	No faeces passed. Bowel still empty from yesterday?
13 June	8.40 am	3	700 mL	Good evacuation today after approx. 20 minutes

For new users of Peristeen Anal Irrigation, the irrigation routine should be tailored to meet their individual requirements. It is helpful to ensure the patient understands that, at first, some trial and error will be required to optimise the process and establish their personalised routine. For some people it can take 4 to 6 weeks to adapt the routine. Make sure to complete a **Health Care Notes form** for the patient and/or caregiver to refer to. The **Anatomy Notes** sheets can also be used to make notes and special recommendations on an individual basis.

There are several parameters that can be adjusted if required:
1. Amount of air in the catheter balloon
2. Amount of water used for irrigation
3. Frequency of irrigation

Amount of air in the catheter balloon
The function of the balloon is to hold the catheter in place in the rectum; the degree to which the balloon must be inflated to achieve this (i.e. the number of pumps of air required) depends on the condition of the individual's sphincter and rectum. The average size adult will probably require 3 to 4 pumps of air in the balloon (maximum 5 pumps); for smaller patients, 1 to 2 pumps may be sufficient. Insufficient air can cause water to leak or the catheter to slide out of the rectum. If water leaks during the procedure, patients and/or caregivers should attempt pumping one more time to a maximum of 5 pumps in total. Conversely, too much air can cause the balloon to be expelled. If this happens, repeating the procedure using a little less air should be attempted. The frequency of expulsions often decreases as a patient becomes used to the procedure.

Please use the following notes to guide the amount of air pumped into the balloon for an average size adult patient:

• Intact sphincter reflexes and muscle tone: 1 to 3 pumps
• Flaccid bowels or low sphincter tone: 3 to 5 pumps. If the catheter still slides out of the rectum, it may be supported by holding in place
• Strong anorectal reflexes: The balloon may be expelled after only 1 to 2 pumps; careful insertion and inflation of the balloon is necessary, using less air

For smaller patients, 1 to 2 pumps is recommended.

Amount of water for irrigation
The volume of water required to effectively empty the bowel depends on several factors including the patient's bowel condition, their diet and the frequency of irrigation.

When first using Peristeen Anal Irrigation in adults, a water volume of 500 ml is recommended, and irrigation should be performed daily. This volume can be gradually increased, over the next few weeks, until the individual feels they are completely empty and have no accidents between irrigations. Increases in volume should be done slowly, especially in younger patients and patients with spina bifida. Many adult patients eventually use a volume in the region of 750 ml; however, studies have shown that the amount of water varies from 200 to 1500 ml in adults. Some patients with upper neurone damage experience evacuation of the bowel at low water volumes (e.g. 200 to 300 ml); in some cases the irrigation procedure might need to be repeated to ensure sufficient emptying.

If leakage occurs after the irrigation try:

• Advising the patient to stay on the toilet a little longer to allow complete emptying of the bowel
• Reducing the volume of water
• Two half volume irrigations (e.g. two 250 ml irrigations instead of one 500 ml irrigation)

If irrigation water is not expelled after sitting on the toilet for 20 to 30 minutes, it could be that the bowel has absorbed the water because the patient is dehydrated or that the irrigation fluid is captured in impacted stools:

• Repeat the irrigation using the same volume of water
• Advise the patient to drink more fluids – at least 1.5 litres per day and more in hot weather

The recommended rate for pumping water into the bowel is one pump per second. Pumping water into the bowel too quickly may cause discomfort, sweating, dizziness and stomach pain; if this occurs, the procedure can be paused at any time and resumed when the discomfort has passed and the patient feels ready. If the discomfort does not pass, the irrigation should be stopped and the patient's usual bowel care routine followed to achieve emptying.

Water should be lukewarm (96 to 100°F). If the water is too hot it may damage the mucous membranes lining the bowel and if it is too cold it may trigger reflexes and increase spasms. Plain tap water is recommended or bottled water when travelling in countries where drinking tap water is not recommended.

Frequency of irrigation
For patients who are new to Peristeen Anal Irrigation, it is recommended to irrigate on a daily basis. After one or two weeks some patients find that irrigation can be tried every second day. As the frequency of irrigation is decreased, it may be necessary to adjust other parameters; for example, the volume of water may need to be increased to achieve complete emptying. Some patients will find it necessary to irrigate every day but eventually most patients settle into a routine of irrigation every other day. Conducting irrigation at approximately the same time each day seems to work best for most people, but is not essential. Eating and drinking stimulate the bowel, so about 30 minutes after a meal gives the best chance of the irrigation working with the natural activity of the bowel and achieving the best emptying. The most convenient time can be chosen by the patient to fit in with their daily routine. Alternatively, it can be varied to fit around a changing routine giving the patient the maximum possible freedom.

The system and the rectal catheters should be stored at room temperature (maximum 77°F) and out of direct sunlight. When storing the system, ensure that you turn the knob on the control unit to the Finish symbol  . Also ensure that the tubes are not kinked and that the system is kept away from sharp objects.

The tubes can be cleaned by turning the knob on the control unit to the water symbol and pumping the dirty water out of the tube. Patients may choose to change the tube with the blue connectors more frequently if desired. The outer surface of all the components (excluding the single use catheter) can be washed in mild soapy water and rinsed thoroughly. The Control Unit knob should be in the Finish position when the Peristeen System is not in use.

Product Evaluation:

Coloplast requests physicians to notify the company of any complications which may develop with the use of this device, and requests return of any used devices or components associated with the complication. For safe handling during shipment and upon receipt, Coloplast requests that devices be decontaminated prior to shipment. This is requested even though Coloplast will autoclave-sterilize any opened product returned. Alteration for the purposes of venting to prevent additional damage will be performed as required. If necessary, Coloplast may analyze the device, and the patient and physician may be asked to allow Coloplast to perform tests that might alter the condition of the device.

Any complications from the use of this device should be brought to our immediate attention by contacting: Quality Assurance, Product Evaluations Department, Coloplast Corp.,1601 West River Road North, Minneapolis, MN 55411
Toll-free telephone (800) 338-7908 in USA; or outside USA: (612) 337-7800

Product Order Information

To order, please contact your local sales representative or Coloplast Customer Service Department at: Coloplast, 1601 West River Road North, Minneapolis, MN 55411; Toll-free telephone: (800) 258-3476; or outside USA: (612) 337-7800; or fax (866) 216-4161 or outside USA: (612) 337-7803.

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Final report

Monaco Anal Irrigation catheter prototype

In vitro cytotoxicity assay
(Elution/XTT assay USP31/ISO 10993-5)

Study Number: TR-0306

Date: 25-05-2011

Author: Peter Ifversen

> CONTENTS

1. Summary

The present study was performed at Coloplast A/S, Holtedam 3, DK-3050 Humlebaek, Denmark.

The Monaco anal irrigation catheter prototype was tested for in vitro cytotoxicity in cultured mammalian cells (L-929 mouse fibroblasts). The test was performed in accordance with the US Pharmacopeia 31th edition and the ISO 10993-5 Elution Test guideline, using the XTT assay to measure the viability.

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2. Signature and Verification

Study Director:	Peter Ifversen, MSc, PhD Head of Cell Biology Coloplast A/S Global R&D, Technology Holtedam 3 DK-3050 Humlebaek Denmark E-mail: dkpi@coloplast.com
Sponsor:	Christine Skak Sr. BioSafety Specialist Coloplast A/S DK-3050 Humlebaek Denmark
Author:	Peter Ifversen,
Test facility:	Coloplast A/S Holtedam 3 DK-3050 Humlebaek Denmark
Protocol Number:	11-063
Experimental start date:	16.05.2011
Experimental end date:	17.05.2011
Draft report:	17.05.2011
Final report:	25.05.2011

Study Director:

Peter Ifversen, MSc, PhD

3. Purpose

The purpose of the present study is to evaluate potential cytotoxic leachables from anal irrigation catheter prototype coated with the hydrophilic EasyCath coating.

4. References

United States Pharmacopeia 31 and National Formulary 26, 2008. <87> Biological Reactivity Tests In Vitro. United States Pharmacopeial Convention, Inc., Rockville, MD.

DS/EN ISO 10993-1: 2009-11-05. Biological evaluation of medical devices – Part 1: Evaluation and testing. Dansk Standard/Comité Européen De Normalisation.

DS/EN ISO 10993-5: 2009-07-14. Biological evaluation of medical devices – Part 5: Test for in vitro cytotoxicity. Dansk Standard/Comité Européen De Normalisation.

ISO 10993-12: 2009-06-15. Biological evaluation of medical devices – Part 12: Sample preparation and reference materials. ISO.

5. Methods and Materials

5.1. Test article

Material:	(b) (4)
Supplier:	Coloplast
Batch no:	N/A
Sterilisation:	Non-sterile
Intended use:	Catheter for anal irrigation

5.2. Culture medium

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5.3. Preparation of samples

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5.4. Cells

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5.5. Cytotoxicity assay - XTT

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6. Results

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7. Conclusion

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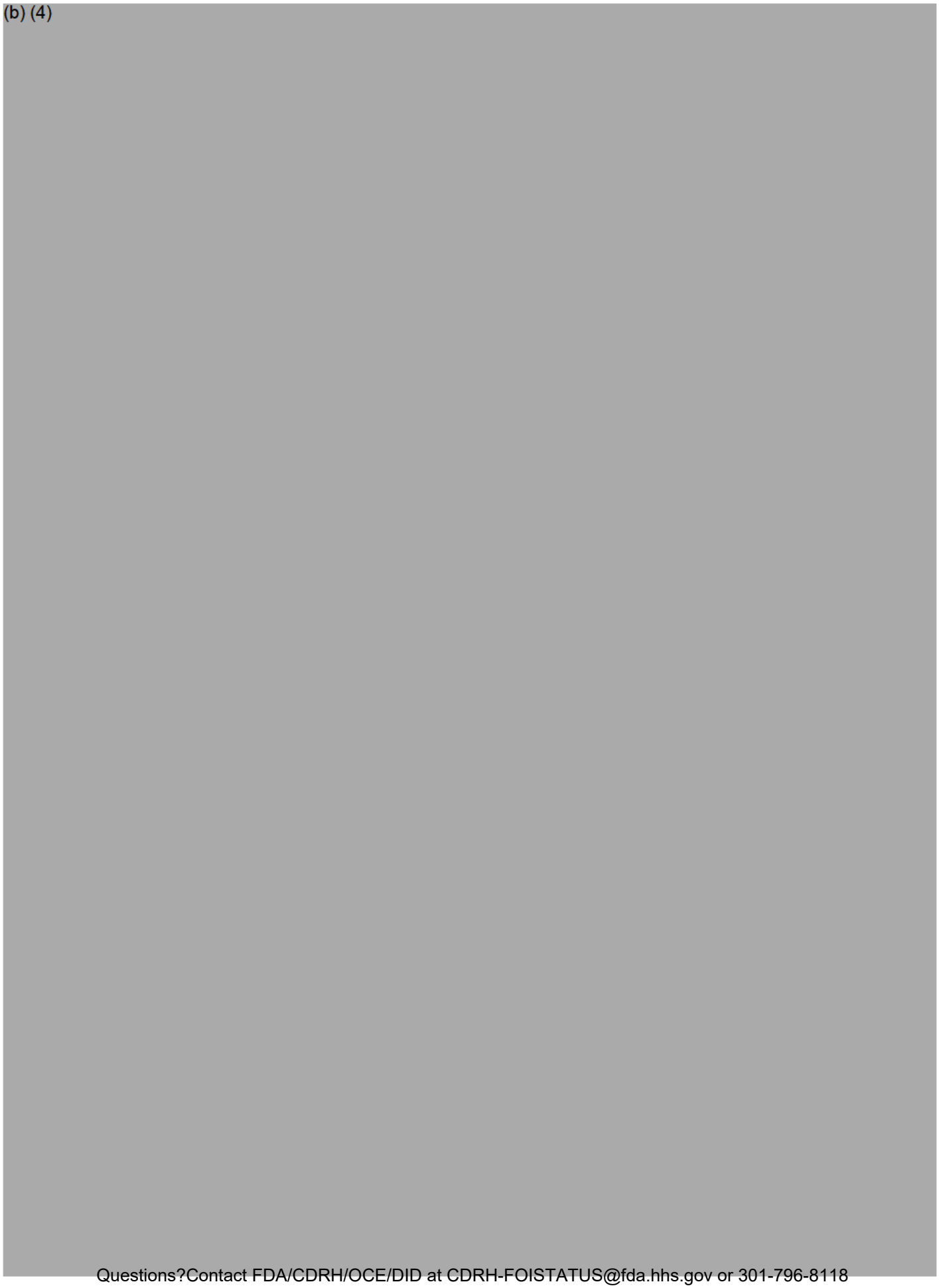

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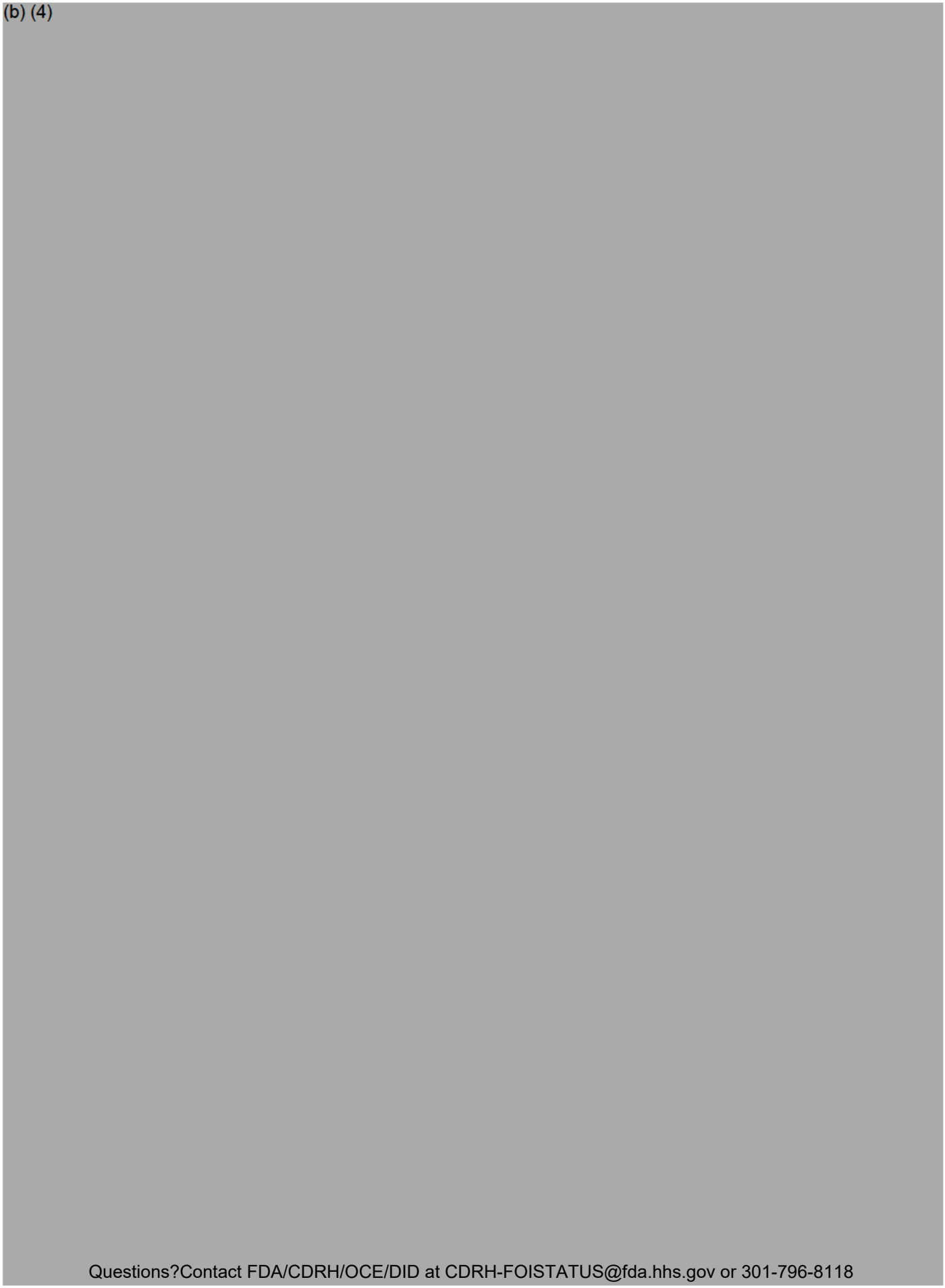

