U.S. Department of Health & Human Services

Food and Drug Administration

SAVE REQUEST

USER:	(cwf)
FOLDER:	K113796 - 551 pages
COMPANY:	EBI, LLC (EBILLC)
PRODUCT:	INTERVERTEBRAL FUSION DEVICE WITH INTEGRATED FIXATION, CERVICAL (OVE)
SUMMARY:	Product: SOLITAIRE-C CERVICAL SPACER SYSTEM
DATE REQUESTED:	Aug 10, 2015
DATE PRINTED:	Aug 10, 2015
Note:	Printed

APR 2 6 2012

BIOMET SPINE

510(k) Summary

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

Preparation Date:	April 25, 2012
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Margaret F. Crowe Phone: 973-299-9300, ext. 2260 Fax: 973-257-0232
Trade name:	Solitaire®-C Cervical Spacer System
Common Name:	Cervical interbody fusion device with integrated fixation
Classification Name (Product Code):	Intervertebral Body Fusion Device (OVE)
Device Panel - Regulation No.:	Orthopedics - 21 CFR 888.3080

Device Description:

The purpose of this submission is to gain market clearance for the Solitaire-C Cervical Spacer System. The Solitaire®-C Cervical Spacer System consists of spacers and bone screws for stand-alone cervical intervertebral body fusion. The Solitaire®-C spacer will be available in a variety of sizes, angles and footprints.
This cervical spacer has a PEEK main body (PEEK-Optima LT1 per ASTM F-2026) with a titanium faceplate and band (Ti-6Al-4V ELI alloy per ASTM F-136), and tantalum markers (unalloyed tantalum per ASTM F-560). This device accepts titanium bone screws that are available in two diameters and multiple lengths.

Indications for Use:

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer is to be used with autograft and implanted via an anterior approach. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the Solitaire-C Cervical Spacer System is the same as, or similar to, the predicate devices. Examples of predicate devices include:

- Solitaire PEEK Anterior Spinal System (Biomet Spine - K081395, K093629)
- Coalition Spacer (Globus Medical – K083389)
- AVS-C Spacer (Stryker Spine – K102606)
- Synthes Zero-P Cervical Spacer (Synthes Spine – K072981, K093762)
- C-Thru Spacer System (Biomet Spine – K092336)

Performance Data

Mechanical testing recommended in the special controls guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was conducted. The testing conducted, along with the ASTM standard, are listed below:

1) Static Axial Compression (ASTM F-2077)
2) Dynamic Axial Compression (ASTM F-2077)
3) Static Compression-Shear (ASTM F-2077)
4) Dynamic Compression-Shear (ASTM F-2077)
5) Static Torsion (ASTM F-2077)
6) Dynamic Torsion (ASTM F-2077)
7) Subsidence (ASTM F-2267 and ASTM F-2077)
8) Expulsion (ASTM Draft F-04.25.02.02)

Additional mechanical testing was conducted to evaluate screw back out, screw push through, and interconnection testing between the spacer body and the faceplate. Wear debris analysis was also presented.

Mechanical testing shows that the mechanical strength of the subject device is sufficient for its intended use.

Substantial Equivalence:

The Solitaire-C Cervical Spacer System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. The predicates listed above are distributed for similar indications, and/or have similar design features.

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

APR 26 2012

Biomet Spine
% Ms. Margaret F. Crowe
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K113796
Trade/Device Name: Solitaire®-C Cervical Spacer System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: OVE
Dated: March 15, 2012
Received: March 16, 2012

Dear Ms. Crowe:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113796

Device Name: Solitaire®-C Cervical Spacer System

Indications for Use:

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer System is to be used with autograft and implanted via an anterior approach. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113796

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

APR 26 2012

Biomet Spine
% Ms. Margaret F. Crowe
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K113796
Trade/Device Name: Solitaire®-C Cervical Spacer System
Regulation Number: 21 CFR 888.3080
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Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113796

Device Name: Solitaire®-C Cervical Spacer System

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113796

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

February 27, 2012

EBI, LLC
100 INTERPACE PKWY.
PARSIPPANY, NEW JERSEY 07054
ATTN: MARGARET CROWE

510k Number: K113796
Product: SOLITAIRE-C CERVICAL SPACER SY

Extended Until: 04/03/2012

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

BIOMET SPINE

February 24, 2012

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

RE: K113796 – Solitaire®- C Cervical Spacer System
Request for an Extension

Dear Sir or Madam:

Biomet Spine would like to request a thirty (30) day extension to respond to questions received on February 2, 2012 regarding the above-referenced premarket notification. If additional information is required regarding this request for an extension, please contact the undersigned at 973-299-9300, extension 2260, or via electronic mail at margaret.crowe@biomet.com.

Thank you for your prompt attention to this matter.

Sincerely,

Margaret F. Crowe
Regulatory Affairs Project Manager

MFC/dl
Enclosure

Submitted in duplicate

EBI, LLC dba
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
800-526-2579

K-52

191

Sanders, Aisha *

From: Crowe, Margaret [Margaret.Crowe@biomet.com]
Sent: Thursday, February 02, 2012 5:13 PM
To: Sanders, Aisha *
Subject: Out of Office: K113796-Hold Letter

I am out of the office this afternoon (February 2nd). I will respond to your message when I return.

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

February 02, 2012

EBI, LLC
100 INTERPACE PKWY.
PARSIPPANY, NEW JERSEY 07054
ATTN: MARGARET CROWE

510k Number: K113796
Product: SOLITAIRE-C CERVICAL SPACER SY
On Hold As of 2/2/2012

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

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

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

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

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

Sincerely yours,

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

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 28, 2011

EBI, LLC
100 INTERPACE PKWY.
PARSIPPANY, NEW JERSEY 07054
ATTN: MARGARET CROWE

510k Number: K113796
Received: 12/23/2011
Product: SOLITAIRE-C CERVICAL SPACER SY

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

Williams, Michael *

From: Crowe, Margaret [Margaret.Crowe@biomet.com]
Sent: Wednesday, December 28, 2011 1:12 PM
To: Williams, Michael *
Subject: Out of Office: Ack Letter for K113796

I will be out of the office on vacation from Friday December 23 through Sunday January 1. I will have limited access to e-mail or voice mail. If you need imeediate assistance please contact Debra Bing in Regulatory. Thanks, and happy holidays!

K113796

BIOMET SPINE

December 22, 2011

FDA CDRH DMC
DEC 23 2011
Received

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Premarket Notification- Solitaire®- C Cervical Spacer System

Dear Sir or Madam:

Biomet Spine hereby submits this Traditional 510(k) for the Solitaire®-C Cervical Spacer System in accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and Title 21 CFR §807, Subpart E.

The information included in the submission supports the substantial equivalence* of the subject device to other commercially available spinal devices. The submission is organized in accordance with the FDA Guidance Document entitled "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s" dated August 12, 2005 and also includes the information requested in the FDA Guidance Document, "Guidance Document for Industry and Staff: Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" dated June 12, 2007. An electronic copy of this submission is being provided and it is an exact duplicate of the paper copy.

Administrative Information	
Type of 510(k) submission	Traditional
Basis for submission	New stand alone cervical spacer – Solitaire®-C
Sponsor Information	Biomet Spine (aka EBI L.P.) 100 Interpace Parkway Parsippany, New Jersey 07054 Establishment Registration #2242816
Contact person	Margaret F. Crowe Regulatory Affairs Project Manager Phone: 973-299-9300 x2260 Fax: 973-257-0232 email: margaret.crowe@biomet.com
Preference for continued confidentiality (21 CFR 807.95)	The existence of this submission, and the data and other information that it contains are confidential, and the protection afforded to such confidential information by 18 U.S.C. § 1905, 21 U.S.C. § 331(j), 5 U.S.C. § 552, and other applicable laws is hereby claimed.

Design and Use of the Device:

QUESTION	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from tissue or other biological device?		X
Is the device provided sterile?	X	X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	-	-
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

Please contact the undersigned if any additional information is required. Permission to call, fax or e-mail information related to this submission is granted by the Sponsor.

Sincerely,

Margaret F Crowe

Margaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine

*Any statement made in conjunction with this submission regarding and/or a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, 42 FR 42520 (Docket No. 76N-0355)]

Solitaire®- C Cervical Spacer System

Table of Contents

Solitaire®- C Cervical Spacer System

Table of Contents

Section 1

Medical Device User Fee Cover Sheet

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: [redacted] 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) EBI LLC 100 INTERPACE PARKWAY PARSIPPANY NJ 07054 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) [redacted]	2. CONTACT NAME Margaret Crowe 2.1 E-MAIL ADDRESS margaret.crowe@biomet.com 2.2 TELEPHONE NUMBER (include Area code) 973-299-9300 2260 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 973-257-0232

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

[redacted]   28-Nov-2011

Form FDA 3601 (01/2007)

"Close Window" Print Cover sheet

Section 2

CDRH Premarket Review Submission Cover Sheet

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: December 31, 2013
See OMB Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
12/21/2011	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Meeting
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-510(K) Meeting
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Pre-IDE Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Pre-PMA Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Pre-PDP Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Day 100 Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Agreement Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Determination Meeting
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify)*:
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission)*:
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
Biomet Spine (aka EBI, LLC)	2242816		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	973-299-9300		
Street Address	**FAX Number *(including area code)***		
100 Interpace Parkway	973-257-0232		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Parsippany	New Jersey	07054	USA
Contact Name			
Margaret F. Crowe			
Contact Title	**Contact E-mail Address**		
Regulatory Affairs Project Manager	margaret.crowe@biomet.com		

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

Company / Institution Name			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
Street Address	**FAX Number *(including area code)***		
City	**State / Province**	**ZIP Code**	**Country**
Contact Name			
Contact Title	**Contact E-mail Address**		

PSC Publishing Services (301) 443-6740 EF

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

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site

- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*

- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager

- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*

- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*

- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment

- ☐ Response to FDA correspondence:

- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address

- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access

- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor

- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final

- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing

- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☒ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology

- ☐ Other Reason *(specify):*

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	OVE	2		3	OVD	4	MAX
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	K081395	1	Solitaire Anterior Spinal System	1	Biomet Spine
2	K083389	2	Coalition Spacer	2	Globus Medical
3	K102606	3	AVS Anchor-C Spacer	3	Stryker Spine
4	K072981, K093762	4	Synthes Zero-P Cervical Spacer	4	Synthes Spine
5	K092336	5	C-Thru Spacer System	5	Biomet Spine
6	K082406	6	Expandable PEEK Implant	6	Biomet Spine

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Stand-alone cervical interbody fusion device

	Trade or Proprietary or Model Name for This Device		Model Number
1	Solitaire-C Cervical Spacer System	1	See Section 11 for a complete list
2		2	
3		3	
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: OVE

C.F.R. Section *(if applicable)*: 888.3080

Device Class

☐ Class I ☒ Class II ☐ Class III ☐ Unclassified

Classification Panel

Orthopedics

Indications *(from labeling)*

The Solitaire-C Cervical Spacer System is indicated for stand-alone cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. See Section 4 for complete Indications for Use Statement.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name: Biomet Spine (aka EBI, LLC)		Establishment Registration Number: 2242816
Division Name *(if applicable)*		Phone Number *(including area code)*: 973-299-9300
Street Address: 100 Interpace Parkway		FAX Number *(including area code)*: 973-257-0232
City: Parsippany	State / Province: New Jersey	ZIP Code: 07054 / Country: USA
Contact Name: Margaret Crowe	Contact Title: Regulatory Affairs Project Manager	Contact E-mail Address: margaret.crowe@biomet.com

☐ Original ☒ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

(b)(4)

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H ***(Continued)***

☐ Original ☒ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☒ Contract Manufacturer ☐ Repackager / Relabeler
(b)(4)		

☐ Original ☒ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
(b)(4)		

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.	FDA Document Number *(if known)*

SECTION H *(Continued)*

☐ Original ☒ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

(b)(4)

[redacted]

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler

Company / Institution Name	Establishment Registration Number
Division Name *(if applicable)*	Phone Number *(including area code)*
Street Address	FAX Number *(including area code)*

City	State / Province	ZIP Code	Country

Contact Name	Contact Title	Contact E-mail Address

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ASTM F-560-08 (FDA Recognition # 8-183)	ASTM	Standard Specification for Unalloyed Tantalum for Surgical Implant Applications	2008	
2	ASTM F-2026-08 (FDA Recognition # 11-219)	ASTM	Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications	2008	
3	ASTM F-136-08 (FDA Recognition # 8-164)	ASTM	Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)	2008	
4	ASTM F-2077-11	ASTM	Test Methods for Intervertebral Body Fixation Devices	2011	
5	ASTM F-2267-04 (FDA Recognition # 11-185)	ASTM	Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Devices under Static Axial Compression	2004	
6	ASTM Draft F-04.25.02.02	ASTM	Static Push-out Method for Intervertebral Body Fusion Devices	2002	
7	(b)(4)				

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

SECTION I — UTILIZATION OF STANDARDS

Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.