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5 Conclusion

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2011/06/23 11:14:05	(b) (4)
Justification	'Issuer, R&D Principal Scientist'

2011/06/23 14:49:40	Jens Høg Truelsen
Justification	GRD PM

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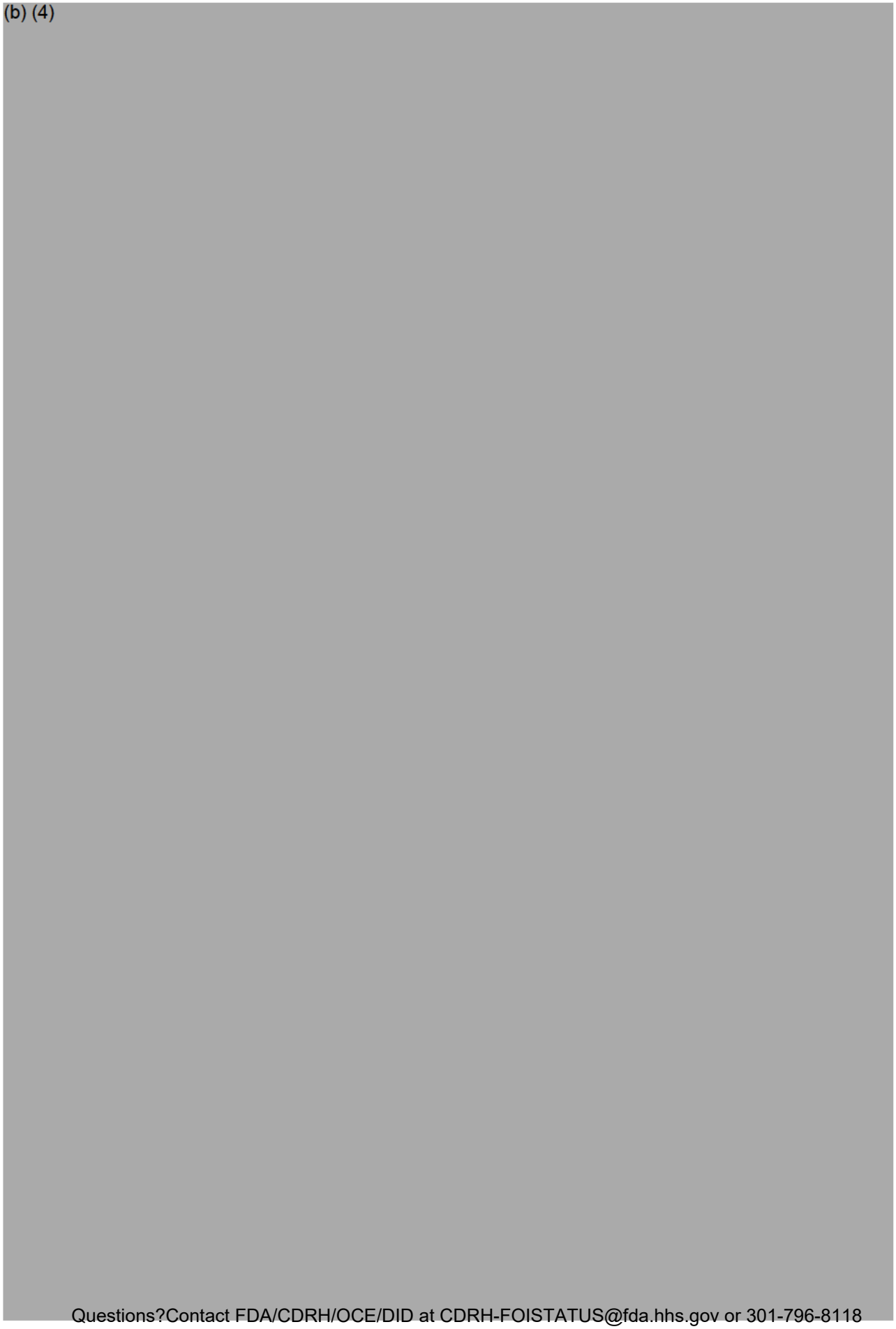

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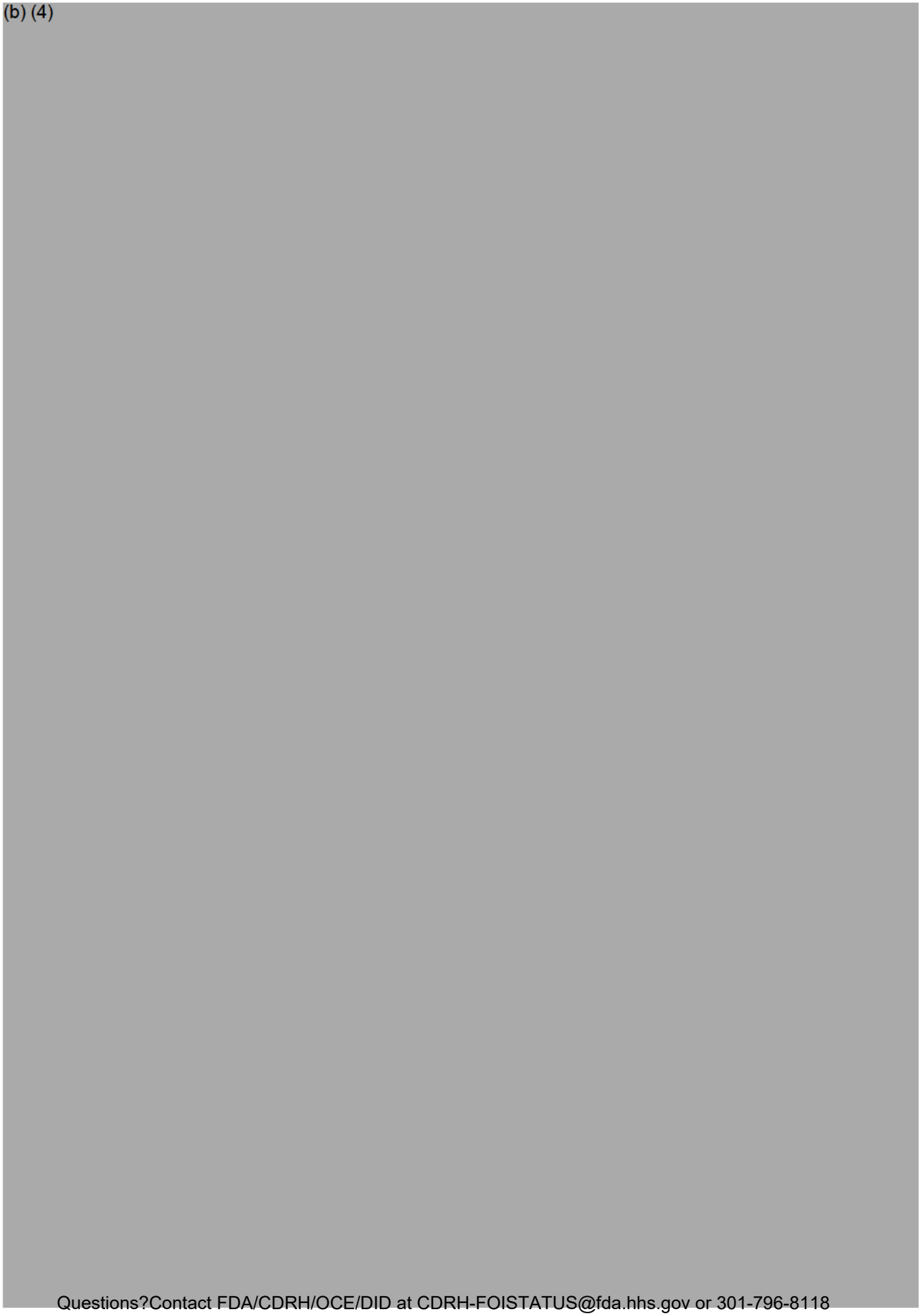

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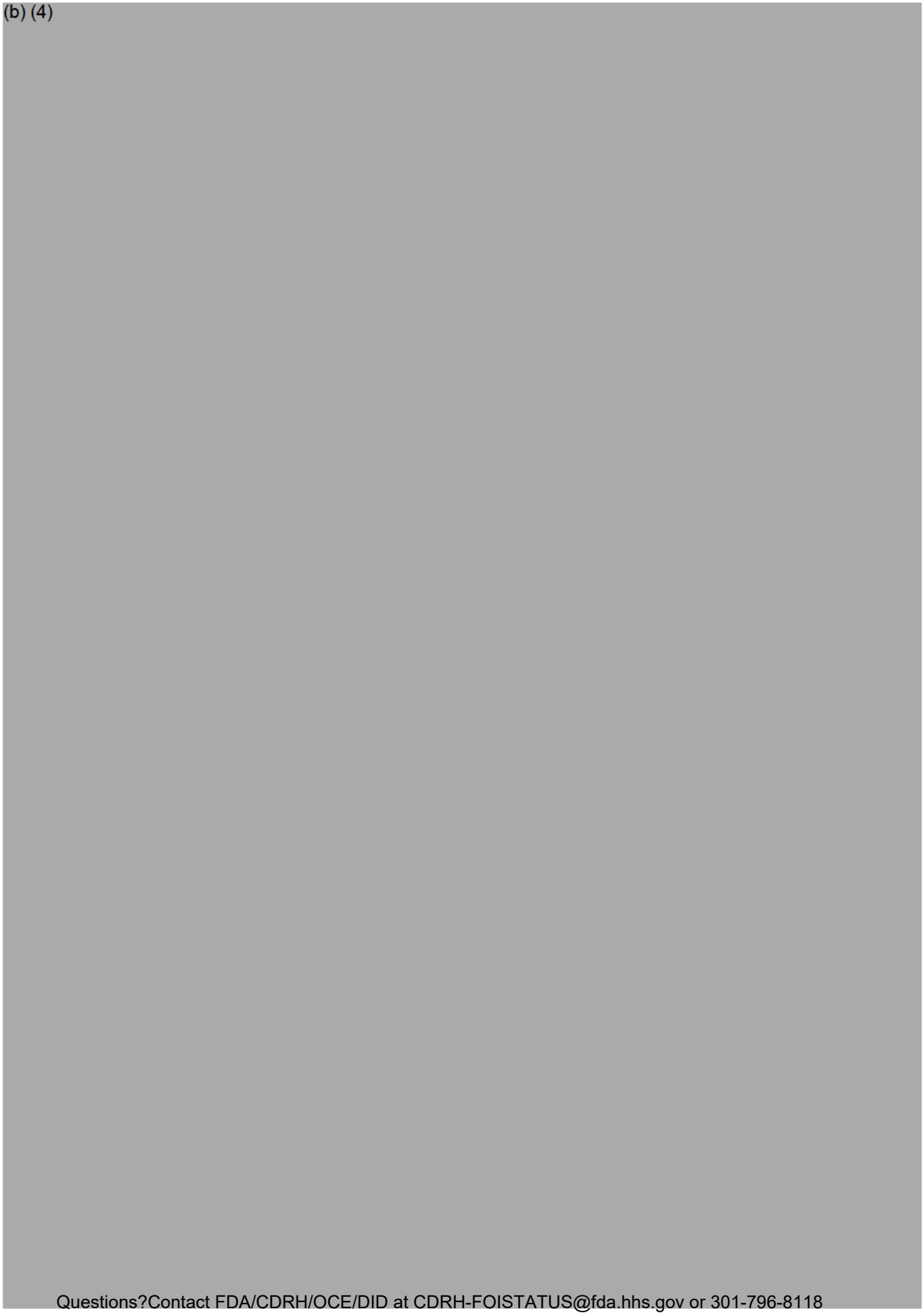

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2011/06/24 14:56:48	Jens Høg Truelsen
Justification	GRD PM

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2011/06/23 14:51:44	Jens Høg Truelsen
Justification	GRD PM

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2011/06/27 18:11:27	Jens Høg Truelsen
Justification	GRD Sr. PM

2011/06/28 10:47:36	Lars Pedersen Broberg
Justification	Document approved

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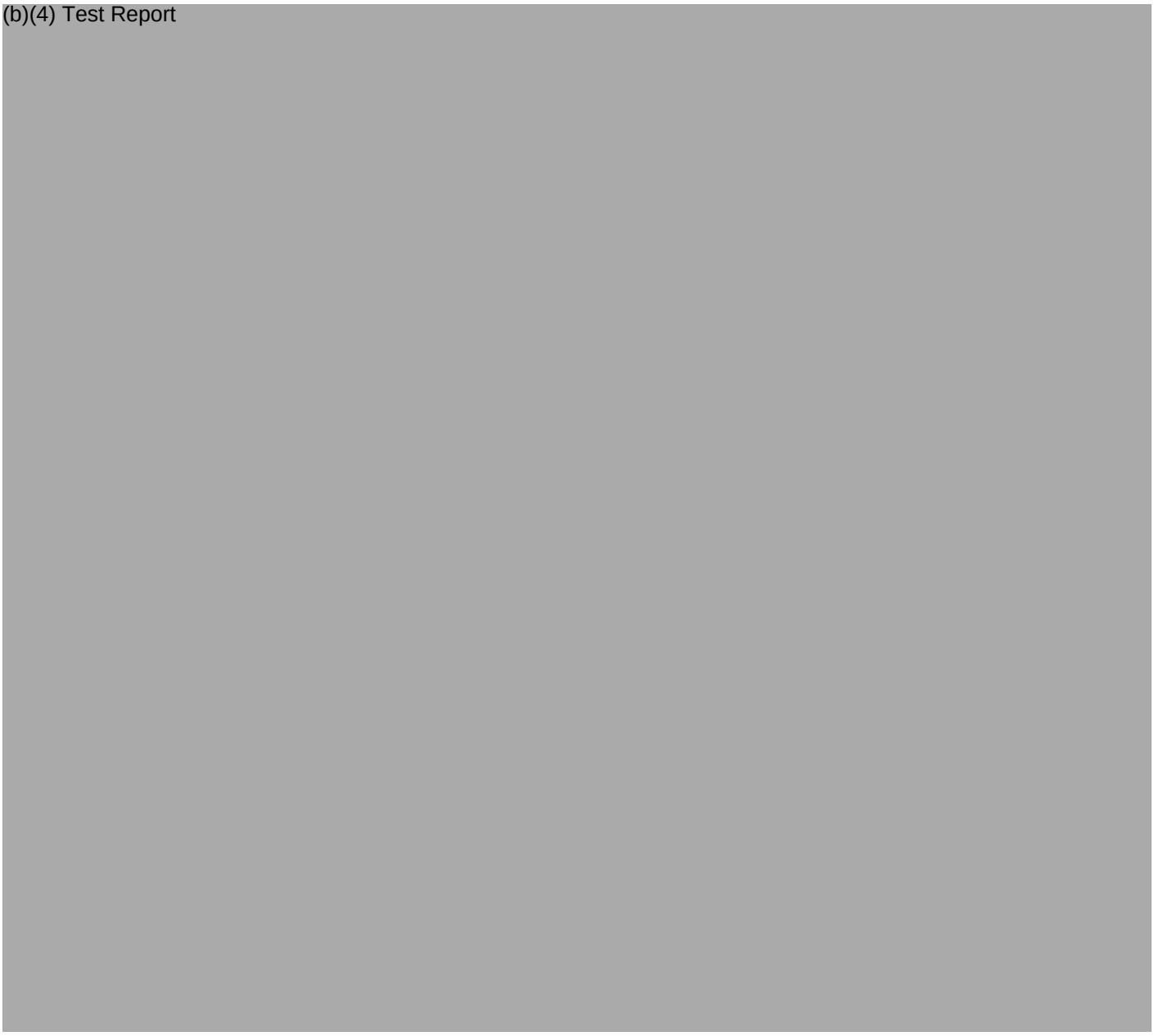

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2011/06/23 14:52:17	Jens Høg Truelsen
Justification	GRD PM

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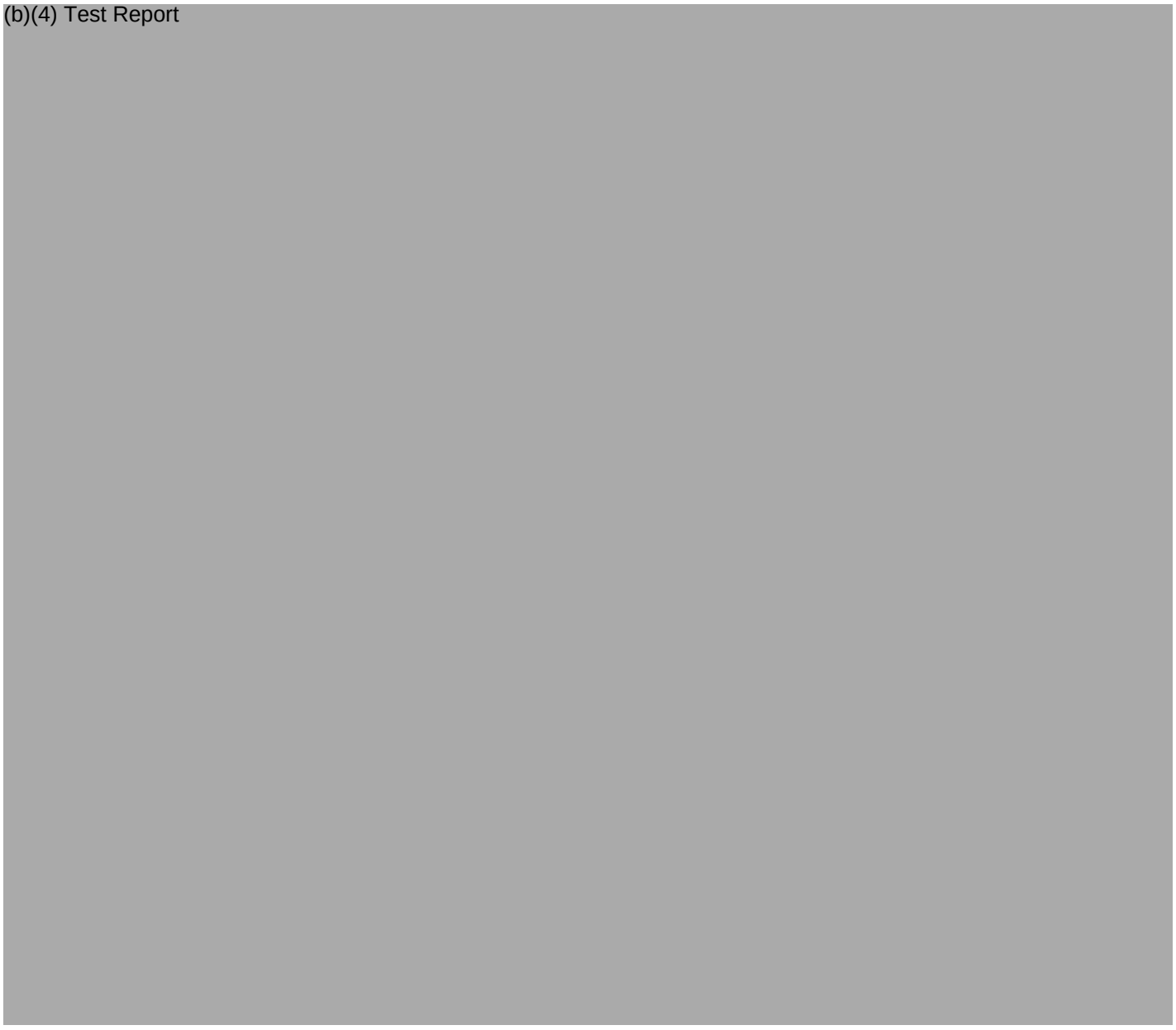

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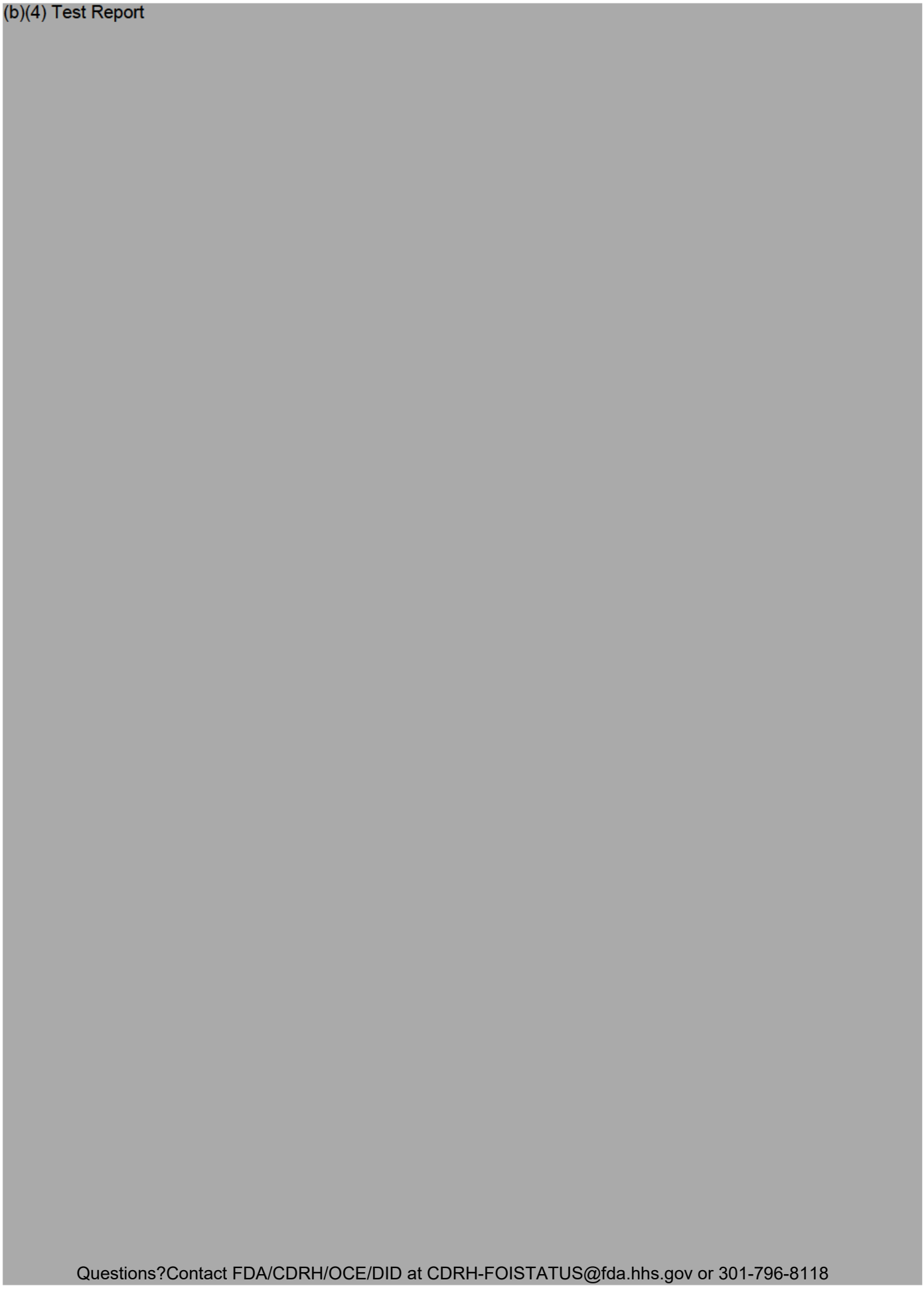

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2011/06/23 14:52:55	Jens Høg Truelsen
Justification	GRD PM

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2011/06/23 14:50:12	Jens Høg Truelsen
Justification	GRD PM

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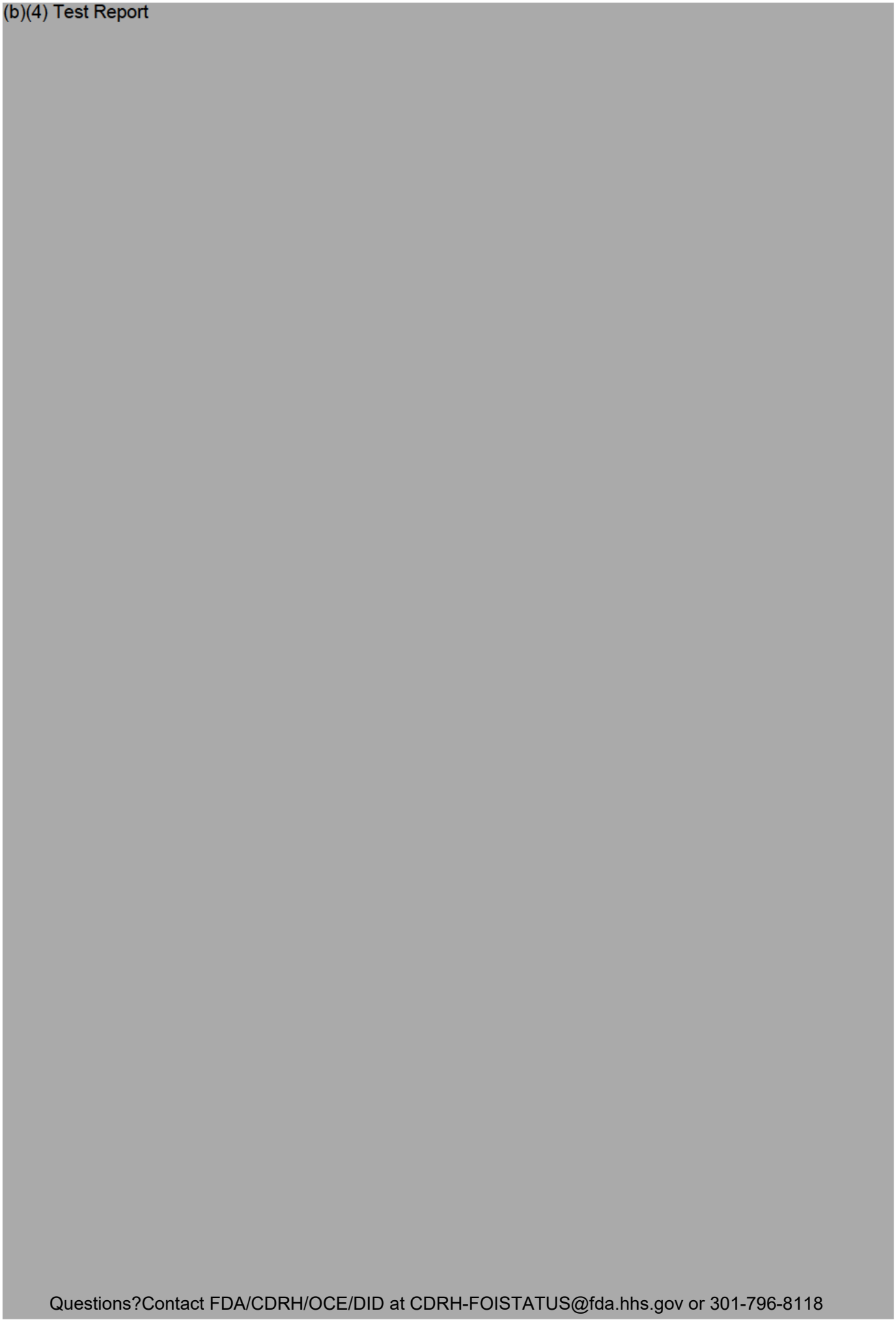

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Justification	'Issuer, R&D Principal Scientist'

2012/01/04 15:34:00	Per Vilstrup-Clausen
Justification	AIM Project Manager

Justification	

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Date (GMT)	Signed by
2012/01/04 15:16:37	(b) (4)
Justification	'Issuer, R&D Principal Scientist'

2012/01/04 15:20:45	Pia Oelgaard
Justification	QA Project Manager

2012/01/04 15:26:12	Per Vilstrup-Clausen
Justification	AIM Project Manager

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1 510(k) Summary

510(k) Owner/SUBMITTER	Coloplast A/S Holtedam 1 3050 Humlebaek - Denmark
CONTACT PERSON	Brian Schmidt Coloplast Corp 1601 West River Road North Minneapolis, Minnesota 55411 USA Telephone: 612-302-4987
DATE PREPARED	29 September 2011
CLASSIFICATION	Gastrointestinal tube & accessories 876.5980 Class II Enema kit 876.5210 Class I (Exempt)
COMMON NAME	Rectal Catheter and Accessories; Enema Kit
PROPRIETARY NAME	Peristeen™ Anal Irrigation System
PREDICATE DEVICE	K083770, K103254
DEVICE DESCRIPTION	The Peristeen™ Anal Irrigation System is a Class II device, consisting of a single-use irrigation catheter with a balloon for retention; a control unit with a manual switch that allows for addition of pressure to the water bag, and inflation and deflation of the balloon on the catheter; a bag with a lid to hold water, leg straps that may be used to fasten the control unit and tubing to the thigh, and tubes with connectors. The system is provided with a nylon storage case. The rectal catheter is single-use, but the other components may be used multiple times.
INDICATIONS	The Peristeen™ Anal Irrigation System is intended to instill water into the colon through a rectal catheter-which incorporates an inflatable balloon-inserted into the rectum to promote evacuation of the contents of the lower colon. The Peristeen™ Anal Irrigation System is indicated for use by children (2 years - <12 years old), adolescent (12 years - < 18 years old), transitional adolescent (18 - <21 years old) and adult patients with neurogenic bowel dysfunction who suffer from fecal incontinence, chronic constipation, and/or time-consuming bowel management procedures. Peristeen™ Anal Irrigation System is a prescriptive device and should only be prescribed by a licensed physician. Peristeen™ Anal Irrigation System has the same indications as the predicate device.

TESTING	The Peristeen rectal catheter has been subjected to biocompatibility and mechanical testing and is substantially equivalent to the predicate Peristeen device (K083770, K103254).
TECHNOLOGICAL CHARACTERISTICS	The Peristeen rectal catheter has the same intended use, general design, and fundamental scientific technology as the predicate Peristeen rectal catheter.
SUMMARY OF THE NONCLINICAL TESTS SUBMITTED	In vitro (bench) tests; flexibility, flow rate, balloon inflation, balloon peak pressure, burst diameter/volume, biocompatibility
SUMMARY OF CLINICAL TESTS SUBMITTED (AS APPLICABLE)	Not applicable
CONCLUSIONS DRAWN FROM THE NONCLINICAL AND CLINICAL TESTS	Substantial equivalence of the Peristeen Rectal Catheter is supported by a comparison of the design and intended use compared to the predicate, as well as acceptable results from functional performance and biocompatibility testing.

G01 DEGUS K112860/32

Coloplast

FDA CDRH DMC
MAY 25 2012
Received K32

May 24, 2012

Dr. Martin Golding
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) - **K112860**; Peristeen™ Anal Irrigation System
Amendment 2

Dear Dr. Golding,

Coloplast A/S hereby submits the additional information to the 510(k) K112860 for the Peristeen™ Anal Irrigation System. This information was requested by FDA in a deficiency letter dated February 16, 2012.

This request is provided in duplicate. Coloplast also provides an electronic version copied to CD-ROM. The electronic copy is an exact duplicate of the paper copy.

Coloplast considers the existence and contents of this submission to be confidential and exempt from public disclosure.

Please contact me for questions or if you need further information.

Best regards,

Brian Schmidt
Regulatory Affairs Manager
Phone: 612.302.4987
Fax: 612.287.4138
Email: usbes@coloplast.com

Coloplast

Ostomy Care
Urology & Continence Care
Wound & Skin Care

May 24, 2012

Dr. Martin Golding
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) – **K112860**; Peristeen™ Anal Irrigation System **Amendment 2**

Dear Dr. Golding,

Coloplast A/S hereby submits the additional information to the 510(k) K112860 for the Peristeen™ Anal Irrigation System. This information was requested by FDA in a deficiency letter dated February 16, 2012.