	Standards No.	Standards Organization	Standards Title	Version	Date
1	ANSI/AAMI ST-79 (FDA Recognition # 14-280)	ANSI/AAMI	Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities	2009	
2	AAMI TIR 12: 2010	AAMI	Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers	2010	
3	AAMI TIR 30: 2003	AAMI	A Compendium of Processes, Materials, Test Methods and Acceptance Criteria for Cleaning Reusable Medical Devices	2003	
4					
5					
6					
7					

Please include any additional standards to be cited on a separate page.

Public reporting burden for this collection of information is estimated to average 0.5 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Section 3

510(k) Cover Letter

BIOMET SPINE

December 22, 2011

Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Traditional 510(k) Premarket Notification- Solitaire®- C Cervical Spacer System

Dear Sir or Madam:

Biomet Spine hereby submits this Traditional 510(k) for the Solitaire®-C Cervical Spacer System in accordance with Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended, and Title 21 CFR §807, Subpart E.

The information included in the submission supports the substantial equivalence* of the subject device to other commercially available spinal devices. The submission is organized in accordance with the FDA Guidance Document entitled "Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s" dated August 12, 2005 and also includes the information requested in the FDA Guidance Document, "Guidance Document for Industry and Staff: Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" dated June 12, 2007. An electronic copy of this submission is being provided and it is an exact duplicate of the paper copy.

Administrative Information	
Type of 510(k) submission	Traditional
Basis for submission	New stand alone cervical spacer – Solitaire®-C
Sponsor Information	Biomet Spine (aka EBI L.P.) 100 Interpace Parkway Parsippany, New Jersey 07054 Establishment Registration #2242816
Contact person	Margaret F. Crowe Regulatory Affairs Project Manager Phone: 973-299-9300 x2260 Fax: 973-257-0232 email: margaret.crowe@biomet.com
Preference for continued confidentiality (21 CFR 807.95)	The existence of this submission, and the data and other information that it contains are confidential, and the protection afforded to such confidential information by 18 U.S.C. § 1905, 21 U.S.C. § 331(j), 5 U.S.C. § 552, and other applicable laws is hereby claimed.

Design and Use of the Device:

QUESTION	YES	NO
Is the device intended for prescription use (21 CFR 801 Subpart D)?	X	
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?		X
Does the device contain components derived from tissue or other biological device?		X
Is the device provided sterile?	X	X
Is the device intended for single use?	X	
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?	-	-
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?		X
Is the device implanted?	X	

Please contact the undersigned if any additional information is required. Permission to call, fax or e-mail information related to this submission is granted by the Sponsor.

Sincerely,

Margaret F Crowe

Margaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine

*Any statement made in conjunction with this submission regarding and/or a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation, Preamble, August 23, 1977, 42 FR 42520 (Docket No. 76N-0355)]

Section 4

Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Solitaire®-C Cervical Spacer System

Indications for Use:

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer System is to be used with autograft and implanted via an anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5

510(K) Summary

510(k) Summary

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

Preparation Date:	December 21, 2011
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Margaret F. Crowe Phone: 973-299-9300, ext. 2260 Fax: 973-257-0232
Trade name:	Solitaire®-C Cervical Spacer System
Common Name:	Cervical interbody fusion device
Classification Name (Product Code):	Intervertebral Fusion Device with Integrated Fixation, Cervical (OVE)
Device Panel - Regulation No.:	Orthopedics - 21 CFR 888.3080

Device Description:

The purpose of this submission is to gain market clearance for the Solitaire-C Cervical Spacer System. The Solitaire®-C Cervical Spacer System consists of spacers and bone screws for stand-alone cervical intervertebral body fusion. The Solitaire®-C spacer will be available in a variety of sizes, angles and footprints. This cervical spacer has a PEEK main body with a titanium faceplate and band, and tantalum markers. This device accepts titanium bone screws that are available in two diameters and multiple lengths.

Indications for Use:

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer is to be used with autograft and implanted via an anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the Solitaire-C Cervical Spacer System is the same as, or similar to, the predicate devices. Examples of predicate devices include:

- Solitaire PEEK Anterior Spinal System (Biomet Spine - K081395, K093629)
- Coalition Spacer (Globus Medical – K083389)
- AVS-C Spacer (Stryker Spine – K102606)
- Synthes Zero-P Cervical Spacer (Synthes Spine – K072981, K093762)
- C-Thru Spacer System (Biomet Spine – K092336)
- Expandable PEEK Spacer (Biomet Spine – K082406)

Performance Data

Mechanical testing recommended in the special controls guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was conducted. The testing conducted, along with the ASTM standard, are listed below:

1) Static Axial Compression (ASTM F-2077)
2) Dynamic Axial Compression (ASTM F-2077)
3) Static Compression-Shear (ASTM F-2077)
4) Dynamic Compression-Shear (ASTM F-2077)
5) Static Torsion (ASTM F-2077)
6) Dynamic Torsion (ASTM F-2077)
7) Subsidence (ASTM F-2267 and ASTM F-2077)
8) Expulsion (ASTM Draft F-04.25.02.02)

Additional mechanical testing was conducted to evaluate screw back out, screw push through, and interconnection testing between the spacer body and the faceplate.

Mechanical testing shows that the mechanical strength of the subject device is sufficient for its intended use.

Substantial Equivalence:

The Solitaire-C Cervical Spacer System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. The predicates listed above are distributed for similar indications, and/or have similar design features.

Section 6

Truthful and Accuracy Statements

TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87(k))

Solitaire-C Cervical Spacer System

I certify, in my capacity as Regulatory Affairs Project Manager, Biomet Spine, I believe to the best of my knowledge, that the data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Margaret F Crowe
Signature

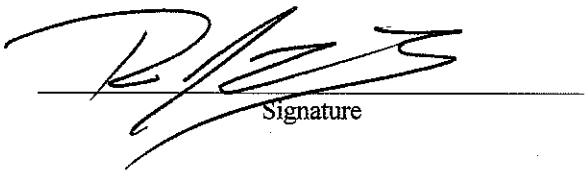
Margaret F. Crowe
Name

12/22/11
Date

TRUTHFUL AND ACCURATE STATEMENT
(As Required by 21 CFR 807.87(k))

Solitaire-C Cervical Spacer System

I certify, in my capacity as a Development Manager of Biomet Spine, 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.



Signature

Rui J. Ferreira

Name

December 22, 2011

Date

Section 7

Class III Summary and Certification

This submission is for a Class II device. Therefore, this section is not applicable.

Section 8

Financial Certification or Disclosure Statement

(b)(4) [redacted].

Section 9

Declarations of Conformity and Summary Reports

A Form FDA 3654 follows for each standard referenced in this 510(k) submission as outlined in the FDA Guidance Document entitled "Recognition and Use of Consensus Standards" dated September 17, 2007. Forms are included for the following standards:

Materials

9_1 ASTM F-2026-08 - Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications

9_2 ASTM F-136-08^{e1} - Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)

9_3 ASTM F-560-08 - Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)

Testing

9_4 ASTM F-2077-11- "Test Methods for Intervertebral Body Fusion Devices"

9_5 ASTM F-2267-04 - "Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression"

9_6 ASTM F-04.25.02.02, Static Push-Out Test Method for Intervertebral Body Fusion Devices (draft standard)

Cleaning/Sterilization

(b)(4)

(b)(4)

[redacted]

Form Approved: OMB No. 0910-0120; Expiration Date: 8/31/10

Department of Health and Human Services

Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F-2026-08 Standard Specification for Polyetheretherketone (PEEK) Polymers for Spinal Implant Applications

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 11-219	
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 the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are descr bed; deviations from the standard; requirements not applicable to the device; and the name 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 of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F-2026-08 STANDARD SPECIFICATION FOR POLYETHERETHERKETONE (PEEK) POLYMERS FOR SPINAL IMPLANT APPLICATIONS

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-4	Scope, Referenced Doments, Terminology, Classification	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Properties	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6-8	Sampling, Biocompatibility, Keywords	☒ 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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Department of Health and Human Services

Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F-136-08e1 - Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401), 2008

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # List 022 # 8-164		
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 the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

[4] The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are descr bed; deviations from the standard; requirements not applicable to the device; and the name 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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[6] The online search of CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F-136-08E1 - STANDARD SPECIFICATION FOR WROUGHT TITANIUM-6 ALUMINUM-4 VANADIUM ELI (EXTRA LOW INTERSTITIAL) ALLOY FOR SURGICAL IMPLANT APPLICATIONS (UNS R56401), 2008

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-6	Scope, Referenced Documents, Terminology, Product Classification, Ordering Information, Materials and Manufacture	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		
7-8	Chemical Requirements,Mechanical Requirements	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		
9-12	Special Requirements, Certification,Quality Program Requirements, Keywords	☒ 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.

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F-560-08 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 8-183	
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 the standard? If yes, report options selected in the summary report table.	☐	☒
Were there any deviations or adaptations made in the use of the standard?	☐	☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) [5]?	☐	☐
Were deviations or adaptations made beyond what is specified in the FDA SIS? If yes, report these deviations or adaptations in the summary report table.	☐	☒
Were there any exclusions from the standard? If yes, report these exclusions in the summary report table.	☐	☒
Is there an FDA guidance [6] that is associated with this standard?	☐	☒
If yes, was the guidance document followed in preparation of this 510k?	☐	☐

Title of guidance: _____

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F-560-08 STANDARD SPECIFICATION FOR UNALLOYED TANTALUM FOR SURGICAL IMPLANT APPLICATIONS (UNS R05200, UNS R05400)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-4	Scope, Referenced Doments, Terminology, Ordering Information	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5-7	Materials and Manufacture, Chemical Requirements, Mechanical Properties	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8-9	Certification, Quality Program Requirements	☒ 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.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2077-11, Test Methods for Intervertebral Body Fusion 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 the standard? 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: Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F2077-11, TEST METHODS FOR INTERVERTEBRAL BODY FUSION DEVICES

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-2, 3(except 3.2.9), 4 , 5	Scope, Referenced Documents, Terminology, Summary of Test Method, Significance & Use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
See attachment for deviation from 3.2.9

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Apparatus	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
See attachment for deviations to this section

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7-12 (except 8.3 and 9.2)	Sampling, Procedure for Static Tests, Procedure for Dynamic Tests, Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
See attachment for deviations to 8.3 and 9.2

DESCRIPTION

JUSTIFICATION

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(b)(4)

Test Mode	Test Location	Deviation	Conformance
(b)(4)			

Test Mode	Test Location	Deviation	Conformance
(b)(4)			

Test Mode	Test Location	Deviation	Conformance
(b)(4)			

Test Mode	Test Location	Deviation	Conformance
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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F2267-04, Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3] # 11-185		
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 the standard? 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: Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Intervertebral Body Fusion Device

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F2267-04, STANDARD TEST METHOD FOR MEASURING LOAD INDUCED SUBSIDENCE OF INTERVERTEBRAL BODY FUSION DEVICE UNDER STATIC AXIAL COMPRESSION

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-5	Scope, Referenced Documents, Terminology, Summary of Test Method, Significance and Use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖

No deviations

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Apparatus	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖

Subsection 6.3, Test apparatus

DESCRIPTION

Section 6.3 of ASTM 2267-04 states that the test apparatus should consist of a universal joint, hollow pushrod, and stainless steel sphere. The test laboratory's default is to use a self-leveling fixture, with a rigid M20 double ended adaptor to the actuator.

JUSTIFICATION

Default equipment used by testing laboratory. Standard lists test apparatus as an example. Apparatus used applies forces in same manner.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7-11	Sampling, Procedure for Static Axial Compression Test, Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖

No deviations

DESCRIPTION

N/A

JUSTIFICATION

N/A

* 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.

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ASTM F-04.25.02.02, Static Push-Out Test Method for Intervertebral Body Fusion Devices

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☐	☒
FDA Recognition number [3]	# N/A	
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 the standard? 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: Guidance for Industry and FDA Staff - Spinal System 510(k)s

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

[2] Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

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

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F-04.25.02.02, STATIC PUSH-OUT TEST METHOD FOR INTERVERTEBRAL BODY FUSION DEVICES

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-5	Scope, Referenced Documents, Terminology, Definitions, Summary of Test Methods, Significance and Use	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
No deviations

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Apparatus	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
s

DESCRIPTION
.

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7-11	Sampling, Procedure for Push Out, Report, Precision and Bias, Keywords	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖
No deviations

DESCRIPTION
N/A

JUSTIFICATION
N/A

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Food and Drug Administration

STANDARDS DATA REPORT FOR 510(K)S

(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

AAMI/ANSI/ISO 11137-2:2006 Sterilization of Healthcare Products: Radiation part 2: Establishing Sterilization Dose

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# 14-225	
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 the standard? 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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

AAMI/ANSI/ISO 11137-2:2006 STERILIZATION OF HEALTHCARE PRODUCTS: RADIATION PART 2: ESTABLISHING STERILIZATION DOSE

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1-6	Scope, references, abbreviations, terms and definitions, definition and maintenance of product families for dose setting, dose substantiation, and sterilization dose auditing, selection and testing of product for establishing and verifying the sterilization dose, methods of dose establishment	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.2	Procedure for Method Vdmax25 for multiple production batches	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
10	Auditing sterilization dose	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED❖		
DESCRIPTION		
JUSTIFICATION		

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Food and Drug Administration

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TYPE OF 510(K) SUBMISSION

☒ Traditional ☐ Special ☐ Abbreviated

STANDARD TITLE [1]

ANSI/AAMI ST79, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities:2006 and A1:2008, A2:2009 (Consolidated Text)

Please answer the following questions	*Yes*	*No*
Is this standard recognized by FDA [2]?	☒	☐
FDA Recognition number [3]	# List 025, 14-280	
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 the standard? 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: _____

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ANSI/AAMI ST79, COMPREHENSIVE GUIDE TO STEAM STERILIZATION AND STERILITY ASSURANCE IN HEALTH CARE FACILITIES:2006 AND A1:2008, A2:2009 (CONSOLIDATED TEXT)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
8.6.1	Sterilization parameters for wrapped or containarized items	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED❖

Table 5 - Minimum cycle times for dynamic air-removal steam sterilization cycles

DESCRIPTION

Wrapped instruments for a 4 minute exposure time at 132°C and drying time of 20 to 30 minutes

JUSTIFICATION

To provide the hospital with validated reprocessing instructions

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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(b)(4)

[redacted]

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(b)(4)

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TYPE OF 510(K) SUBMISSION

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STANDARD TITLE [1]

AAMI TIR 30: A Compendium of Processes, materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices, 2003

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, was the guidance document followed in preparation of this 510k?	☐	☐

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

(b)(4)

[redacted]

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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Section 10

Executive Summary

Purpose

Biomet Spine markets a stand-alone lumbar intervertebral body fixation device with integrated fixation – the Solitaire® PEEK Anterior Spinal System (found substantially equivalent in K081395). Biomet Spine has developed a stand-alone cervical intervertebral body fixation device with integrated fixation – the Solitaire®-C Cervical Spacer System. This new cervical interbody fusion device is similar in design to its' lumbar predecessor in terms of materials, and locking feature for the bone screws.

The purpose of this premarket notification is to gain market clearance for the Solitaire-C Cervical Spacer System.

Device Description

The Solitaire®-C Cervical Spacer System consists of spacers and bone screws for stand-alone cervical intervertebral body fusion. The Solitaire®-C spacer will be available in a variety of sizes, angles and footprints, as outlined in Size section below.

Intended Use

The Solitaire®-C Cervical Spacer System consists of spacers (with bone screws) of various sizes, angles and footprints, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion procedures. The screws

(b)(4) [redacted]

Indications for Use

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer System is to be used with autograft and implanted via an anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Materials

(b)(4) [redacted]

(b)(4)

Performance Data

(b)(4)

- (b)(4)
- [redacted]
- [redacted]
- [redacted]
- [redacted]

Additional testing (b)(4) [redacted]

Clinical Information:

(b)(4) [redacted]

Summary:

The following information summarizes the characteristics of the Solitaire-C Cervical Spacer System and its predicates. More detailed information is provided in the Substantial Equivalence Table in Section 12. Based on this information, the Solitaire-C Cervical Spacers do not raise any additional questions regarding safety and/or effectiveness.

- The Solitaire-C Cervical Spacer has the same indications for use as the Synthes Zero-P and the AVS Anchor-C Spacer, and similar indications for use as the Globus Medical Coalition Spacer.

- The sizing options for the Solitaire-C Cervical Spacer are the similar to the named cervical spacer predicate devices.

- The design features of the Solitaire-C Spacer are similar to those of the named predicates. All of the devices have a central cavity for placement of graft material, endplate engaging surfaces that provide stability, resist shear and rotational forces, and help to prevent migration. All of the named products are offered in a variety of sizes and heights. The named stand-alone devices (Coalition, AVS Anchor-C and Zero-P) have integrated fixation features.

- The Solitaire-C Spacer is comprised of the exact same materials – PEEK, titanium and tantalum – as the Solitaire lumbar, Coalition, Zero-P and AVS Anchor-C. The other named predicates, C-Thru and Expandable PEEK, utilize PEEK and tantalum.

- The Solitaire-C Spacer body is provided in a sterile configuration. The predicate PEEK spacers manufactured by Biomet Spine are provided sterile. The devices are packaged in the same manner with the same materials as other cleared Biomet Spine sterile spacers. The Solitaire-C bone screws are available non-sterile or sterile. The Solitaire Lumbar bone screws cleared in K093629 are also available in these 2 configurations.

- Mechanical testing shows that the mechanical strength of the subject device is sufficient for the intended use.

In conclusion, the subject device is substantially equivalent to other predicate spacer devices. The mechanical testing provided in Section 18 and the supporting information included in Section 12 sufficiently demonstrates the substantial equivalence of the subject device to its predicates. Based on this information, the Solitaire-C Spacer does not raise any new issues regarding safety or efficacy.

Section 11

Device Description

Purpose of Submission:

The purpose of this submission is to gain market clearance for a new stand-alone cervical intervertebral body fusion device with integrated fixation – the Solitaire®-C Cervical Spacer System.

Intended Use:

The Solitaire®-C Cervical Spacer System consists of spacers (with bone screws) of various sizes, angles and footprints, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion procedures. The screws protrude through the spacer portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The large hollow geometry of the implant allows it to be packed with autogenous bone graft to facilitate fusion. The implant is contained within the excised disc space, and does not protrude past the anterior wall of the vertebral body. This feature is designed to reduce soft tissue irritation. The Solitaire-C is designed to address the risk of adjacent level ossification by remaining 5mm or greater from the adjacent level disc spaces. The Solitaire®-C incorporates integrated fixation, so supplemental fixation is not required. The Solitaire®-C Cervical Spacer System is intended to be implanted with Solitaire®-C bone screws.

Indications for Use:

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer System is to be used with autograft and implanted via an anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Device Description:

The Solitaire®-C Cervical Spacer System consists of spacers and bone screws for stand-alone cervical intervertebral body fusion. The Solitaire®-C spacer will be available in a variety of sizes, angles and footprints, as outlined in Size section below.

The **spacer body** consists of the following sub-components:

1) (b)(4) [redacted]

2) (b)(4)

3)

4)

(b)(4)

These sub-components are factory assembled.

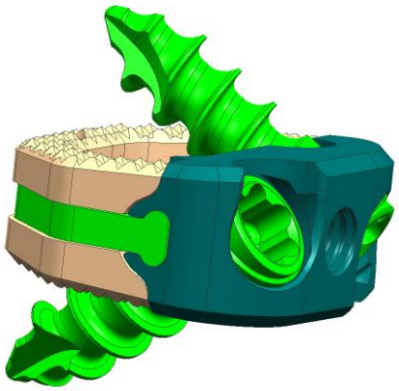


Figure 1. Illustration of the Solitaire-C Cervical Spacer System ((b)(4))

(b)(4)

Figure 2. Illustration of Solitaire-C Bone Screw

The **locking mechanism** (b)(4) This locking mechanism is based on the design of the Solitaire lumbar spacer cleared in K081395.

(b)(4)

Figure 3. Illustration of friction fit locking mechanism

(b)(4)

Sizes:

The Solitaire®-C spacers will be available in the following widths/depths:

- 14mm width x 12mm depth
- 14mm width x 14mm depth

- 16mm width x 12mm depth
- 16mm width x 14mm depth
- 16mm width x 15mm depth
- 16mm width x 16mm depth
- 18mm width x 12mm depth
- 18mm width x 14mm depth
- 18mm width x 15mm depth
- 18mm width x 16mm depth
- 20mm width x 14mm depth
- 20mm width x 15mm depth
- 20mm width x 16mm depth

The spacers will be available in heights from 6mm to 12mm. All sizes will be available in both parallel and lordotic styles.

(b)(4)

Standard Manual Surgical Instruments

The instruments used to implant the device are general manual surgical instruments (21 CFR 888.4540). These types of instruments are generally fabricated from titanium alloy, various types of stainless steel, and polymeric materials. Types of instruments include, but are not limited to:

- Inserters (various styles)
- Trials (various styles)
- Rasps (various styles)

- Inserter Guides (various styles)
- Modular Handles (various styles)
- Awls (various styles)
- Drill Sleeves (various styles)
- Drill Bits (various styles)
- Drivers (various styles)
- Torque Wrenches
- Slotted Mallet
- Slide Hammer
- Bone Graft Mold
- Instrument Trays/Caddies
- Instrument Trays/Caddies with QR codes

A sample instrument label and the draft Instructions for Use for the Solitaire®-C instruments is included in Section 13.

Representative Drawings:

Engineering drawings for the subject implants are included in Attachment 11-2.

Attachment 11-1

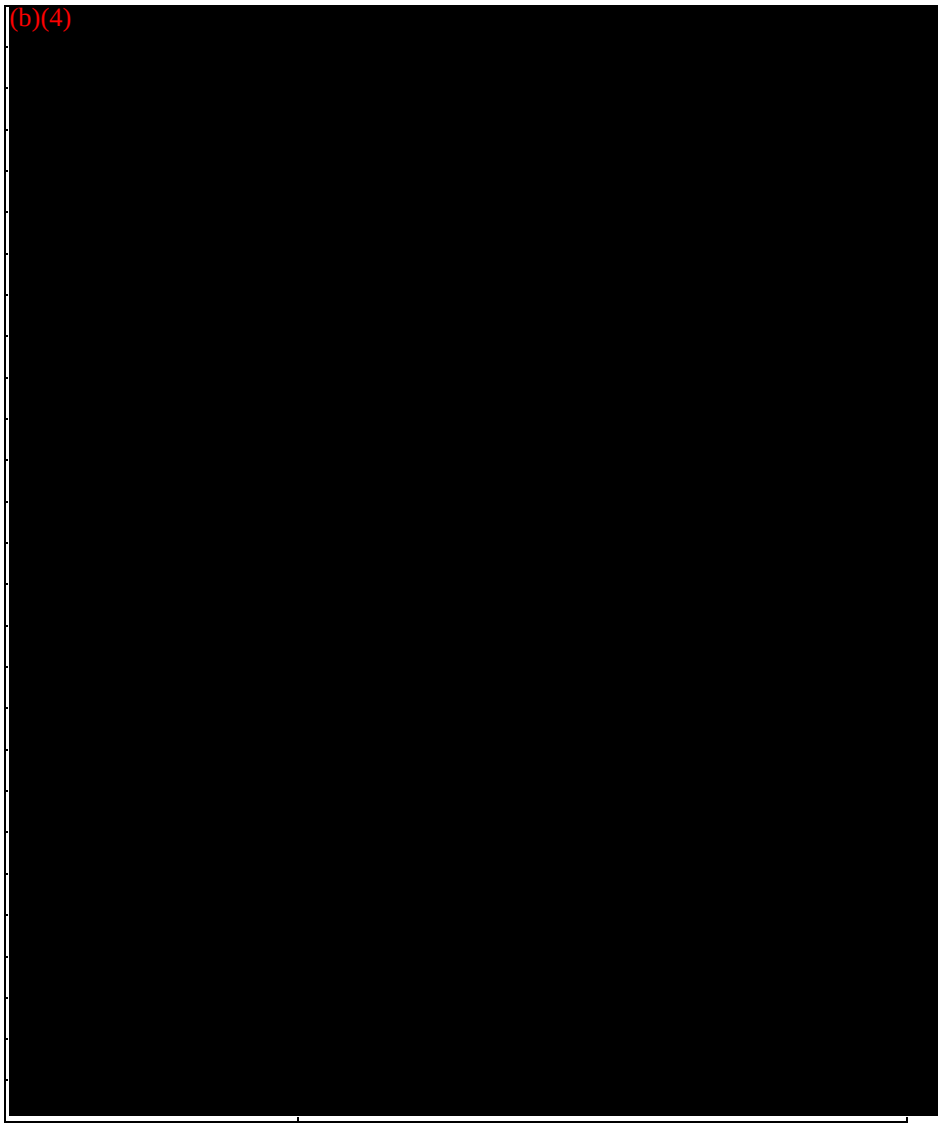
Solitaire®-C Implant Part Numbers

Lordotic Spacers

Part Number	Description
(b)(4)	