This request is provided in duplicate. Coloplast also provides an electronic version copied to CD-ROM. The electronic copy is an exact duplicate of the paper copy.

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Please contact me for questions or if you need further information.

Best regards,

Brian Schmidt
Regulatory Affairs Manager
Phone: 612.302.4987
Fax: 612.287.4138
Email: usbes@coloplast.com

Traditional 510(k) – K112860
Peristeen™ Anal Irrigation System
Coloplast's Response to FDA

Coloplast is providing a response to the deficiencies cited in the K112860 letter from FDA. All items have been addressed. Each FDA recommendation is presented in italics; Coloplast responses are provided in normal type bold.

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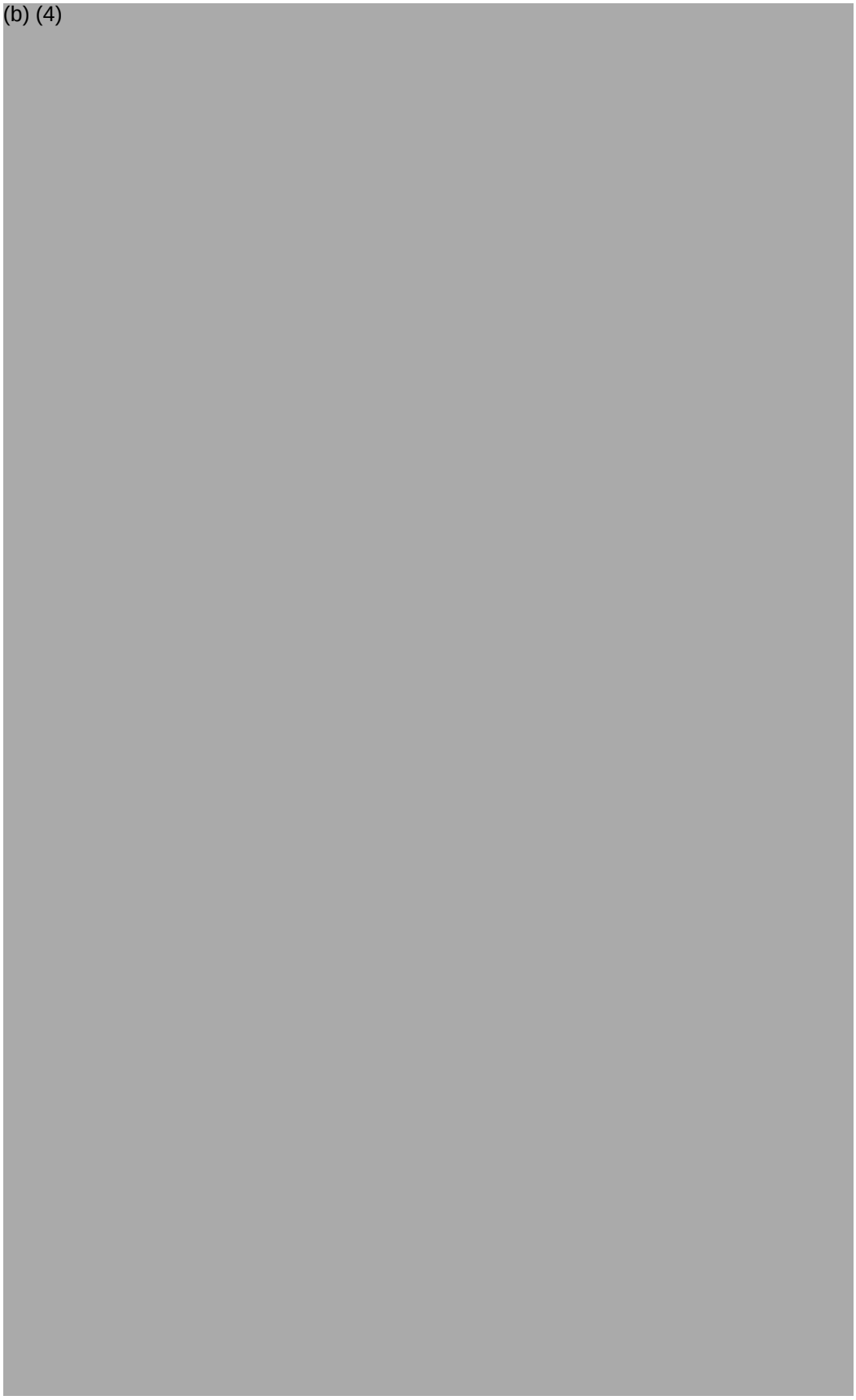

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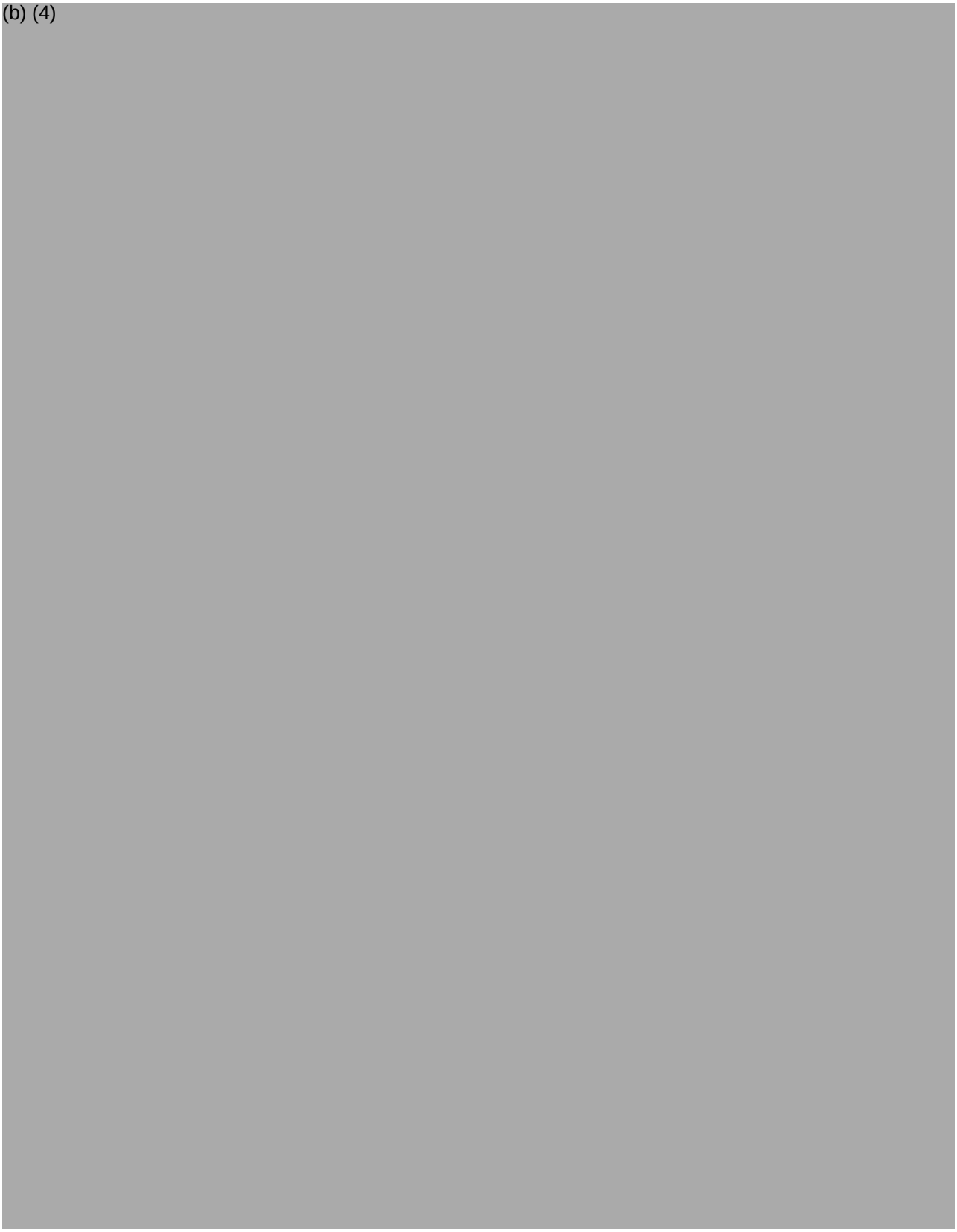

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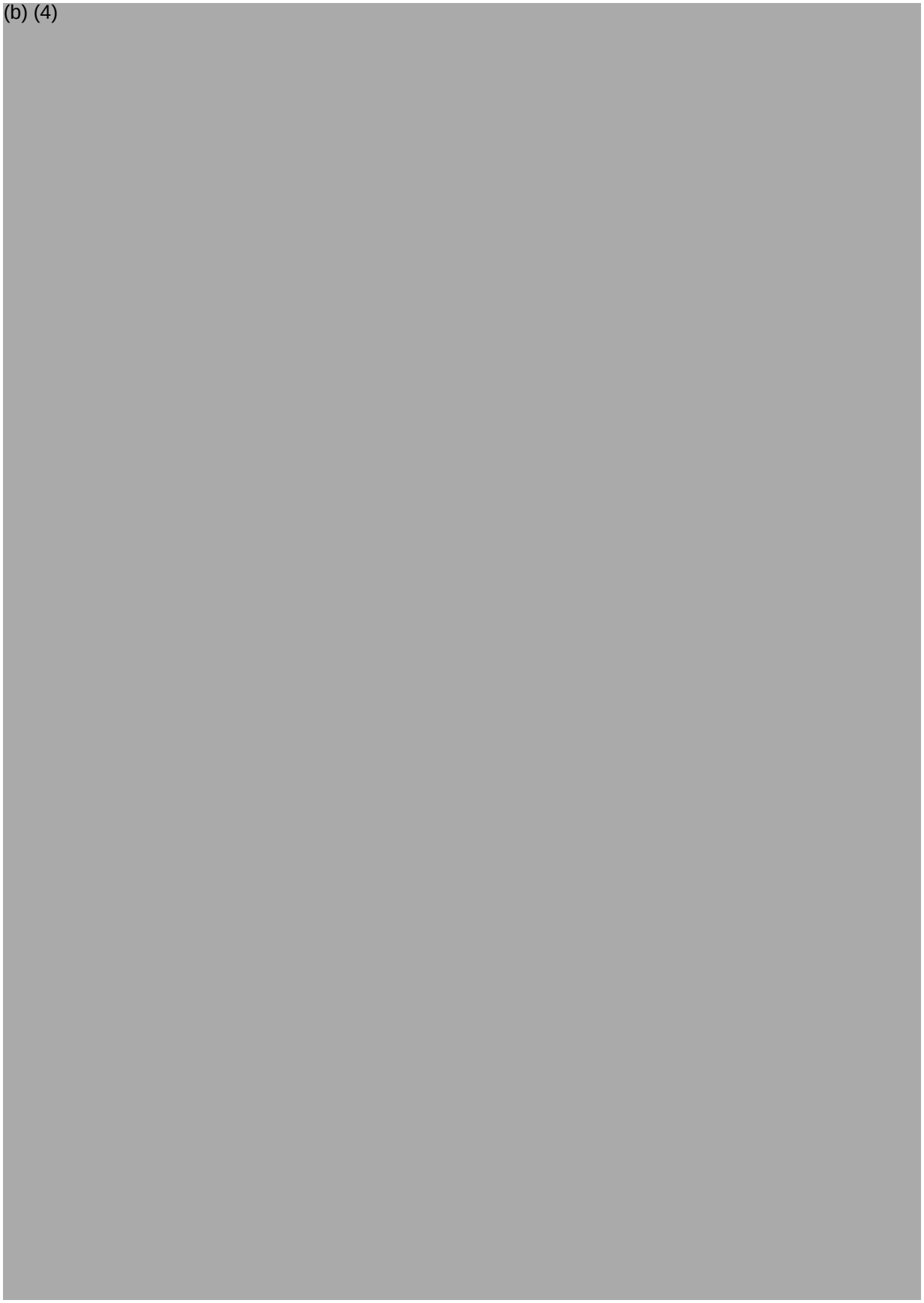

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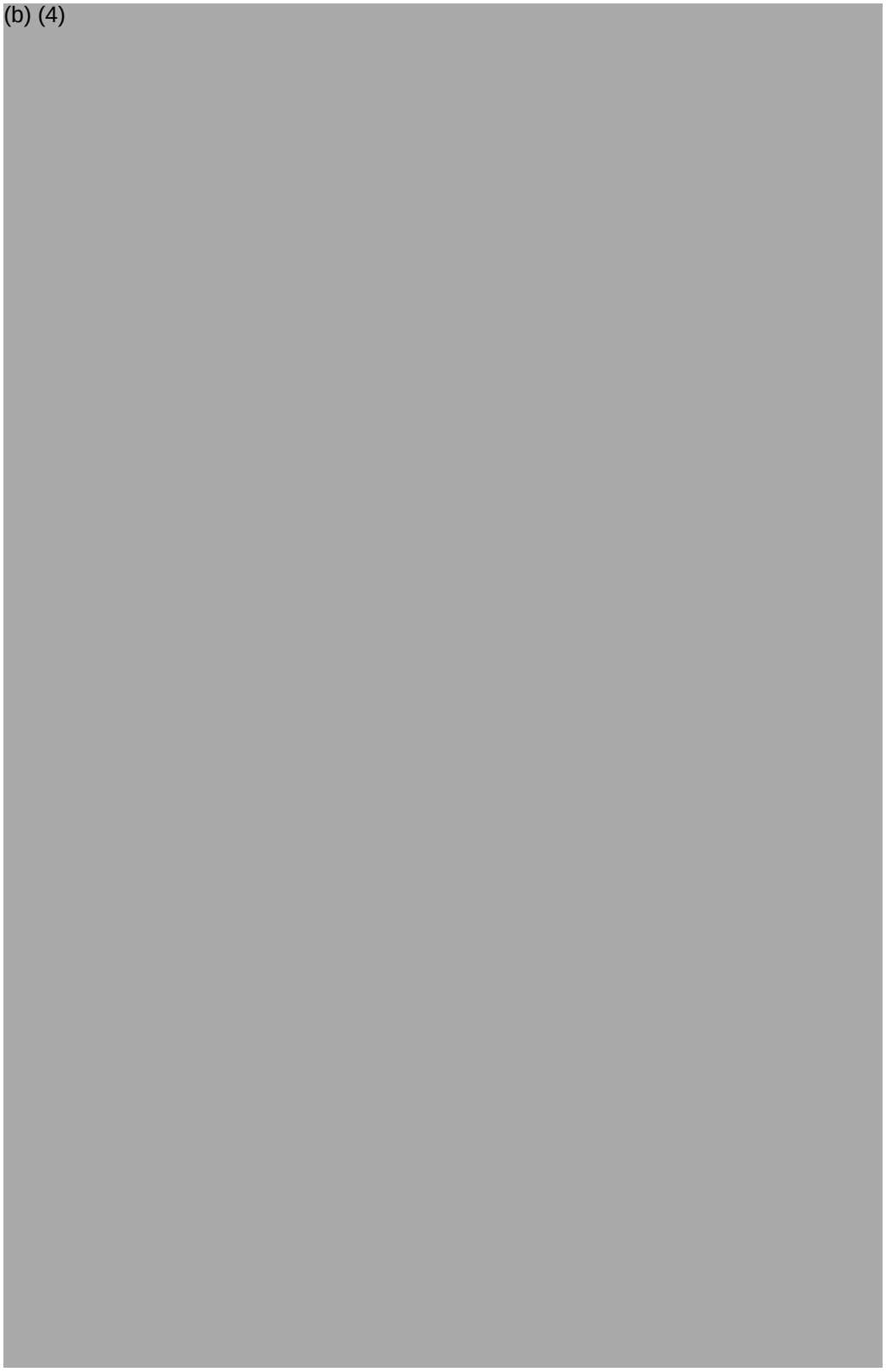

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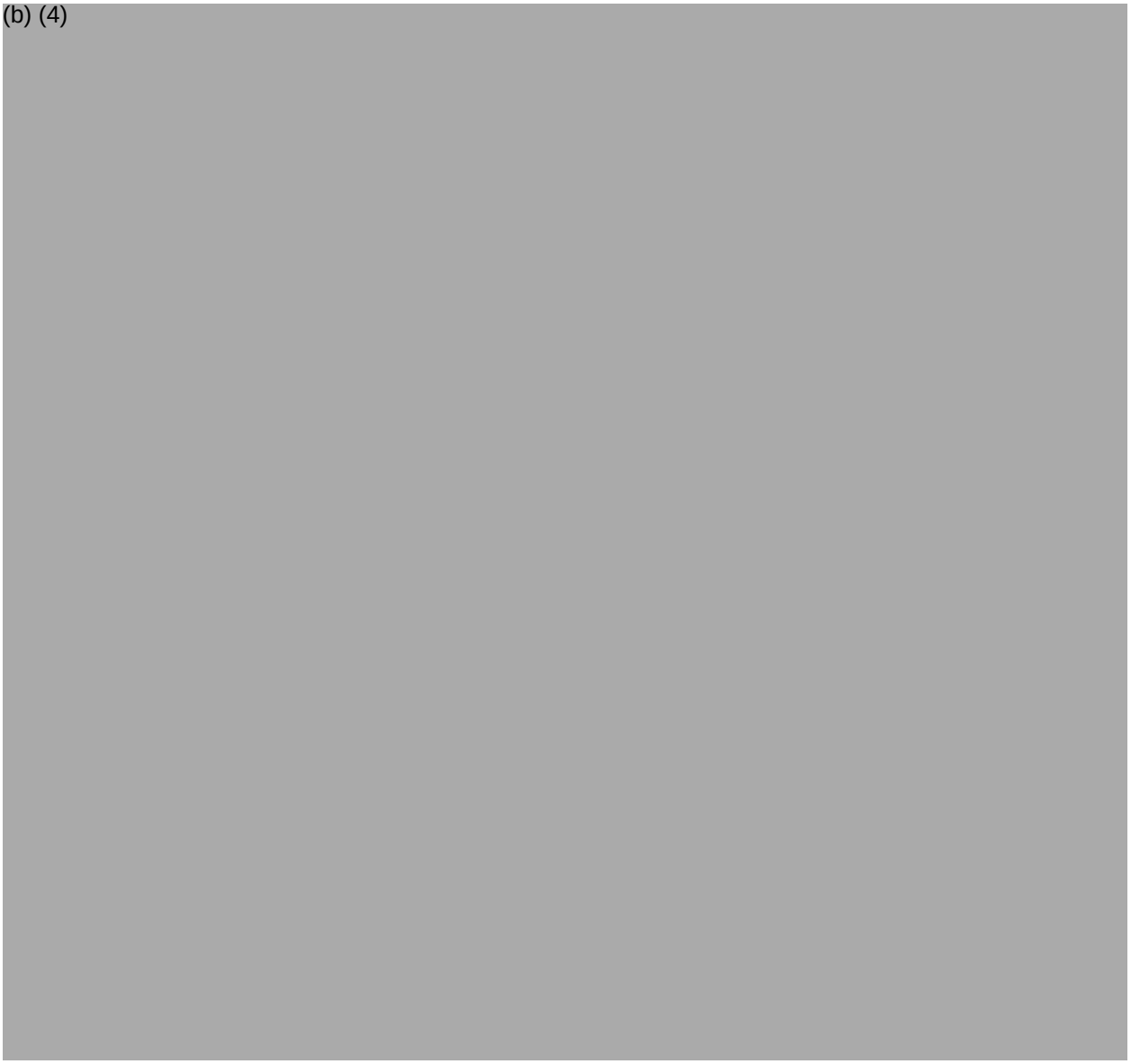

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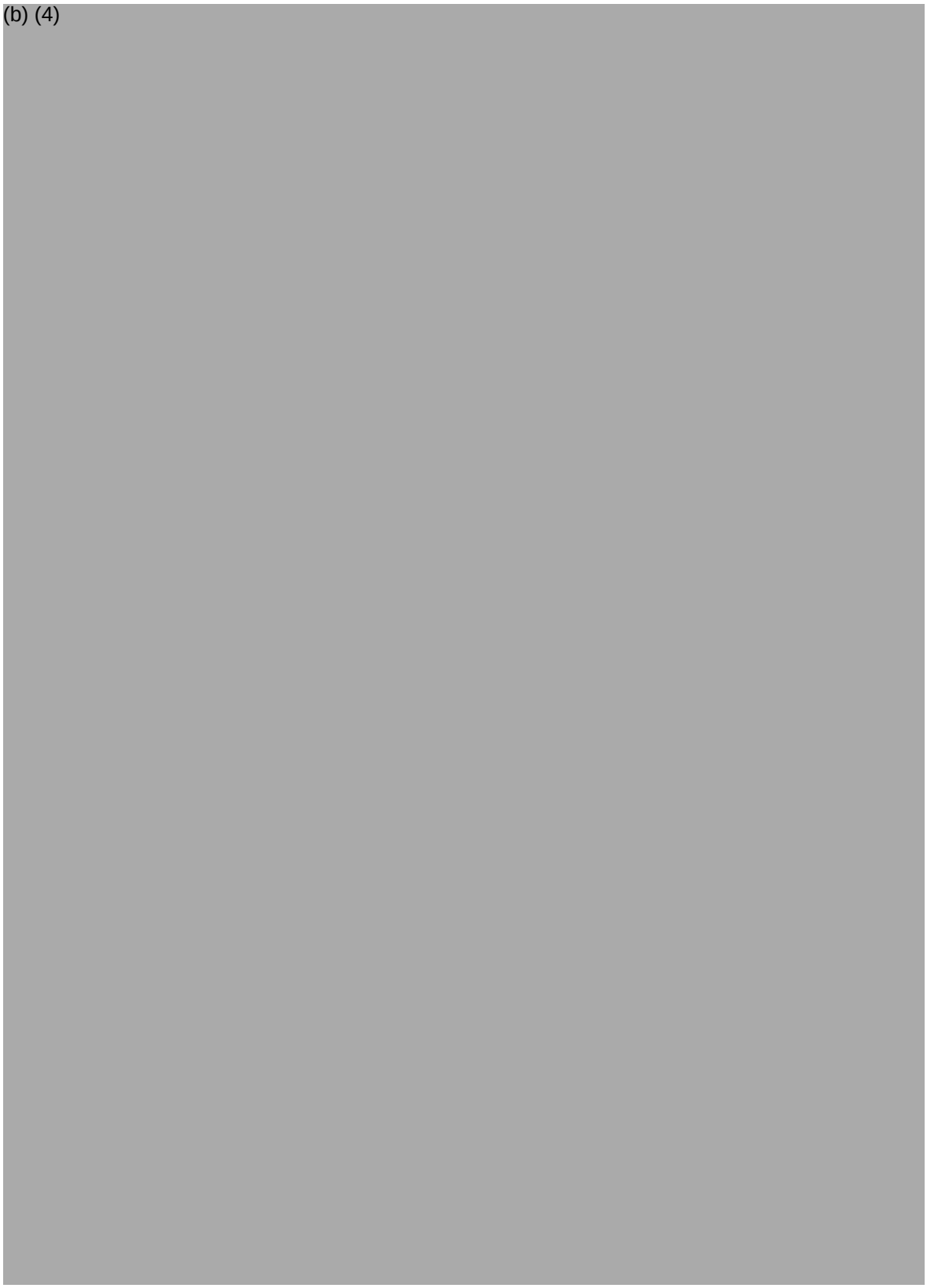

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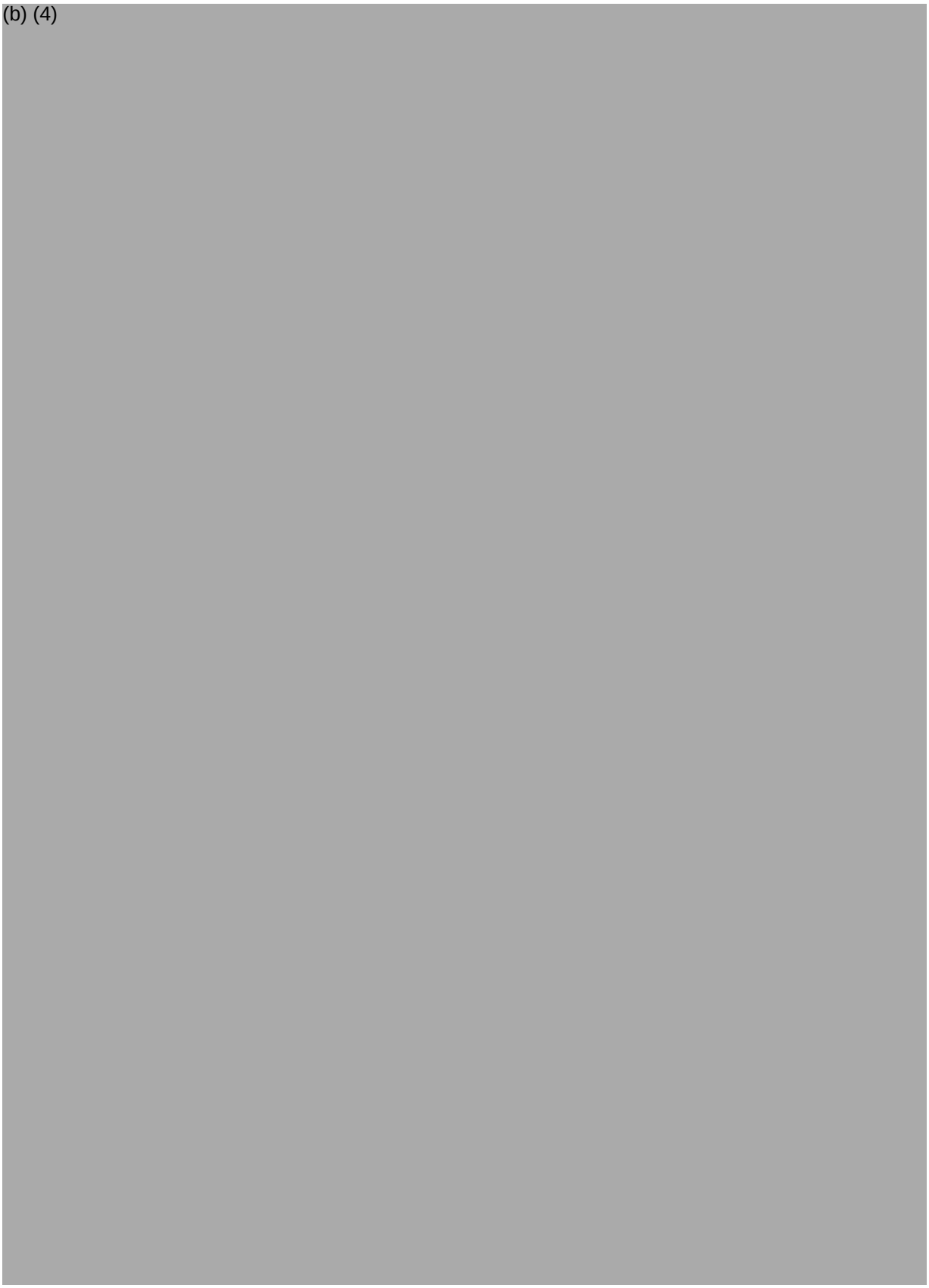

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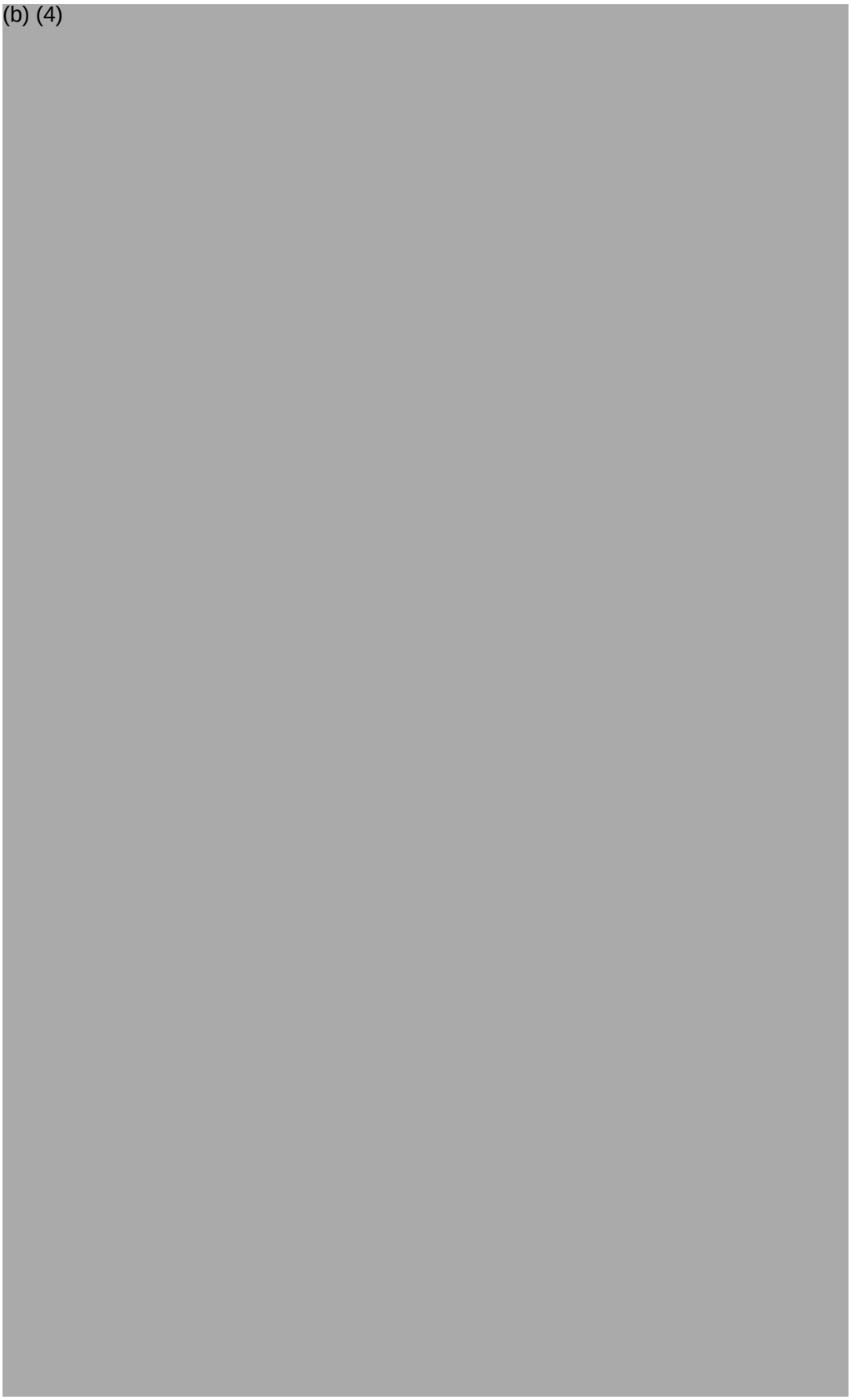