(b)(4)

(b)(4)

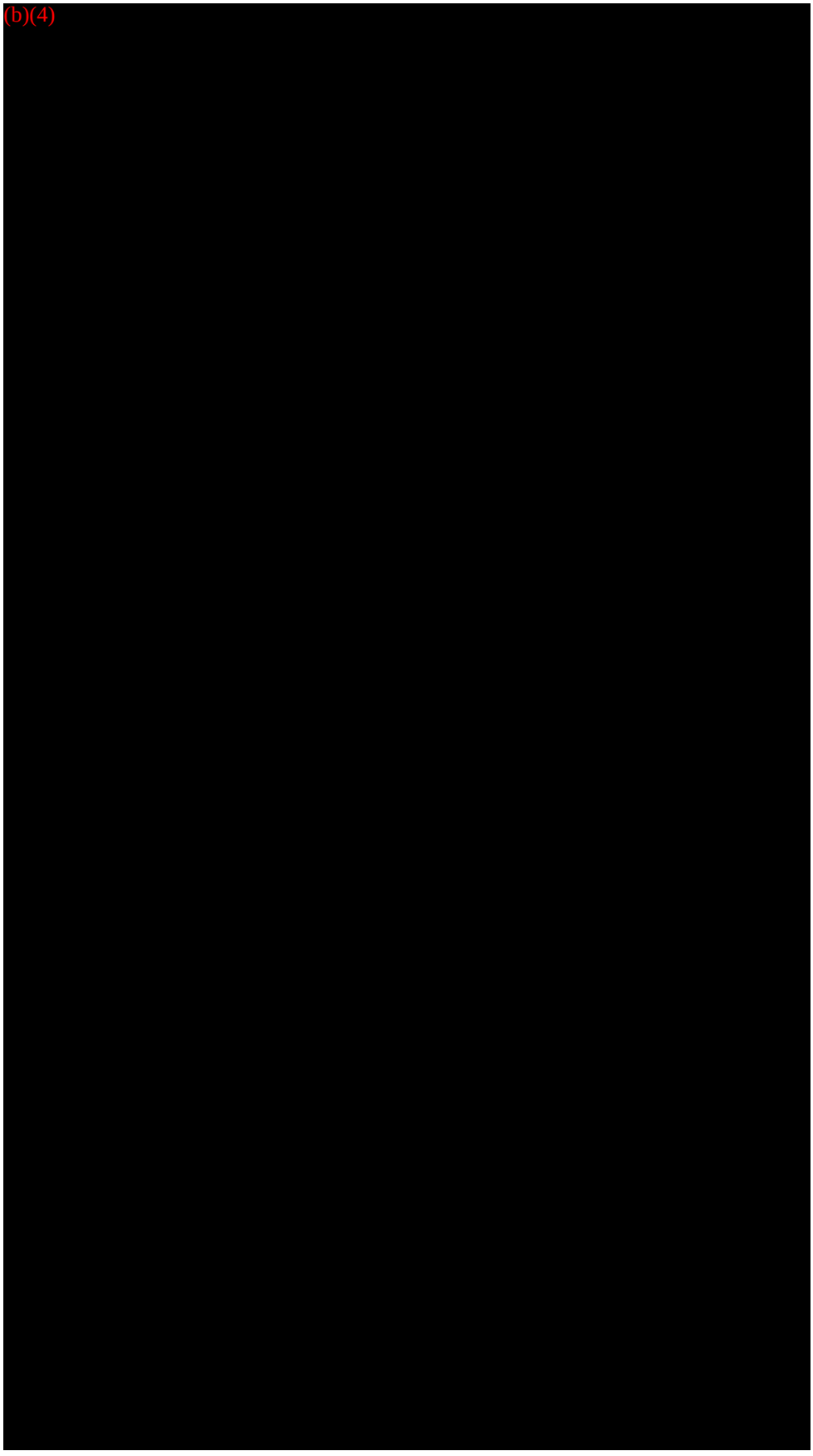


Parallel Spacers

(b)(4)

(b)(4)

(b)(4)



(b)(4)

Bone Screws

(b)(4)

Attachment 11-2

Engineering Drawings

11_2_1: Spacer Body Assembly

11_2_2: Titanium Faceplate

11_2_3: PEEK Spacer Body

11_2_4: Titanium Band

11_2_5: Bone Screws

(b)(4) Schematic drawing

(b)(4) CCI

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

(b)(4) Engineering Drawings

Section 12

Substantial Equivalence Discussion

The subject Solitaire-C Cervical Spacer System components are substantially equivalent to the predicates as intervertebral body fusion devices in regards to intended use, design, materials, and operational principles. Listed below are examples of other predicate cervical spacer systems with integrated fixation (OVE) commercially distributed for similar indications. The Solitaire PEEK Anterior Spinal System (cleared under product code OVD) is also listed as a predicate device because of the similarities in design. The C-Thru Spacer system, which is cleared for use in anterior cervical fusion procedures under the ODP product code, is listed as a predicate device because of design and material comparisons. The additional anterior cervical plating systems are listed below as they are referenced in the Mechanical Testing section of the submission. A Substantial Equivalence table comparing the indications, materials and design features to demonstrate that the subject components are substantially equivalent to the predicates is attached. Additional information on the predicate devices follows the Substantial Equivalence table.

The Solitaire-C Cervical Spacer System is substantially equivalent to the following systems:

- Solitaire PEEK Anterior Spinal System (Biomet Spine- K081395, K093629)
- Coalition Spacer (Globus Medical – K083389)
- AVS Anchor-C Spacer (Stryker Spine – K102606)
- Synthes Zero-P Cervical Spacer (Synthes Spine – K072981, K093762)
- C-Thru Spacer System (Biomet Spine – K092336)
- Expandable PEEK Spacer (Biomet Spine – K082406)

The following additional devices have been referenced in the Mechanical Testing report in Section 18:

- Uniplate Anterior Cervical Plating System (DePuy Spine – K042544)
- SpineLink Anterior Cervical Spinal System (Biomet Spine – K973923)
- Synthes Cervical Spine Locking Plate (Synthes Spine – K945700)

Intended Use
The Solitaire-C subject device has the same intended use as two of the other devices cleared under the OVE product code (AVS Anchor-C, and Zero-P) – all are indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease

Biomet Spine
Traditional 510(k) Premarket Notification

(b)(4) CCI

[redacted]

Design

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

Materials

(b)(4) CCI

[redacted]

Packaging/Sterilization

The subject Solitaire-C spacer body is packaged sterile in the same manner as the Solitaire lumbar, Expandable PEEK and C-thru spacers. The Solitaire-C bone screws will be packaged either sterile or non-sterile. The sterile packaging will be similar to the packaging used for the Biomet sterile pacers. The Solitaire-C bone screws will be available in a sterile or non-sterile configuration, just as the Solitaire lumbar screws cleared in K093629.

Operational Principles

The method of site preparation and implantation are similar for the subject and predicate OVE devices for intervertebral body fusion. Similar types of instrumentation are used to implant the subject device as the predicate implants. All of the predicate OVE devices may be implanted without supplemental fixation.

Conclusion:

The following information summarizes the characteristics of the Solitaire-C Cervical Spacer and its predicates.

- The intended use for the subject Solitaire-C device is similar to the indications for the other stand-alone cervical interbody devices listed as predicates.
- The sizing options for the Solitaire-C Spacer System are similar to those for the named cervical interbody fusion predicates.
- The design features of the Solitaire-C Spacer are similar to those of the named lumbar/cervical stand-alone predicates.
- The Solitaire-C Spacer is fabricated from the same materials as the named predicate devices. All of these materials have a long history of successful clinical use.
- The Solitaire-C Spacer will be provided sterile, as is the Solitaire lumbar and the C-thru spacer. The Solitaire-C will be packaged in the same manner with the same

materials as other cleared Biomet Spine spacers. The bone screws will be packaged in the same manner as the Solitaire lumbar bone screws.

- Similar instrumentation is used to implant the Solitaire-C, as well as the predicate devices.

- Mechanical testing shows that the mechanical strength of the subject device is sufficient for the intended use. A full discussion of the mechanical testing is included in Section 18.

In conclusion, the subject Solitaire-C device is substantially equivalent to the named predicate spacer devices. The mechanical testing provided in Section 18 and the supporting information included in this section sufficiently demonstrates the substantial equivalence of the Solitaire-C device to its predicates. Based on this information, the Solitaire-C Spacer System does not raise any new issues regarding safety or efficacy.

Substantial Equivalence Table

Device	Solitaire-C	Solitaire Lumbar	Coalition	AVS Anchor-C	Synthes Zero-P	C-Thru Spacer
Manufacturer						
	Biomet Spine	Biomet Spine	Globus Medical	Stryker Spine	Synthes Spine	Biomet Spine
Device Information						
510(k) Number	Subject	K081395 K093629	K083389	K102606	K072981 K093762	K092336
Product Codes	OVE	OVD	OVE	OVE	OVE	ODP/MQP
Intended Use						
Stand-alone cervical interbody fusion	√	Lumbar stand-alone	√	√	√	Cervical interbody with supplemental fixation
Material						
	(b)(4) CCI [redacted]					
Design						
Styles						
Heights						
Footprints (mm) Width x Depth						
Bone Screws						
Locking Mechanism						
Operational Principle						
Stand-alone Spacer						
Use with autograft						

([redacted]

Attachment 12-1

Predicate Device Information

- Solitaire PEEK Anterior Spinal System (Biomet Spine- K081395, K093629)
- Coalition Spacer (Globus Medical – K083389)
- AVS Anchor-C Spacer (Stryker Spine – K102606)
- Synthes Zero-P Cervical Spacer (Synthes Spine – K072981, K093762)
- C-Thru Spacer System (Biomet Spine – K092336)
- Expandable PEEK Spacer (Biomet Spine - K082406)

Predicates cited in Mechanical Testing Section 18:

- Uniplate Anterior Cervical Plating System (DePuy Spine – K042544)
- SpineLink Anterior Cervical Spinal System (Biomet Spine – K973923)
- Synthes Cervical Spine Locking Plate (Synthes Spine – K945700)

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

SEP 12 2011

Biomet Spine
% Ms. Vivian Kelly, MS, RAC
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, NJ 07054

Re: K081395
Trade/Device Name: Solitaire™ PEEK-Optima® Anterior Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVD
Dated: May 12, 2008
Received: May 19, 2008

Dear Ms. Kelly:

This letter corrects our substantially equivalent letter of June 25, 2008.

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 (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.

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 Surveiilance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K081395

Device Name: Solitaire™ PEEK-Optima® Anterior Spinal System

Indications for Use:
The Solitaire™ PEEK-Optima® Anterior Spinal System is designed for use with autograft and is indicated for stand-alone intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bressler for MKM

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K081395

BIOMET SPINE

MAR - 9 2010

510(k) Summary

Preparation Date:	November 20, 2009
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Vivian Kelly, MS, RAC Phone: 973-299-9300 Fax: 973-257-0232
Trade name:	Solitaire™ and Solitaire™ PEEK Anterior Spinal System with Solitaire™ Osteotite® Screws
Common Name:	Non-cervical spinal spacer
Classification Name:	Intervertebral fusion device, 21 CFR §888.3080 Spinal Intervertebral Body Fixation Orthosis, 21 CFR § 888.3060
Device Panel /Product Code:	Orthopedic MAX & MQP

Device Description:

The Solitaire™ Osseotite® Screws are used with the spacers in the Solitaire™ and Solitaire™ PEEK Anterior Spinal System. The screws are fabricated from Titanium alloy and are acid etched to create a roughened surface.

Indications for Use:

The Solitaire™ and Solitaire™ PEEK Anterior Spinal System is designed for use with autograft and is indicated for stand-alone intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Additionally, the Solitaire™ Anterior Spinal System is indicated for use in the thoracolumbar spine (i.e., T10 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Solitaire System is also indicated for treating fractures of the thoracic and lumbar spine. The Solitaire System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

Summary of Technologies:

The technological characteristics such as material, design and sizing of the Solitaire™ Osseotite® Screws in the Solitaire™ and Solitaire™ PEEK Anterior Spinal System are the same as, or similar to, the predicate devices.

Performance Testing:

Mechanical testing demonstrates that the Solitaire™ Osseotite® Screws when used with the spacers in the Solitaire™ and Solitaire™ PEEK Anterior Spinal System are substantially equivalent to other spacers currently on the market and is adequate for its intended use. Although animal data is not necessarily indicative of human clinical outcomes, animal testing has demonstrated that the roughened surface area of the screw increases osseointegration and enhances screw fixation strength in the spine in a healthy sheep model.

Substantial Equivalence:

The Solitaire™ Osseotite® Screws when used with the spacers in the Solitaire™ and Solitaire™ PEEK Anterior Spinal System are substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. Examples of predicate intervertebral body fusion devices and vertebral replacement devices include the Solitaire™ and Solitaire™ PEEK (K022143, K062810, K081501 & K081395) from Biomet Spine as well as Biomet Trauma's Acid Etched Lag Screws (K070955) and the BioDrive® Cannulated Screw System (K082874) as predicates for the proprietary Osseotite® process.

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

MAR - 9 2010

Biomet Spine
% Ms. Vivian Kelly, MS, RAC
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K093629
Trade/Device Name: Solitaire™ and Solitaire™ PEEK Anterior Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: February 24, 2010
Received: February 25, 2010

Dear Ms. Kelly:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093629

Device Name: Solitaire™ and Solitaire™ PEEK Anterior Spinal System

Indications for Use:

The Solitaire™ and Solitaire™ PEEK Anterior Spinal System is designed for use with autograft and is indicated for stand-alone intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Additionally, the Solitaire™ Anterior Spinal System is indicated for use in the thoracolumbar spine (i.e., T10 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Solitaire System is also indicated for treating fractures of the thoracic and lumbar spine. The Solitaire System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093629

510(k) SUMMARY: COALITION™ SPACER

MAR 2 6 2009

Company: Globus Medical Inc.
2560 General Armistead Ave.
Audubon, PA 19403
(610) 415-9000

Contact: Kelly J. Baker, Ph.D
Director, Clinical Affairs & Regulatory

Device Name: COALITION™ Spacer

Classification: Product Code ODP. Class II.
21 CFR §888.3080 Intervertebral body fusion device.

Predicate(s): PATRIOT™ Cervical Spacer (Colonial™ ACDF Spacer) K072991 and other legally marketed devices.

Device Description:
The COALITION™ Spacer is a stand-alone cervical interbody fusion device used to provide structural stability in skeletally mature individuals following discectomy. The spacers are available in various heights and geometric options to fit the anatomical needs of a wide variety of patients. Protrusions on the superior and inferior surfaces of each device grip the endplates of the adjacent vertebrae to aid in expulsion resistance. Screws are inserted through the anterior titanium portion of the implant into adjacent vertebral bodies for bony fixation. The spacer is to be filled with autogenous bone graft material.

The COALITION™ Spacer is made from radiolucent polymer, with titanium alloy or tantalum markers, as specified in ASTM F2026, F136, F1295, and F560. The anterior portion of the implant and the mating screws are manufactured from titanium alloy, as specified in ASTM F136 and F1295.

Intended Use:
The COALITION™ Spacer is a stand-alone interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The COALITION™ Spacer is to be filled with autogenous bone graft material, and is to be used with two titanium alloy screws which accompany the implant.

Basis for Substantial Equivalence:
The COALITION™ Spacer has been evaluated in accordance with the "Class II Special Controls Guidance Document: Intervertebral Fusion Device", June 12, 2007 and have been found to meet the criteria set forth in the guidance document in terms of indications, design, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Globus Medical, Inc.
% Kelly Baker, Ph.D
Director, Clinical Affairs & Regulatory
2560 General Armistead Avenue
Audubon, Pennsylvania

MAR 2 6 2009

Re: K083389
Trade/Device Name: COALITION™ Spacer
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP
Dated: March 23, 2009
Received: March 24, 2009

Dear Dr. Baker:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K083389

Device Name: COALITION™ Spacer

Indications:

The COALITION™ Spacer is a stand-alone interbody fusion device intended for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3-T1) at one level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. The COALITION™ Spacer is to be filled with autogenous bone graft material, and is to be used with two titanium alloy screws which accompany the implant.

Prescription Use X OR Over-The-Counter Use___
(Per 21 CFR §801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K083389

K102606

APR 2 2 2011

510(k) Summary: AVS® Anchor-C Cervical Cage System	
Submitter:	Stryker Spine 2 Pearl Court Allendale, New Jersey 07401
Contact Person	Ms. Kimberly Lane Sr. Regulatory Affairs Specialist Phone: 201-760-8215 Fax: 201-760-8415 Email: kimberly.lane@stryker.com
Date Prepared	April 19, 2011
Trade Name	AVS® Anchor-C Cervical Cage System
Proposed Class	Class II
Classification Name and Number	Intervertebral body fusion device, 21 CFR 888.3080
Product Code	ODP
Predicate Devices	The AVS® Anchor-C Cervical Cage System was shown to be substantially equivalent to the devices listed below: • LDR *MC+*, 510(k) # K091088 • Surgicraft *STALIF C*, 510(k) #K072415 • Depuy *Bengal* #K081917 • Spinal Elements *Crystal* #K073351 • Zimmer *BAK/C* # P980048 • Medtronic *AFFINITY* #P000028
Device Description	The AVS® Anchor-C Cervical Cage is a hollow, rectangular-shaped PEEK Optima® LT1 (per ASTM F2026) cage assembled to a titanium alloy Ti6Al4V (per ASTM F136 and ISO 5832-3) plate and has one tantalum marker (per ASTM F560). It is intended for use as an interbody fusion device and is offered in a variety of heights, footprints, and lordotic angles to adapt to varying patient anatomies. The PEEK Optima® LT1 cage

sheet 1 of 3

510(k) Summary: AVS® Anchor-C Cervical Cage System	
	portion consists of one closed pocket for graft containment and has serrations on the superior and inferior surfaces of the cage. The implant is designed to be used exclusively with the internal supplemental fixation provided (AVS® Anchor-C Fixation Screws). The AVS® Anchor-C Fixation Screws are constructed from titanium alloy Ti6Al4V (per ASTM F136 and ISO 5832-3) and possess clips (also constructed from titanium alloy Ti6Al4V per ASTM F136 and ISO 5832-3) that mate with internal features located within the AVS® Anchor-C Cervical Cage. Once fully seated into the holes, the screws are designed to lock into the titanium plate.
Intended Use	The Stryker Spine AVS® Anchor-C Cervical Cage System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The AVS® Anchor-C Cervical Cage is to be used with autogenous bone graft and implanted via an open, anterior approach. The AVS® Anchor-C Cervical Cage must be used with the internal screw fixation provided by AVS® Anchor-C Fixation Screws. This cervical device is to be used in patients who have had six weeks of non-operative treatment.
Summary of the Technological Characteristics	The subject AVS® Anchor-C implant system and the predicates share similar design features: • Graft windows for packing autogenous bone

sheet 2 of 3

510(k) Summary: AVS® Anchor-C Cervical Cage System	
	• Serrations on the superior and inferior surfaces • Comparable heights, widths, depths, and lordotic angles Testing in compliance with FDA's June 12, 2007 "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was performed for the AVS® Anchor-C implant system and demonstrated substantially equivalent performance to the identified predicate device systems. The following mechanical tests were performed: • Static Compression (per ASTM F2077) • Dynamic Compression (per ASTM F2077) • Static Compression Shear (per ASTM F2077) • Dynamic Compression Shear (per ASTM F2077) • Static Torsion (per ASTM F2077) • Dynamic Torsion (per ASTM F2077) • Expulsion (per ASTM F04-25-02-02 Draft) • Subsidence (per ASTM F2267)

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

Stryker Spine
% Ms. Kimberly Lane
Senior Regulatory Affairs Specialist
2 Pearl Court
Allendale, New Jersey 07401

APR 2 2 2011

Re: K102606
Trade/Device Name: Stryker Spine AVS® Anchor-C Cervical Cage System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP
Dated: April 4, 2011
Received: April 5, 2011

Dear Ms. Lane:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K K102606

Device Name: Stryker Spine AVS® Anchor-C Cervical Cage System

Indications For Use:

The Stryker Spine AVS® Anchor-C Cervical Cage System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The AVS® Anchor-C Cervical Cage is to be used with autogenous bone graft and implanted via an open, anterior approach.

The AVS® Anchor-C Cervical Cage must be used with the internal screw fixation provided by AVS® Anchor-C Fixation Screws. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102606

K072981

FEB 11

510(k) Summary

510(k) Summary	
Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Susan Lewandowski Manager, Spine Regulatory Affairs Telephone: 610-719-5712 Facsimile: 610-719-5102 Email: lewandowski.susan@synthes.com
Date Prepared:	January 15, 2008
Trade Name:	Synthes Zero-P
Classification:	21 CFR 888.3080 – Intervertebral fusion device Class II (special controls) Orthopaedic and Rehabilitation Devices Panel (87) Product Code ODP (Intervertebral Fusion Device with Bone Graft, Cervical)
Predicates:	P980048 BAK/Cervical Interbody Fusion Device (Sulzer Spine-Tech) P000028 Affinity Anterior Cervical Cage System (Medtronic Vascular) K072253 SynFix-LR (Synthes Spine) K011037 Vertebral Spacer (Synthes Spine)
Device Description:	The Synthes Zero-P is a radiolucent and radiopaque cervical intervertebral body fusion device. The Zero-P is composed of a PEEK spacer with a radiopaque marker, a titanium alloy anterior plate and screws. The screws are inserted through the plate into the adjacent vertebral bodies. The screws lock securely to the plate using a tapered-thread locking mechanism. The Synthes Zero-P is available as assembled components in various heights and geometries to suit individual pathology and anatomical conditions.
Intended Use/ Indications for Use:	The Synthes Zero-P is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the spacer component of the Synthes Zero-P should be packed with autogenous bone graft and implanted via an anterior approach.

Comparison of the device to predicate device(s):	The Synthes Zero-P is substantially equivalent to the predicates in design, function, material, and intended use.
Performance Date (Nonclinical and/or Clinical):	*Non-Clinical Performance and Conclusions:* Bench testing results demonstrate that the Synthes Zero-P is substantially equivalent to the predicate devices. *Clinical Performance and Conclusions:* Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2008

Synthes Spine
% Ms. Stacey Bonnell
Associate Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

Re: K072981
Trade/Device Name: Synthes Zero-P
Regulation Number: 21 CFR 888.3080
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: ODP
Dated: January 15, 2008
Received: January 16, 2008

Dear Ms. Bonnell:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES® Spine

Indications for Use Statement

510(k) Number: K072981
(if known)

Device Name: Synthes Zero-P

The Synthes Zero-P is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the spacer component of the Synthes Zero-P should be packed with autogenous bone graft and implanted via an anterior approach.