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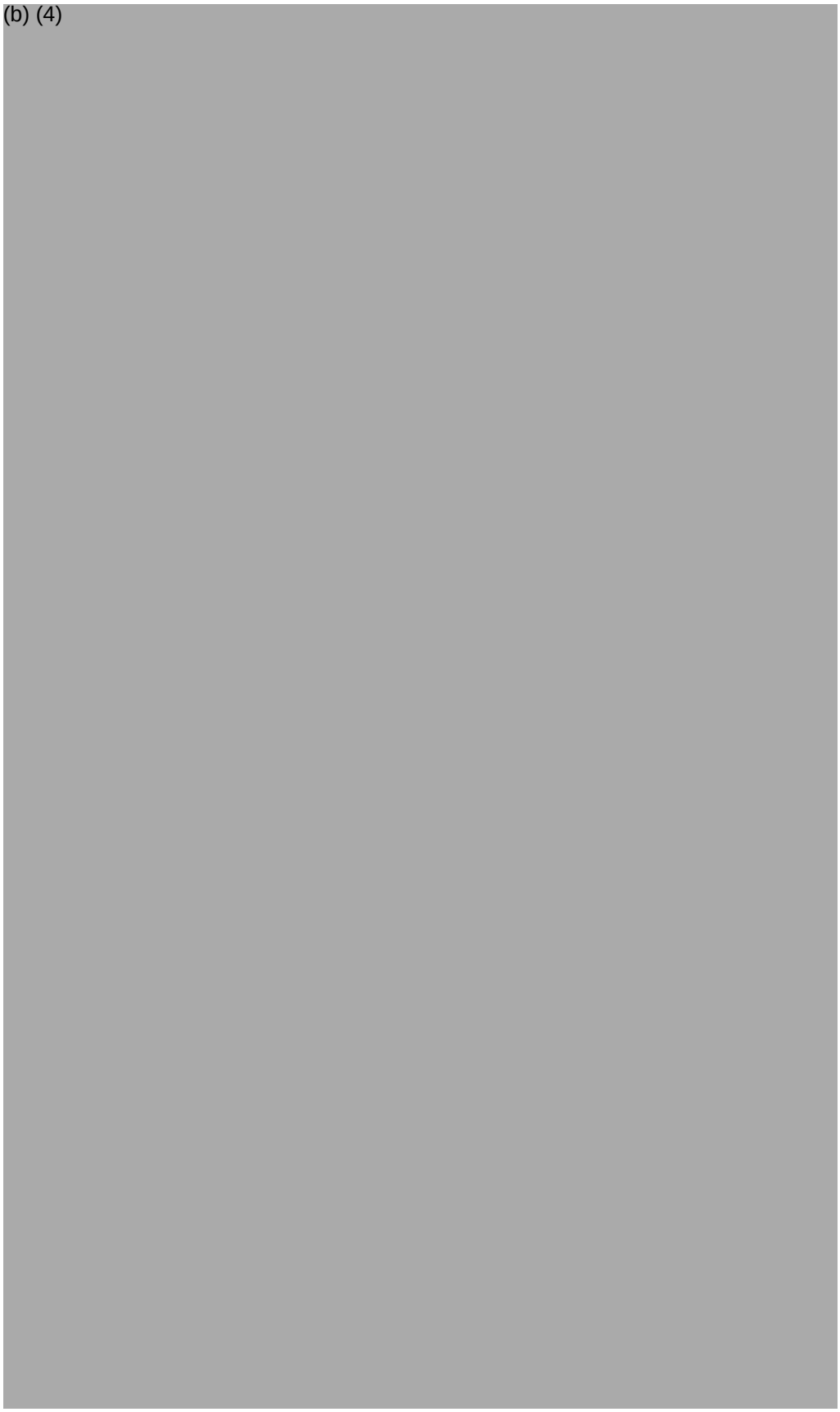

Attachment 1

Attachment 2

Attachment 3

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Attachment 4

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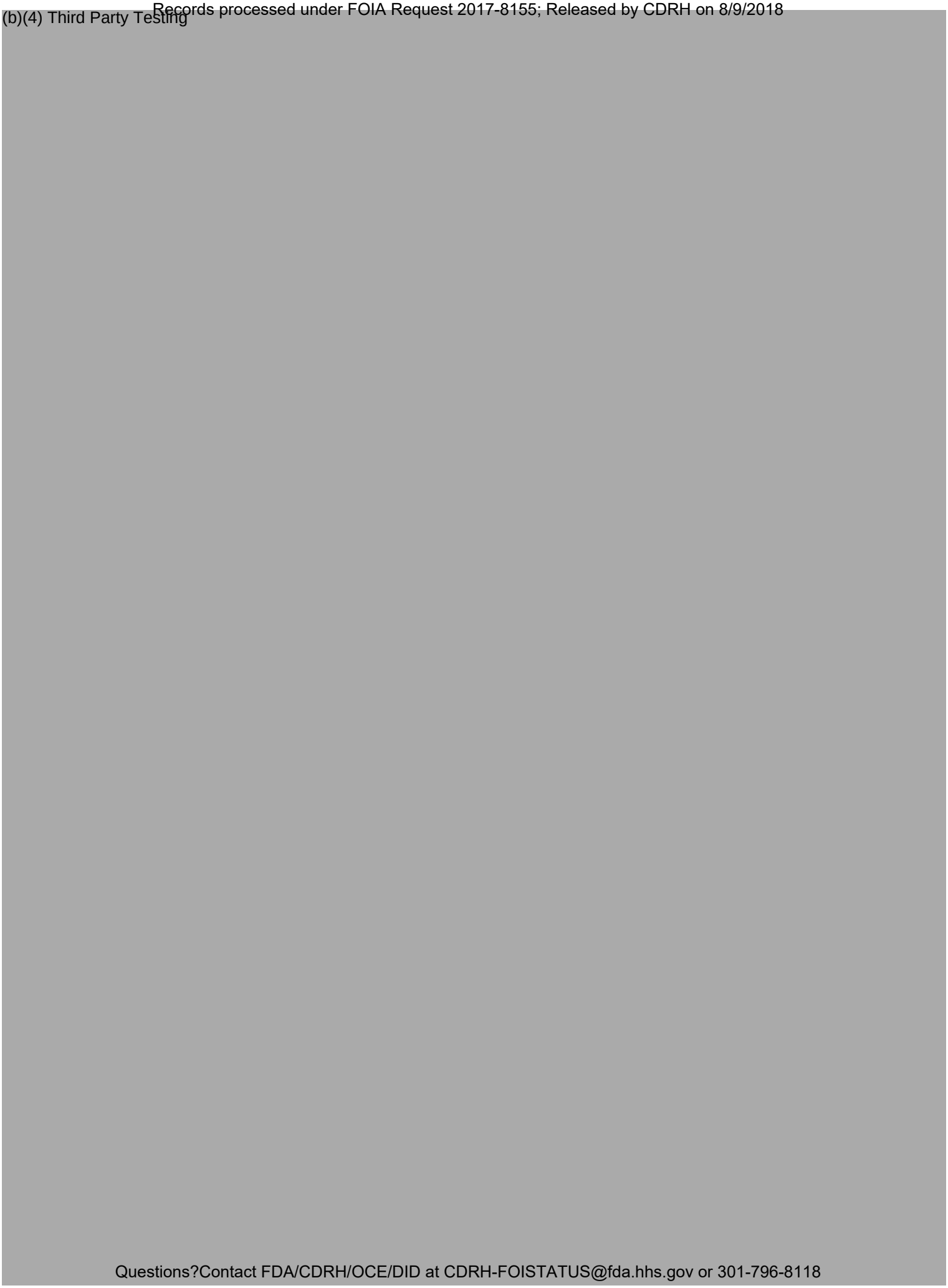

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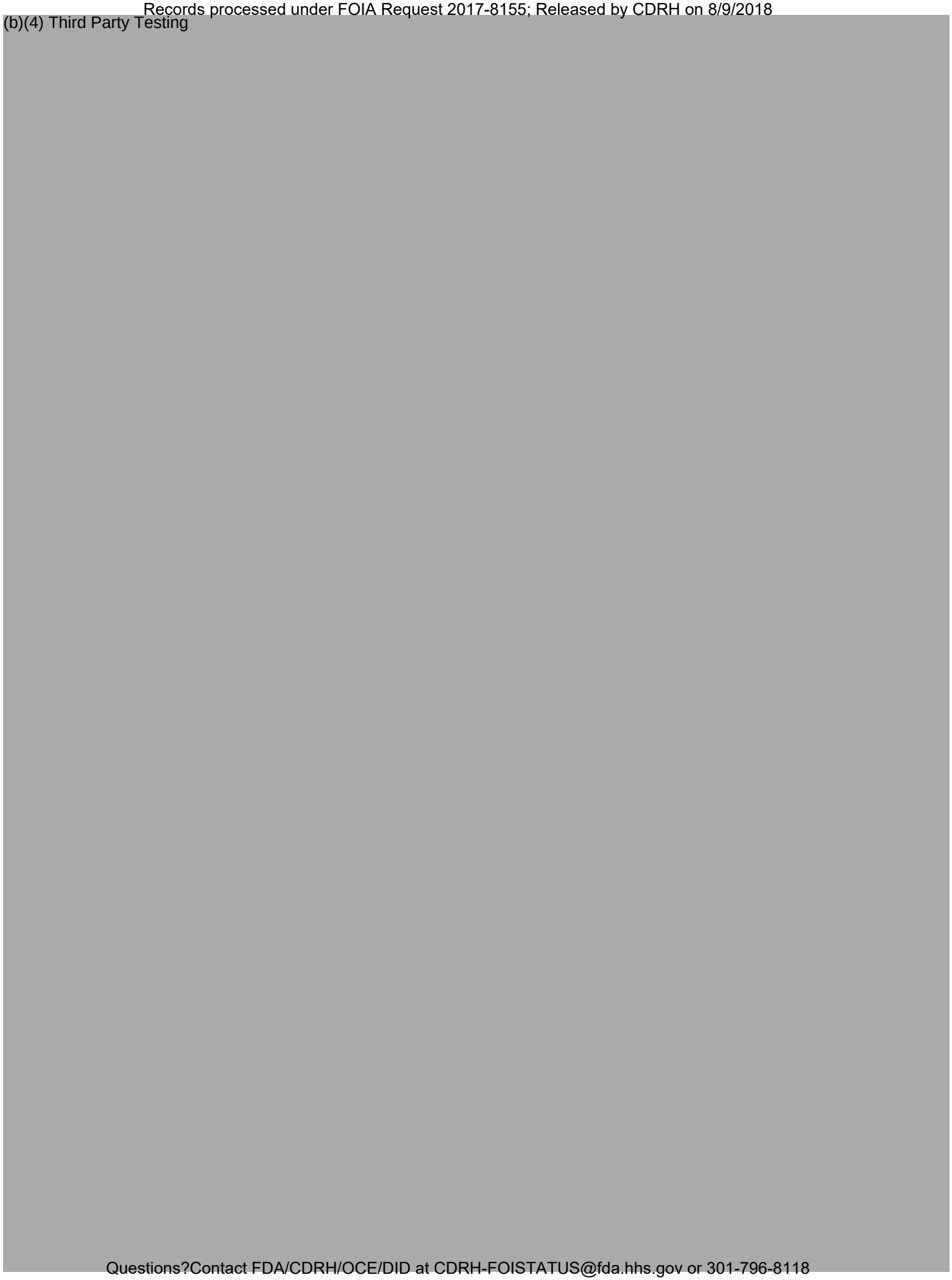

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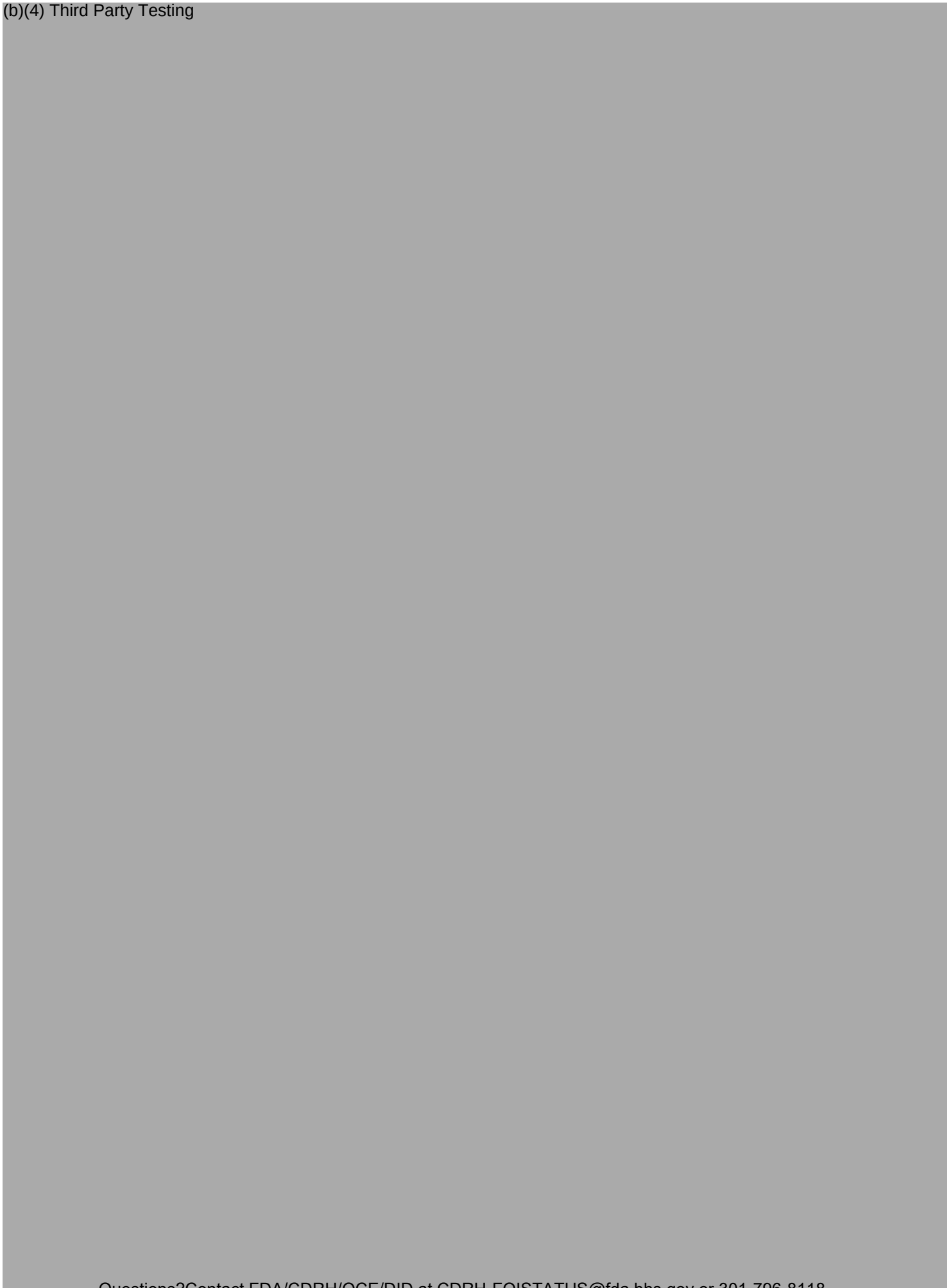

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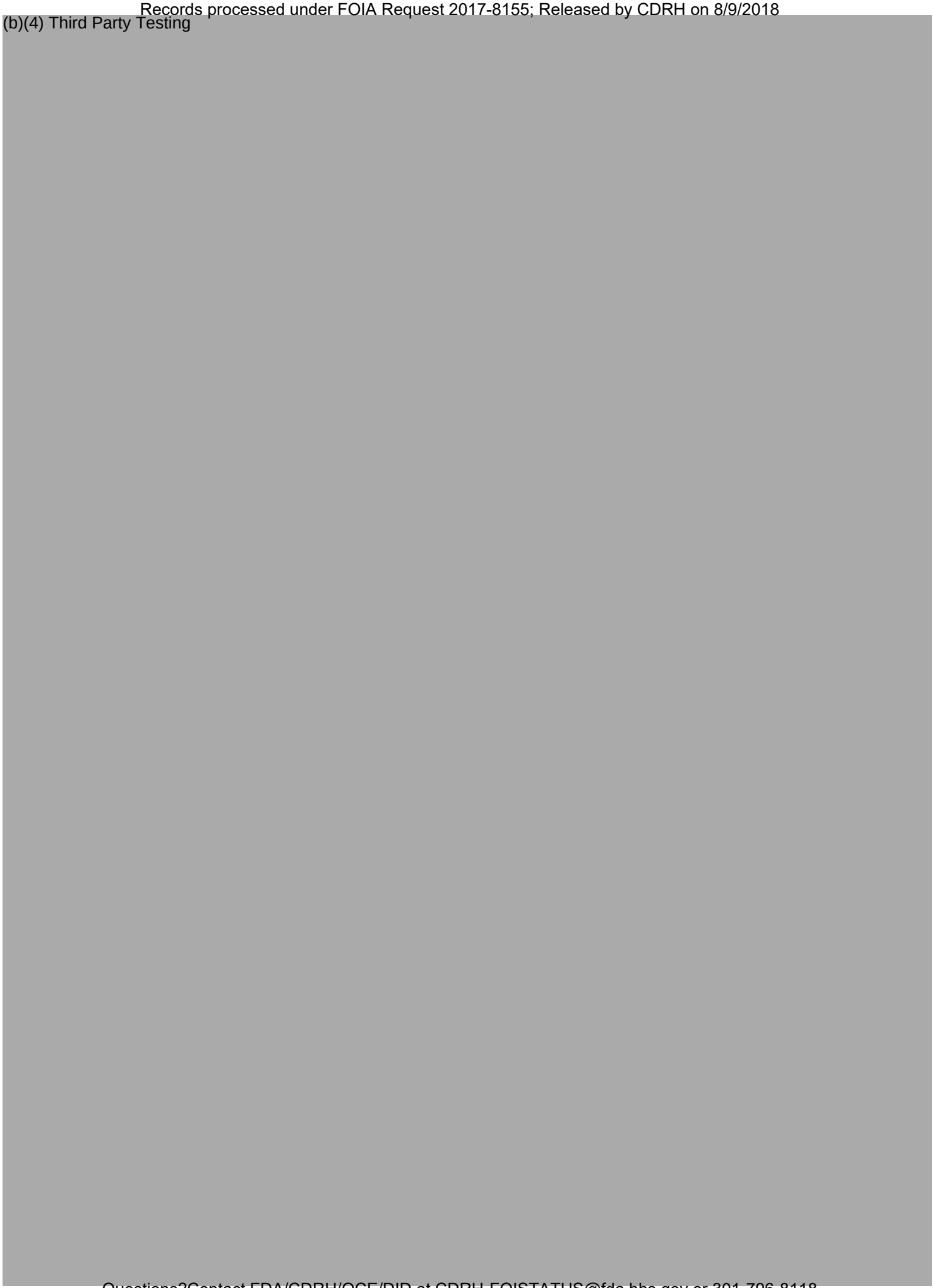