Prescription Use **X** AND / OR Over-the-Counter Use
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Burns

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072981

K093762

SYNTHES® Spine

DEC 20 2010

510(k) Summary

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Amnon Talmor Regulatory Affairs Specialist Telephone: 610-719-5446 Facsimile: 610-719-5102 Email: talmor.amnon@synthes.com
Date Prepared:	November 29, 2010
Trade Name:	Synthes Zero-P
Common Name:	Intervertebral fusion device
Classification:	21 CFR 888.3080 Intervertebral fusion device Class II (special controls) Orthopaedic and Rehabilitation Devices Panel Product Code: ODP
Predicate Device:	Synthes Zero-P System is substantially equivalent to the Synthes Zero-P System (K072981).
Device Description:	The Synthes Zero-P is a radiolucent and radiopaque cervical intervertebral body fusion device. The Zero-P is composed of a PEEK (ASTM F2026) spacer with a radiopaque marker (ASTM F136-2a), a titanium alloy anterior plate and screws (ASTM F F1295). The screws are inserted through the plate into the adjacent vertebral bodies and lock securely to the plate using a tapered-thread locking mechanism. The Synthes Zero-P is available as assembled components in various heights and geometries to suit individual pathology and anatomical conditions. This line extension covers the addition of sterile screws.
Intended Use / Indications for Use:	The Synthes Zero-P is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-TI. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the spacer component of the Synthes Zero-P should be packed with autogenous bone graft and implanted via an anterior approach.
Comparison of the technological characteristics of the device to the	The Synthes Zero-P device is substantially equivalent to its predicates in indications, fundamental scientific technology, material, mechanical performance, surgical technique, screw fixation and design.

SYNTHES®
Spine

predicate device:	
Performance Data (Nonclinical and/or Clinical)	Mechanical and clinical data and conclusions were not needed for this device. The enclosed information demonstrates the subject device is as safe, effective and performs as well as the predicate.

Pg 2 of 2

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

Synthes Spine
% Mr. Amnon Talmor
Spine Regulatory Affairs Specialist
1302 Wrights Lane East
West Chester, Pennsylvania 19380

DEC 2 0 2010

Re: K093762
Trade/Device Name: Synthes Zero-P
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: ODP
Dated: November 29, 2010
Received: November 30, 2010

Dear Mr. Talmor:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number: K093762
(if known)

DEC 2 0 2010

Device Name: **Synthes Zero-P**

The Synthes Zero-P is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-TI. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the spacer component of the Synthes Zero-P should be packed with autogenous bone graft and implanted via an anterior approach.

Prescription Use **X** (21 CFR 801 Subpart D)	AND / OR	Over-the-Counter Use (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093762

Pg 1 of 1

 K092336

BIOMET SPINE

510(k) Summary

Preparation Date:	July 31, 2009
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Vivian Kelly Phone: 973-299-9300 Fax: 973-257-0232
Trade name:	C-Thru™ Anterior Spinal System
Common Name:	Cervical and non-cervical spinal spacer
Classification Name:	Intervertebral fusion device, 21 CFR §888.3080 Spinal Intervertebral Body Fixation Orthosis, 21 CFR § 888.3060
Device Panel /Product Code:	Orthopedic ODP & MQP

OCT 15 2009

Device Description:

The C-Thru™ Anterior Spinal System consists of a spacer constructed of medical grade Polyetheretherketone (PEEK) with tantalum radiographic markers for spinal applications.

Indications for Use:

The C-Thru™ Anterior Spinal System is indicated for vertebral body replacement and intervertebral fusion. When used as a vertebral body replacement device, the C-Thru™ Spacers are indicated for use in the thoracolumbar spine (i.e., T1 to L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The C-Thru™ Spacers are also indicated for partial vertebral body replacement for the treatment of fractures of the thoracic and lumbar spine. The C-Thru™ Spacers are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

When used as a cervical intervertebral fusion device, the C-Thru™ Anterior Spinal System is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. The C-Thru™ Spacers are intended for use with supplemental fixation and autogenous bone graft to facilitate the fusion.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the C-Thru™ Spacer is the same as, or similar to, the predicate devices.

Substantial Equivalence:

The C-Thru™ Anterior Spinal System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. An example of a predicate intervertebral body fusion device distributed for the similar indications includes the Expandable PEEK Implant (K040928 and K082406), and Novel® Spinal Spacer System (K081730), while the Small Stature Spacer System (K063393) has similar design features. Based upon the mechanical testing, C-Thru™ Anterior Spinal System is substantially equivalent for its intended use to other spacers currently on the market.

~~Page 5-2~~ pg 1 of 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Biomet Spine
% Ms. Vivian Kelly
100 Interpace Parkway
Parsippany, New Jersey 07054

OCT 1 5 2009

Re: K092336
Trade/Device Name: C-Thru™ Anterior Spinal System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: ODP, MQP
Dated: July 31, 2009
Received: August 4, 2009

Dear Ms. Kelly:

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.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092336

Device Name: C-Thru™ Anterior Spinal System

Indications for Use:

The C-Thru™ Anterior Spinal System is indicated for vertebral body replacement and intervertebral fusion. When used as a vertebral body replacement device, the C-Thru™ Spacers are indicated for use in the thoracolumbar spine (i.e., T1 to L5) for partial replacement of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The C-Thru™ Spacers are also indicated for partial vertebral body replacement for the treatment of fractures of the thoracic and lumbar spine. The C-Thru™ Spacers are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period.

When used as a cervical intervertebral fusion device, the C-Thru Anterior Spinal System is intended for spinal fusion procedures at one level (C2 to T1) in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. The C-Thru Spacers are intended for use with supplemental fixation and autogenous bone graft to facilitate the fusion.

Prescription Use **X**
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K092336

~~Page 4 2~~
pg 1 of 1

K082406

BIOMET SPINE

510(k) Summary

JAN 14 2009

Preparation Date:	August 20, 2008
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Vivian Kelly Phone: 973-299-9300 Fax: 973-257-0232
Trade name:	Expandable PEEK-OPTIMA® Implant
Common Name:	Non-cervical spinal implant
Classification Name:	Intervertebral fusion device, 21 CFR §888.3080 Spinal Intervertebral Body Fixation Orthosis, 21 CFR § 888.3060
Device Panel /Product Code:	Orthopedic MAX & MQP

Device Description:

The Expandable PEEK-OPTIMA® Implant is a rectangular, expandable device constructed of medical grade Polyetheretherketone (PEEK), for spinal applications.

Indications for Use:

The Expandable PEEK-OPTIMA® Implant is indicated for vertebral body replacement and intervertebral fusion. When used for vertebral body replacement, The Expandable PEEK-OPTIMA® Implant is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Expandable PEEK-OPTIMA® Implant is also indicated for treating fractures of the thoracic and lumbar spine. The Expandable PEEK-OPTIMA® Implant is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

As an intervertebral body fusion device, the Expandable PEEK-OPTIMA® Implant is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The Expandable PEEK-OPTIMA® Implant is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the Expandable PEEK-OPTIMA® Implant are the same as, or similar to, the predicate devices.

Substantial Equivalence:

The Expandable PEEK-OPTIMA® Implant is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. An example of a predicate intervertebral body fusion device distributed for the similar indications includes the PEEK-OPTIMA® ALIF Spacer (K081636) and the Expandable PEEK-OPTIMA® Implant has similar design features. Based upon the mechanical testing, the Expandable PEEK-OPTIMA® Implant is substantially equivalent for its intended use to other spacers currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Spine
% Ms. Vivian Kelly, MS, RAC
Regulatory Affairs Project Manager
100 Interpace Parkway
Parsippany, New Jersey 07054

JAN 14 2009

Re: K082406
Trade/Device Name: Expandable PEEK-OPTIMA® Implant
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX, MQP
Dated: January 5, 2009
Received: January 6, 2009

Dear Ms. Kelly:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K082406

Device Name:

Indications for Use:

The Expandable PEEK-OPTIMA® Implant is indicated for vertebral body replacement and intervertebral fusion. When used for vertebral body replacement, The Expandable PEEK-OPTIMA® Implant is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Expandable PEEK-OPTIMA® Implant is also indicated for treating fractures of the thoracic and lumbar spine. The Expandable PEEK-OPTIMA® Implant is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

As an intervertebral body fusion device, the Expandable PEEK-OPTIMA® Implant is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The Expandable PEEK-OPTIMA® Implant is designed for use with autograft to facilitate fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

Page 1 of 1

Page 4-2

510(k) Number K082406

X. 510(k) Summary

NOV 2 3 2004

SUBMITTER: DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02780

CONTACT PERSON: Jennifer Mooney

DATE PREPARED: September 17, 2004

CLASSIFICATION NAME: Spinal Intervertebral Body Fixation Orthosis

PROPRIETARY NAME: Uniplate Anterior Cervical Plate System

PREDICATE DEVICES: DePuy Spine Acroplate Anterior Cervical Plate System (cleared as the Top Cervical Spine Stabilization System) K914362

DEVICE DESCRIPTION: Uniplate Anterior Cervical Plate System consists of an assortment of plates and screws.

The Uniplate Anterior Cervical Plate System also contains Class 1 manual surgical instruments and cases that are considered exempt from premarket notification.

INTENDED USE: The Uniplate Anterior Cervical Plate System is intended for anterior cervical intervertebral body fixation. This system is indicated for patients in which stability is desired following anterior cervical fusion for the indications listed below. The intended levels for treatment range from C2 to T1.

Indication includes symptomatic cervical spondylosis, trauma, fracture, post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, re-operation for failed fusion, or instability following surgery for the above indications.

MATERIALS: Manufactured from ASTM F-136 implant grade titanium alloy.

K042544

PERFORMANCE DATA:

Performance data were submitted to characterize the Uniplate Anterior Cervical Plate System.

Page 2 of 2

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 3 2004

Ms. Sharon Starowicz
Director, Regulatory Affairs
DePuy Spine, Inc.
325 Paramount Drive
Raynham, Massachusetts 02767

Re: K042544
Trade/Device Name: Uniplate Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: September 17, 2004
Received: September 20, 2004

Dear Ms. Starowicz:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. Indications for Use

510(k) Number (if known): K042544

Device Name: Uniplate Anterior Cervical Plate System

Indications For Use:

The Uniplate Anterior Cervical Plate System is intended for anterior cervical intervertebral body fixation. This system is indicated for patients in which stability is desired following anterior cervical fusion for the indications listed below. The intended levels for treatment range from C2 to T1.

Indication includes symptomatic cervical spondylosis, trauma, fracture, post-traumatic kyphosis or lordosis, tumor, degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), spinal stenosis, re-operation for failed fusion, or instability following surgery for the above indications.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

Page 1 of ____

510(k) Number K042544

JAN 3 1998

510(k) Summary of Safety & Effectiveness

K973923

This 510(k) Summary of Safety and Effectiveness for the EBI SpineLink™ Anterior Cervical Spinal System is provided as required per Section 513(I)(3) of the Food, Drug, and Cosmetic Act.

1. **Submitter:** Electro-Biology, Inc.
6 Upper Pond Road
Parsippany, NJ 07054

Contact Person: Jon Caparotta
Telephone: (973) 299-9022

Date prepared: October 14, 1997

2. **Proprietary Name:** EBI SpineLink™ Anterior Cervical Spinal System
Common Name: Spinal Fixation Device
Classification Names: Spinal Intervertebral Body Fixation Orthosis

3. **Predicate or legally marketed devices that are substantially equivalent:**
   - The EBI Anterior Cervical Spine System - Electro-Biology, Inc.
   - The Anterior Cervical Plate System - Sofamor Danek
   - The Synthes® Cervical Spine Locking Plate - Synthes® Spine

4. **Description of the device:** The EBI SpineLink™ Anterior Cervical Spinal System is an anterior cervical spinal fixation system.

5. **Intended Use:** The EBI SpineLink™ Anterior Cervical Spinal System is intended for anterior interbody screw fixation of the cervical spine at levels C3-C7. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

6. **Materials:** The components of the system are manufactured from Ti-6Al-4V ELI per ASTM F136.

7. **Comparison of the technological characteristics of the device to predicate devices:** There are no significant differences between EBI SpineLink™ Anterior Cervical Spinal System and other currently marketed spinal systems. The EBI SpineLink™ Anterior Cervical Spinal System uses links instead of plates for the same intended use in a similar construct. It is substantially equivalent* to the predicate devices in regards to intended use, materials and function. Bench testing comparing the system to a predicate system demonstrated that the device complies with applicable standards and meets all of its functional requirements.

*Any statement made in conjunction with this submission regarding a determination of substantial equivalence to any other product is intended only to relate to whether the product can be lawfully marketed without pre-market approval or reclassification and is not intended to be interpreted as an admission or any other type of evidence in patent infringement litigation. [Establishment Registration and Premarket Notification Procedures, Final Regulation. Preamble. August 23. 1977. FR 42520 (Docket No. 76N-0355.)]

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 1998

Mr. Jon Caparotta
Manager, Regulatory Affairs
Electro-Biology, Inc. (EBI)
6 Upper Pond Road
Parsippany, New Jersey 07054

Re: K973923
EBI SpineLink™ Anterior Cervical Spinal System
Regulatory Class: II
Product Code: KWQ
Dated: October 14, 1997
Received: October 15, 1997

Dear Mr. Caparotta:

We have reviewed your Section 510(k) notification of intent to market the device system referenced above and we have determined the device system is substantially equivalent (for the indications for use stated in the enclosure) to device systems marketed in interstate commerce prior to May 28, 1976 or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market your device system subject to the general controls provisions of the Act and the limitations identified below.

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. Note that labeling or otherwise promoting this device system for pedicular screw fixation/attachment would cause the device system to be adulterated under 501(f)(1) of the Act.

FDA identifies that any device system, if intended for use in pedicular screw fixation/attachment, except for some limited indications, would be found not substantially equivalent and would be a class III device under Section 513(f) of the Act. Class III devices are required to have an approved premarket approval (PMA) application prior to marketing. Accordingly:

1. You may not label or in any way promote this device system for pedicular screw attachment to, or fixation of the cervical, thoracic or lumbar vertebral column. Therefore, in order to prevent off-label promotion, the package insert must include the following statement, "**WARNING:** This device system is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.";

2. All labeling for this device system, including the package label, must state that there are labeling limitations. The package insert must prominently state that the device system is intended for the specific use(s) described in the enclosure only; and

3. Pedicular screw fixation/attachment to the cervical, thoracic or lumbar vertebral column, except for limited indications, of any device system is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulations under 21 CFR, Part 812. All users of the device system for pedicular screw fixation/attachment must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) prior to conducting an investigation.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

FDA advises that the use of the subject device system and/or device components with any other device components but those identified in this 510(k) would require submission of a new 510(k) providing documentation of design, material, and labeling compatibility between the device components. Mechanical testing of a spinal system consisting of the subject device components and other device components, whether yours or other manufacturers', may also be required.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use:

The EBI SpineLink™ Anterior Cervical Spinal System is intended for anterior interbody screw fixation of the cervical spine at levels C3-C7. The System is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defined as kyphosis, lordosis, or scoliosis), pseudarthrosis, and/or failed previous fusions.

WARNING: This device is not approved for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K073923

Quick Links: Skip to main page content Skip to Search Skip to Topics Menu Skip to Common Links

510(k) Premarket Notification

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search Back To Search Results

Device Classification Name	Appliance, Fixation, Spinal Intervertebral Body
510(K) Number	K945700
Device Name	SYNTHES (USA) ANTERIOR CERVICAL VERTEBRAE PLATE SYSTEM
Applicant	SYNTHES (USA) 1690 Russell Rd. P.O. Box 1766 Paoli, PA 19301
Contact	Diane T Brown
Regulation Number	888.3060
Classification Product Code	KWQ
Date Received	11/16/1994
Decision Date	07/20/1995
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Orthopedic
Review Advisory Committee	Orthopedic
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

Section 13

Proposed Labeling

Samples of the following proposed labeling are attached:

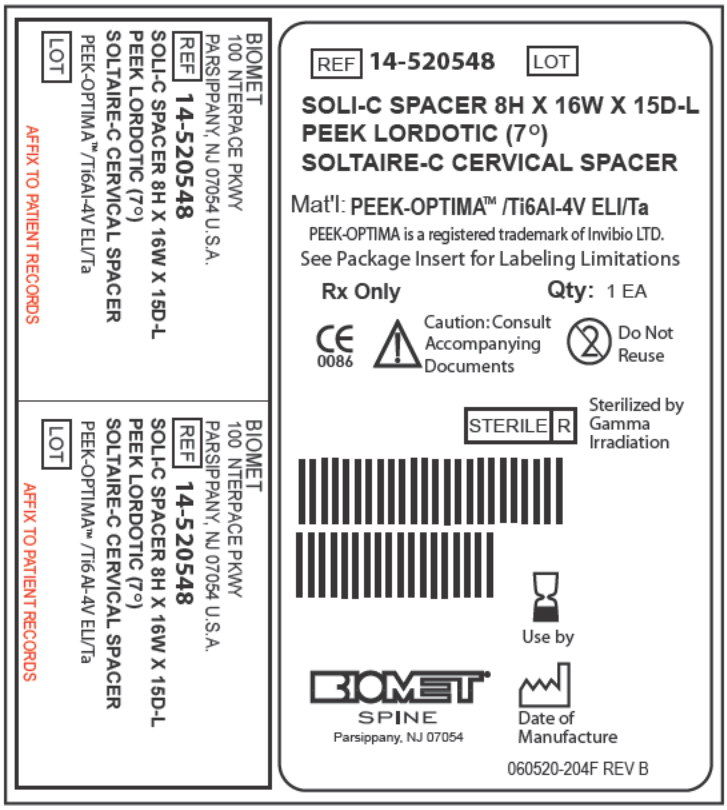
Attachment 13-1 Draft carton labels for Solitaire-C implants

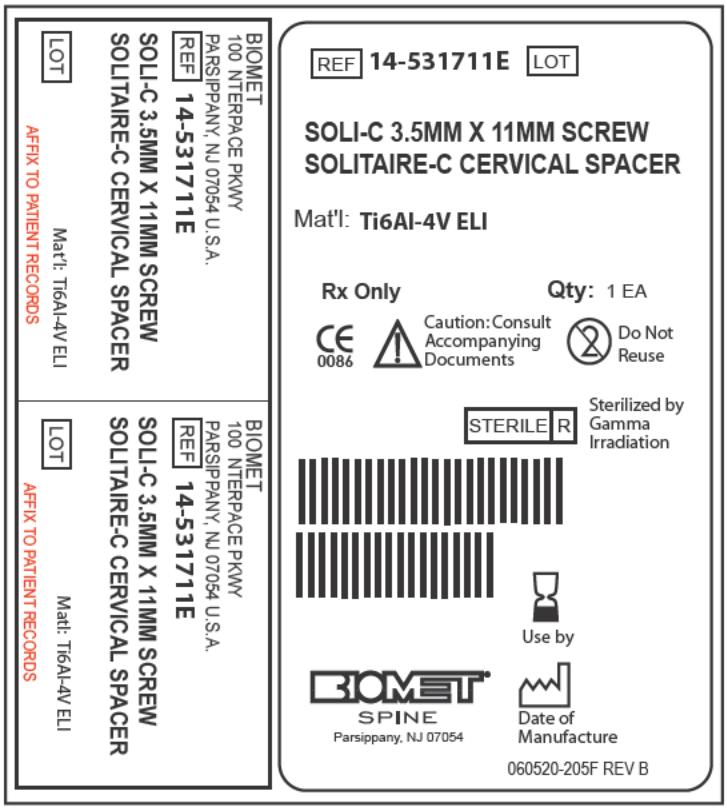
Attachment 13-2 Draft Instructions for Use for Solitaire-C implants

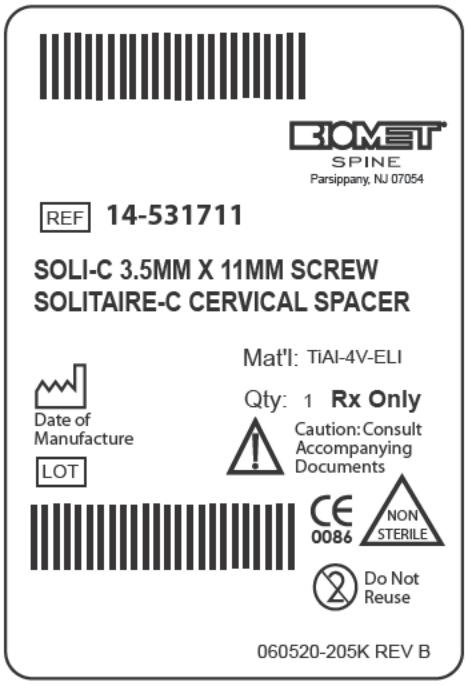
Attachment 13-3 Draft Surgical Technique

Attachment 13-4 Draft carton label for reusable instruments

Attachment 13-5 Draft Instructions for Use for Reusable Surgical Instruments







Attachment 13-2

Draft Package Insert

Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054

Solitaire®-C Cervical Spacer System

060582-00
Date: 2011-12

Attention Operating Surgeon

DEVICE DESCRIPTION

The Solitaire®-C Cervical Spacer System consists of spacers and bone screws for stand-alone cervical intervertebral body fusion. The Solitaire®-C spacer will be available in a variety of sizes, angles and footprints to accommodate variations in patient anatomy. The Solitaire-C dimensions are designed to accommodate skeletally mature patients.

The main PEEK body is C-shaped, with walls to provide structural integrity. The top and bottom walls have a macrotextured surface to grip into the endplates of the vertebral body to reduce implant migration, while providing optimum surface contact with the vertebral body. The spacer is available in two styles- lordotic and parallel. The lordotic style will have incorporate 7° of lordosis, while the parallel style will have flat superior and inferior surfaces.

The titanium faceplate is located on the anterior aspect of the spacer implant. The faceplate has two threaded holes for bone screw interference and accepts the Solitaire®-C bone screws. The titanium alloy band sits in a groove on the exterior surface of the main PEEK body. This band attaches the PEEK spacer body to the titanium faceplate, and is designed to provide stability and strength to the spacer, as well as to aid in visualization of the implant on X-ray or fluoroscopy. Tantalum markers are present in the PEEK body to aid in visualization of the implant.

Bone screws will be available in two diameters and multiple lengths.

MATERIALS

The Solitaire®-C Cervical Spacer System is fabricated from the following materials:

- PEEK Optima LT1 (provided by Invibio, Ltd.) per ASTM specification F-2026 (spacer body)
- Titanium alloy (Ti-6Al-4V-ELI) per ASTM specification F-136 (Titanium faceplate, band and bone screws)
- Unalloyed tantalum per ASTM specification F-560 (markers in spacer body)

INTENDED USE

The Solitaire®-C Cervical Spacer System consists of spacers (with bone screws) of various sizes, angles and footprints, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion procedures. The screws protrude through the spacer portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The large hollow geometry of the implant allows it to be packed with autogenous bone graft to facilitate fusion. The implant is contained within the excised disc space, and does not protrude past the anterior wall of the vertebral body. This feature is designed to reduce soft tissue irritation. The Solitaire-C is designed to address the risk of adjacent level ossification by remaining 5mm or greater from the adjacent level disc spaces. The Solitaire®-C incorporates integrated fixation, so supplemental fixation is not required. The Solitaire®-C Cervical Spacer System is intended to be implanted with Solitaire®-C bone screws.

INDICATIONS FOR USE

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer System is to be used with autograft and implanted via an anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

INSTRUCTIONS FOR USE

Caution: The Solitaire-C Cervical Spacer System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgical techniques. Refer to the Solitaire-C Surgical Technique for complete Instructions-for-Use. For a copy of the surgical technique, please contact your sales representative at the address provided below.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection, systemic, spinal or localized
2. Morbid obesity
3. Signs of local inflammation
4. Fever or leukocytosis
5. Metal sensitivity/allergies to the implant materials
6. any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
7. Grossly distorted anatomy due to congenital abnormalities
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft)
9. Any case not needing a bone graft and fusion or where fracture healing is not required
10. Any patient having inadequate tissue coverage over the operative site

11. Any patient unwilling to cooperate with the postoperative instructions
12. Prior fusion at the level(s) to be treated.