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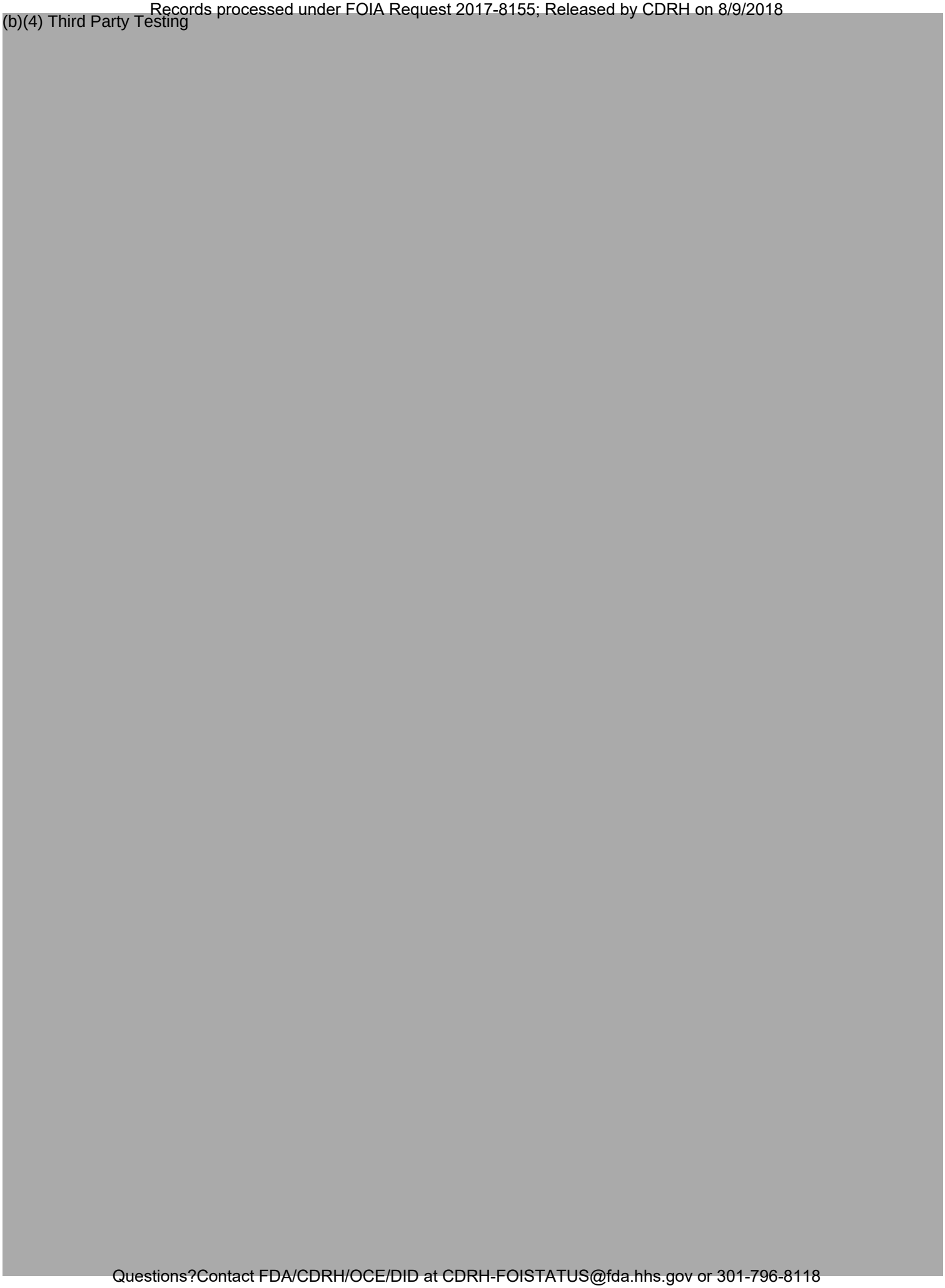

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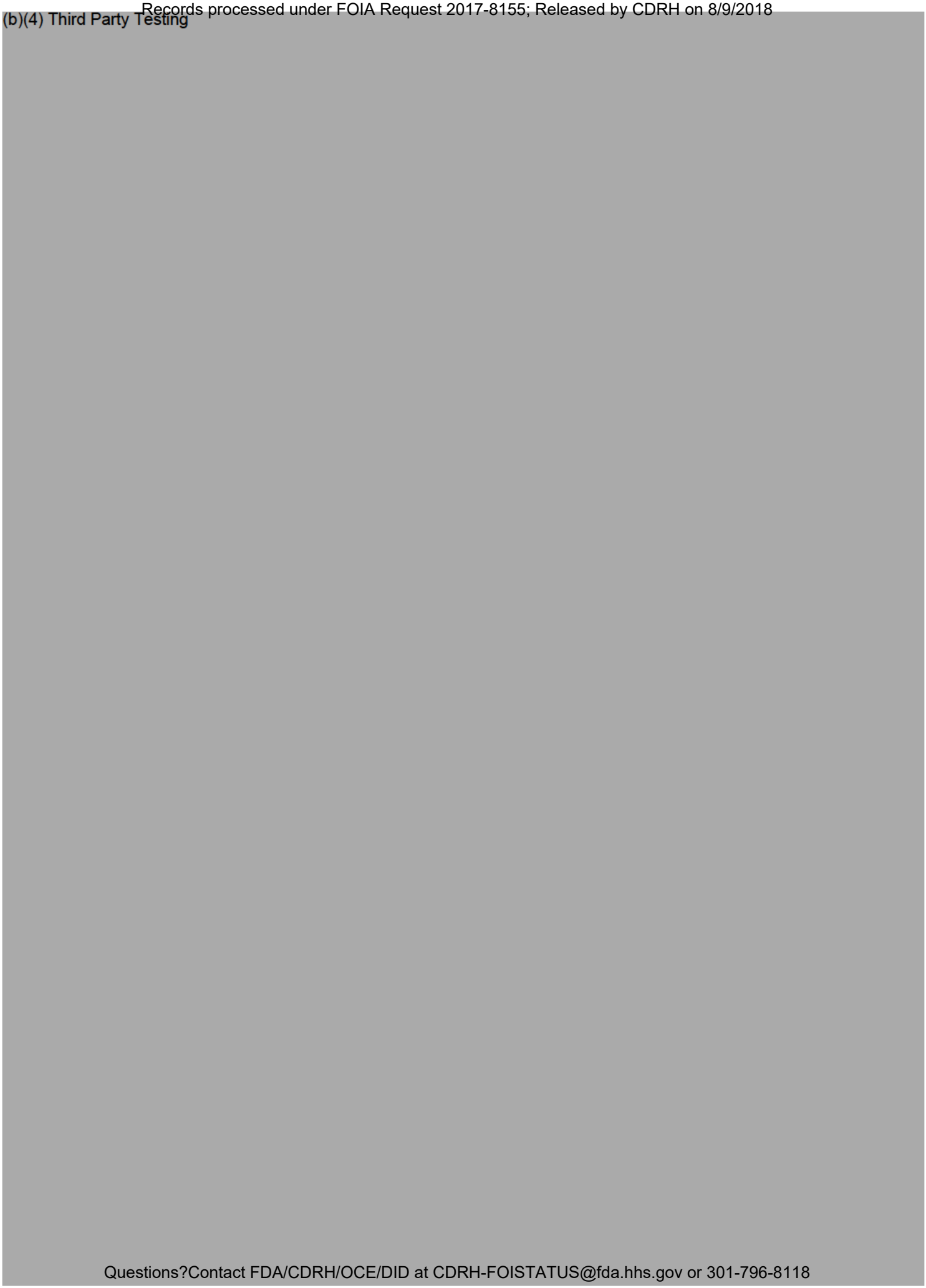

Material Safety Data Sheet

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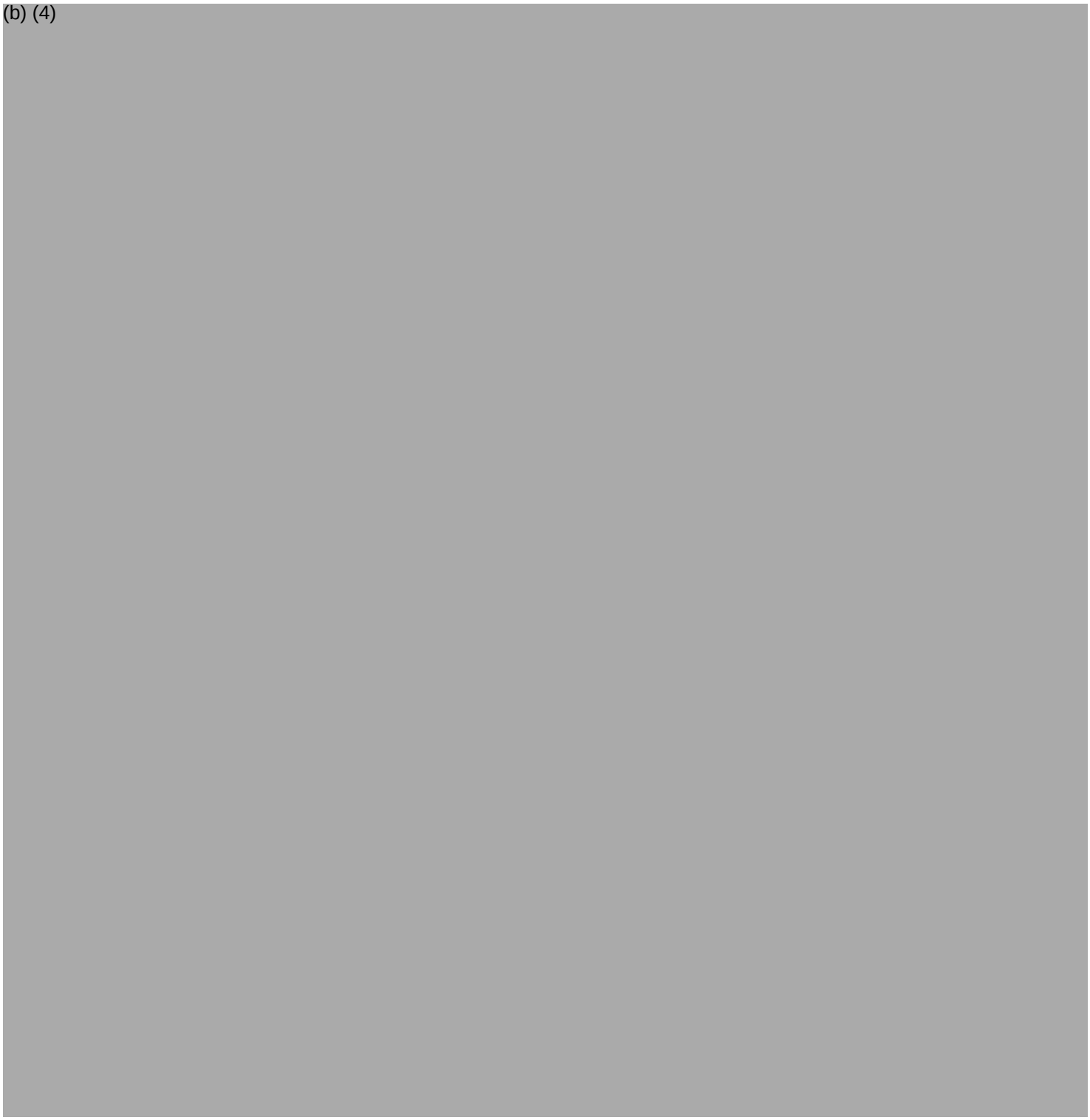

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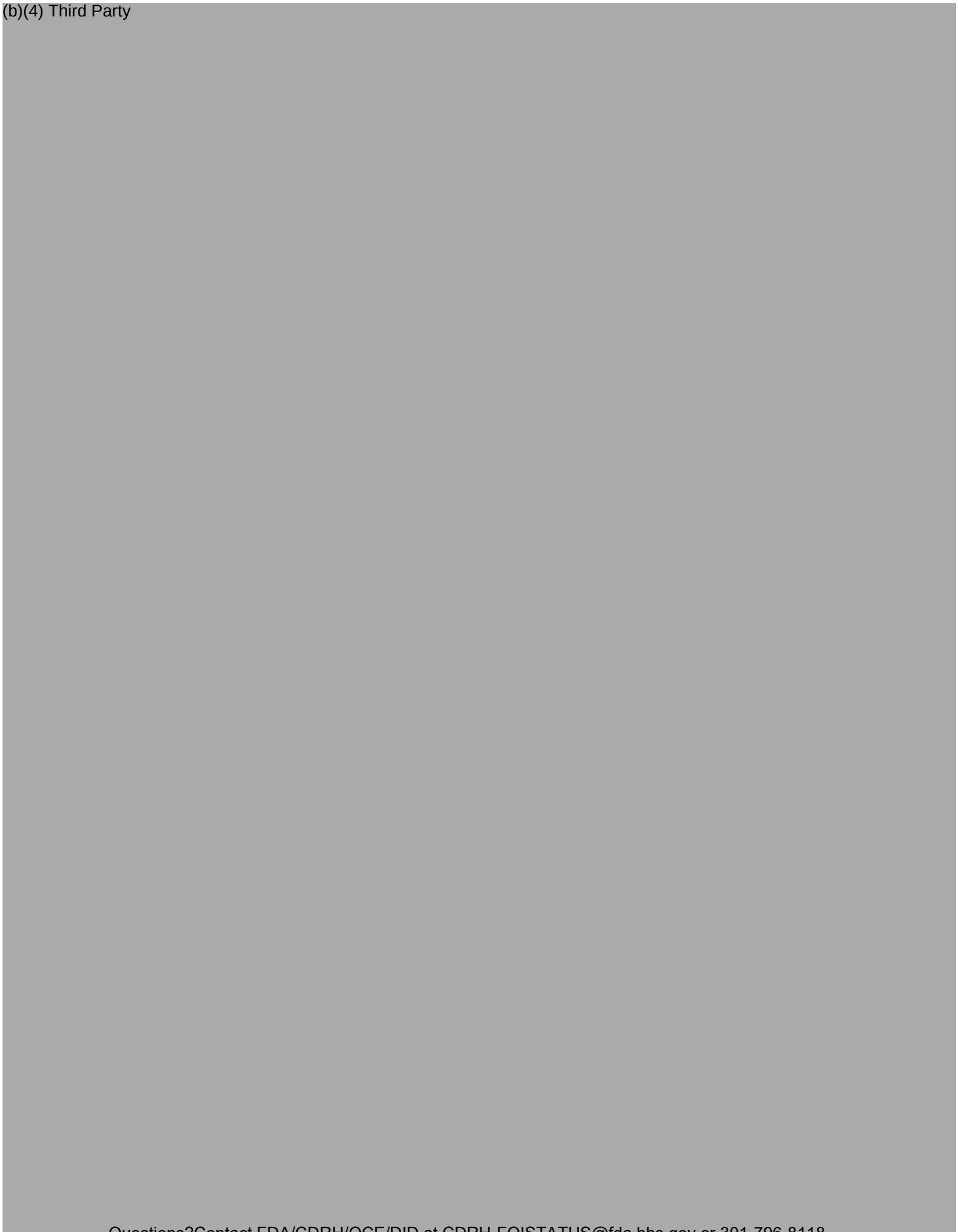

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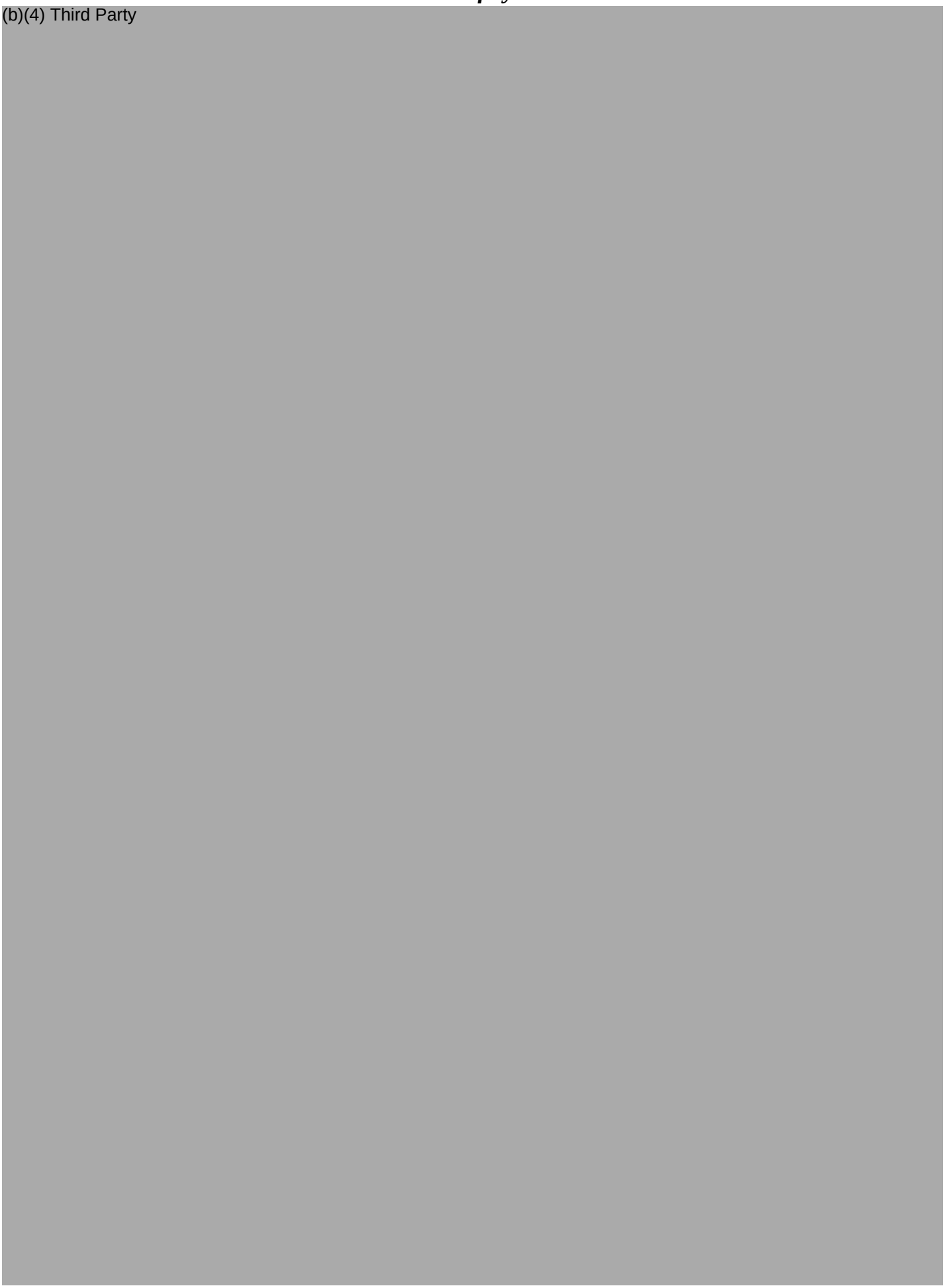

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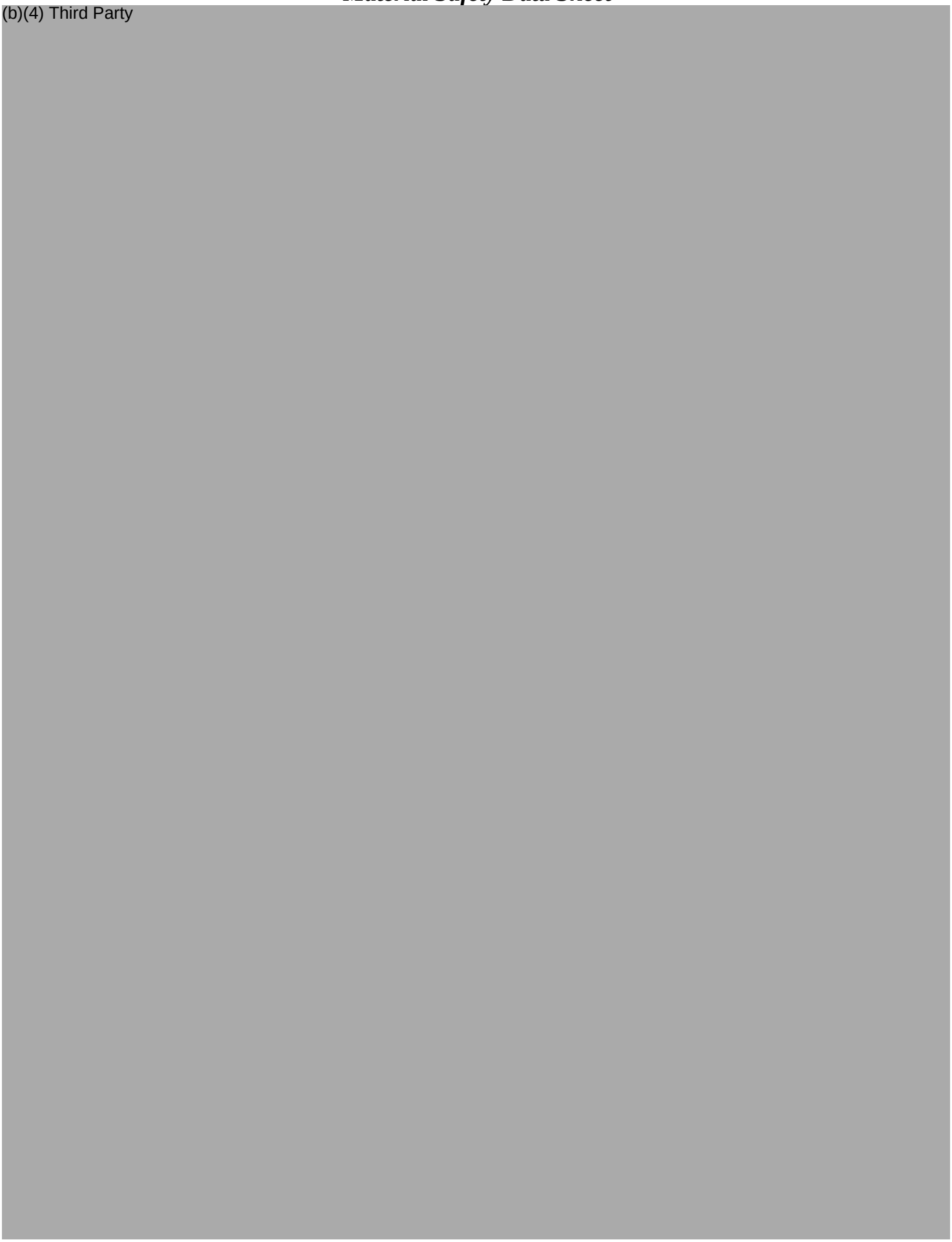

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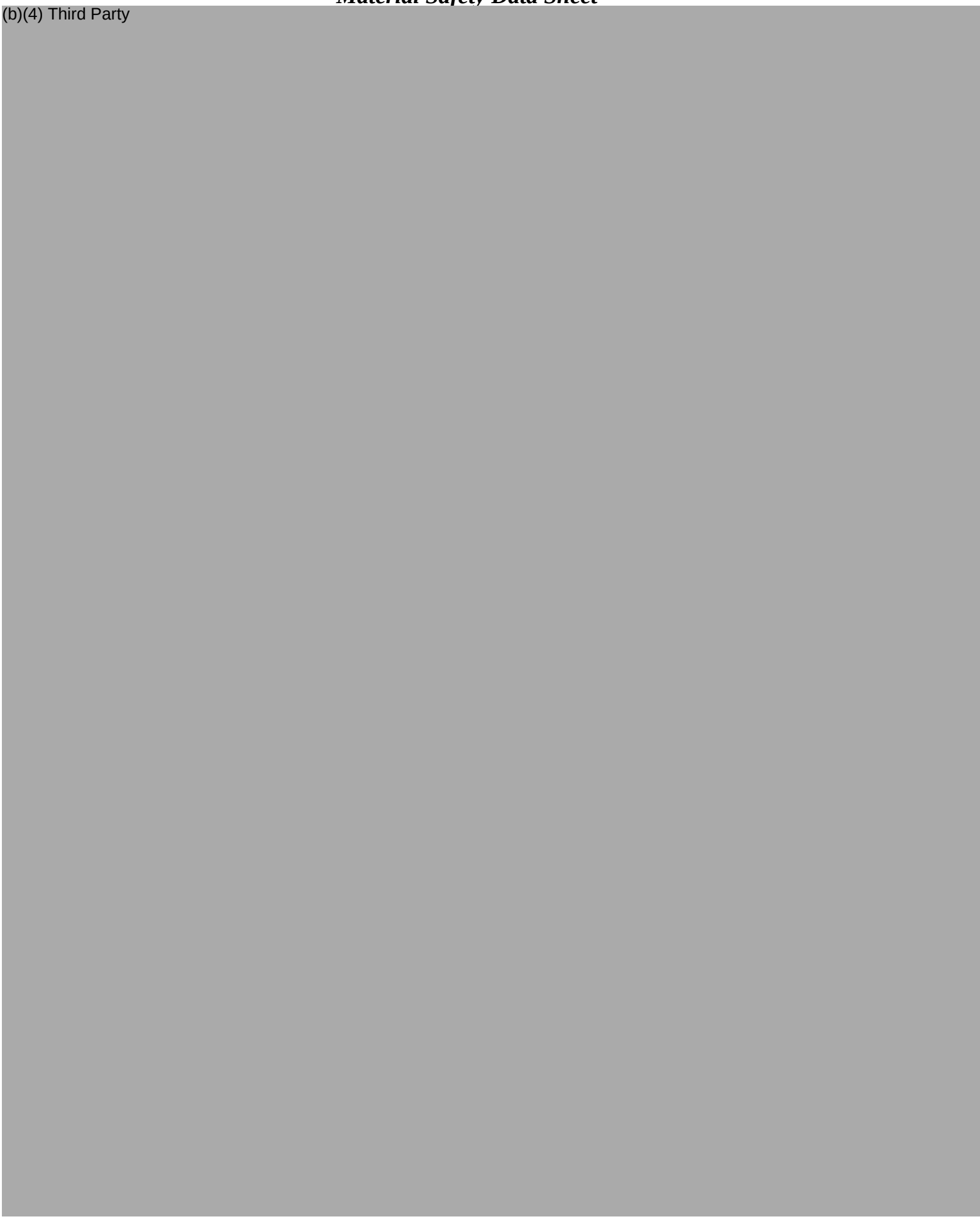

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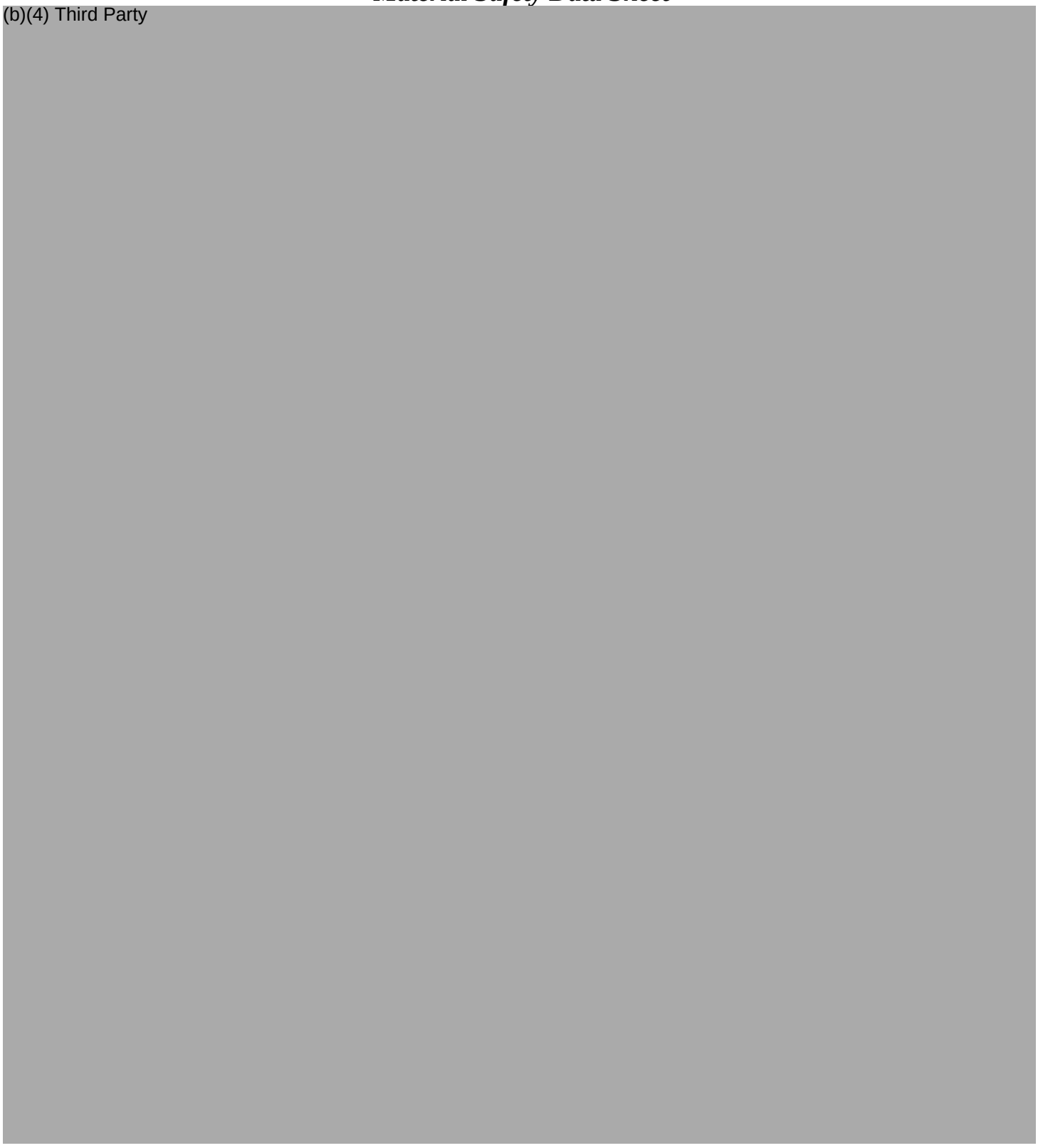

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Attachment 6

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