WARNINGS
The surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.

2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.

3. All instruments must be cleaned and sterilized prior to surgery.

4. Do not reuse implants/devices. While an implant/device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant/device.

5. Do not treat patients with implants/devices that have been even momentarily placed in or used on a different patient.

6. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.

7. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

8. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

9. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system.

9. The Solitaire-C Cervical Spacer System has not been evaluated for safety and Compatibility in the MR environment. The Solitaire-C Cervical Spacer System has not been tested for heating or migration in the MR environment.

PRECAUTIONS
Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.

2. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.

3. Biomet Spine implants should not be used with implants or instruments from another manufacturer for reasons of metallurgy, mechanics and design.

Intraoperative:
1. Any instruction manuals should be carefully followed.

2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions. Bone grafts must be placed in the area to be fused.

Postoperative:
1. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

2. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components is complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented, or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.

3. To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.

4. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the Solitaire-C

Cervical Spacer System components should ever be reused under any circumstances.

POTENTIAL ADVERSE EFFECTS AND COMPLICATIONS

Possible adverse effects include, but are not limited to:
1. Bending, loosening, migration or fracture of the implants or instruments
2. Loss of fixation
3. Sensitivity to a metallic foreign body, including possible tumor formation
4. Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications
5. Nonunion or delayed union
6. Infection
7. Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage
8. Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium
9. Pain or discomfort at the operative and/or bone graft donor site
10. Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level or surgery (fracture of the vertebra)
11. Hemorrhage of blood vessels and/or hematomas
12. Misalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height
13. Bursitis
14. Inability to resume activities of normal daily living
15. Reoperation
16. Death

STERILIZATION

Unless supplied sterile, devices must be sterilized prior to surgical use. Product provided sterile is sterilized by exposure to a minimum dose of 2.5 Megarads (25kGy) gamma radiation. Where specified, do not use implants after expiration date. Re-sterilization is not recommended.

For product supplied non-sterile, all packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended:

U.S. Sterilization Parameters:
Cycle: Pre-vacuum Steam
Temperature: 270°F/132°C
Time: 4 minutes
Drying Time: 30 minutes
Note: Allow for cooling

FDA cleared sterilization wraps should be used to maintain sterility after processing.

European Union Sterilization Parameters:

Cycle: Pre-vacuum Steam
Temperature: 275°F/135°C
Time: 3 minutes
Drying Time: 30 minutes
Note: Allow for cooling

Biomet does not recommend stacking of trays during the sterilization process.
Individuals or hospitals not using the recommended method, temperature, and time are advised to validate any alternative methods or cycles using an approved method or standard.

Additional information about instrumentation (including assembly/disassembly) may be found in the system surgical technique, reference guide and/or associated package inserts.

Refer to the Biomet Non-sterile Instrument IFU for full processing instructions for instruments.

CAUTION
Federal (USA) law restricts these devices to sale by or on the order of a licensed physician.

INFORMATION
For further information, please contact the Customer Service Department at:

Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
(973) 299 9300, (800) 526 2579
www.biometspine.com

Key to label symbols:

By prescription only

Do not reuse

Date of Manufacture

Caution, consult accompanying documents

Batch Code

Sterilized using Gamma radiation

See Package Insert for Labeling Limitations

Attachment 13-3
Draft Surgical Technique
Solitaire-C Cervical Spacer System

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer System is to be used with autograft and implanted via an anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

1. Surgical Approach

The patient is positioned supine on the operative table with a folded towel beneath the intrascapular region to maintain the head in slight extension. The use of a head halter attached to an outrigger for traction may be helpful. If fluoroscopy is used, it can be utilized at this point to confirm positioning and check that the desired vertebral levels can be adequately visualized.

A standard anterior approach to the mid and lower cervical spine is utilized. This can be through one of several incisions with the exposure typically medial to the carotid sheath and lateral to the trachea and esophagus. Adequate fascial plane release is important for optimal exposure. After identification of the disc space through intraoperative confirmation of levels with x-ray, preparation for anterior interbody fusion is begun.

2. Vertebral Body Distraction And Discectomy

The Distraction Pins are loaded into the Distraction Pin/Tack Inserter by pulling back on the locking sleeve, sliding the Pin into place and releasing the sleeve. Place one distraction pin in the vertebral body superior to the affected level and the other distraction pin in the vertebral body inferior to the affected level. The Pin Distractor is placed over the Pins and opened as needed. The discectomy and resection of osteophytes is now completed, and further preparation of the interbody fusion bed is performed as indicated.

3. Preparing the Endplates and Sizing Disc Space

Rasps and Trials are double sided to add efficiency in utilizing different sizes before committing to a certain disc height. These instruments correspond to the implant footprints and are available in 5-12mm heights in 1mm increments similar to the implants. Please note that while trials and rasps contain a 5mm height, that height is not available in an implant.

After determining which implant footprint the surgeon would like to use, use the corresponding rasps and trials to prepare the endplates and size the disc space respectively.

Note that the rasps are designed so that the teeth cut on the backstroke as the instrument is being pulled away from the spinal cord. A single sided rasp can also be utilized to prepare the endplates.

When trialing, use incrementally larger sizes until a tight fit is achieved. There should be no gaps between the prepared site and trial.

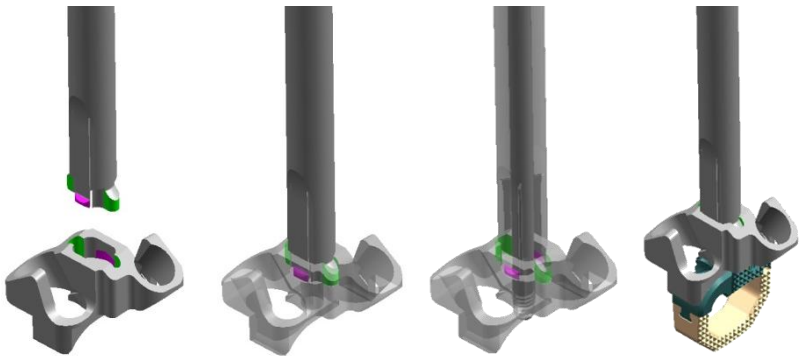
Notes: Trial and rasp heights are measured to the height of the implant. Each implant height is measured from the peaks serrations. Each rasp height is measured from the tip of the teeth.

CAUTION: Aggressive preparation of the endplate may remove excessive bone and weaken the endplate.

4. Inserter Guide Assembly

The Solitaire-C system offers inserter guides which attach to modular shaft/handles and facilitate screw hole preparation and screw insertion through the same instrument. Select the inserter guide that corresponds to the final implant size to be used. Each implant width and height has a corresponding guide tip which is color coded to match a particular spacer height.

Attach the inserter guide to the modular shaft/handle by inserting the distal tip of the modular shaft/handle into the mating connection feature on the inserter guide. Now place the inner shaft down the modular shaft/handle and turn the knob at the proximal end of the inner shaft clockwise to capture the inner shaft in the modular shaft/handle.



5. Implant Attachment

Attach the implant to the inserter guide assembly by placing the anterior aspect of the implant against the mating distal end of the inserter guide assembly. Since the implant and inserter guide are rotationally symmetric, orientation is not a concern. Turn the knob at the proximal end of the

inserter guide assembly clockwise to thread the inner shaft into the center fixation hole on the spacer.

OR tip: Confirm proper orientation of guide to implant by inserting an awl or drill with centering sleeve or driver option down one of the inserter guide tubes. The instrument should easily seat into the guide with no manipulation.

6. Implant Insertion

Impact the implant into the fusion site by striking the knob of the inserter guide assembly. Each implant contains two markers 1mm from the posterior wall of the implant that can be used as a reference when inserting and using fluoroscopy. Additionally the implant guide assemblies have stops which countersink the implant a maximum of 2mm into the disk space relative to the anterior face of the vertebral body. Release any distractors in use to ensure implant is fully engaged with endplates.

7. Screw Hole Preparation

A variety of drills, awls, and centering sleeves are available to aid in screw hole preparation and meet anatomical challenges. The following combinations are available:

	Straight Awl	**Straight Drill**	**Angled Awl**	**Angled Drill Bit which attaches to the Fixed Angle Driver**
Drill/Awl Sleeve This stand alone tube is placed directly into the inserter guide after implant insertion. Straight Awls and Drills can be used with this instrument. Both have a positive hard stop just below color- coded sleeve.	X	X		
Drill/Awl Spring Sleeve This tube is intended to be pre-attached to straight drills and awls prior to insertion into the inserter guide. Standard drills and awls have a positive hard stop just below the color coded sleeve that interacts with this guide tube.	X	X		
Tip with Malleable Shaft for Angled Drill/Awl This tip with malleable shaft can be used with any awl or drill option but is primarily used with the angled awls and angled drill bits. It is intended to be placed directly into the inserter guide prior to inserting a drill or awl. It has a malleable nitinol	X	X	X	X

handle that can be positioned to help avoid anatomical challenges. Angled drills and awls have a visible hard stop against the face of this guide. Straight drills and awls have an internal stop.				
Short Centering Tip for Angled Drill/Awl This centering tip can be used with any awl or drill option but is primarily used with the angled awls and angled drill bits. It is intended to be placed directly into the inserter guide prior to inserting a drill or awl. Angled drills and awls have a visible hard stop against the face of this guide. Straight drills and awls have an internal stop.	X	X	X	X

All awls and drills are available in 11 to 18mm lengths and are designed to be connected to an AO quick connect handle while preparing the screw hole. The standard awl, standard drill, and angled awl have color coded sleeves that match screw length to help ensure proper drill depth. Awls or drills must be used with one of the above centering sleeve options passing through the inserter guide to ensure proper drilling depth.

8. Screw Insertion

Affix the desired size screw to the desired screw driver by seating the distal tip of the driver into the hexalobe on the screw head. This is fixed via a stab-and-grab mechanism and requires no secondary tightening of the inserter into the screw. Multiple screw driver options are available. These include an auto-centering driver, driver with centering sleeve, driver with spring loaded sleeve, flexible link driver, and driver bits which attach to the fixed angle driver. (Non-retaining screw drivers that do not have a stab and grab mechanism are also available.)

9. Final Tightening

Place the screw into the appropriate screw hole through the inserter guide assembly. Insert each screw until solid engagement of the cancellous thread occurs. Repeat for the contralateral hole. Place the torque driver into the hexalobe drive of the screw and turn handle until an audible "click" is heard at approximately 15±1 in. lbs. of force. The inserter guide assembly should remain engaged during screw insertion and final tightening to serve as a counter torque.

10. Closure and Postoperative Care

A routine wound closure is then performed.

- Routine monitoring of the vital signs, and of the hemodynamic and neurologic status of the patient
- Pain medication
- NG tubes and/or Foley catheters are discontinued within 24 - 48 hours
- Diet is restricted to small amounts of liquids until return of bowel function is completed
- The patient is encouraged to ambulate as soon as possible. The individual surgeon determines activity level

- Braces are to be used at each surgeon's discretion

11. Implant Removal

Should it become necessary to remove the Solitaire-C Spacer, the following guidelines should be observed:

- Removal follows the reverse order of implantation
- Soft tissue on the anterior surface of the implant should be removed.
- Place the inner shaft into the implant remover.
- Attach the implant remover to the implant by turning the knob clockwise until tight.
- Remove the screws using a screw driver.
- Once screws are removed, remove implant from wound site. The slotted mallet or slide hammer can be used to aid in implant removal if necessary.

12. Angled Driver Bit Removal

The driver bit and drill bits placed on the fixed angle driver should be removed using the angled driver bit remover. To remove a bit, place the bit through the custom tips of the remover until the face of the tips contact the housing of the fixed angle driver. Squeeze the handles of the remover to disengage the bit.

INDICATIONS FOR USE

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer System is to be used with autograft and implanted via an anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection, systemic, spinal or localized
2. Morbid obesity
3. Signs of local inflammation
4. Fever or leukocytosis
5. Metal sensitivity/allergies to the implant materials
6. any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
7. Grossly distorted anatomy due to congenital abnormalities
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft)
9. Any case not needing a bone graft and fusion or where fracture healing is not required
10. Any patient having inadequate tissue coverage over the operative site
11. Any patient unwilling to cooperate with the postoperative instructions
12. Prior fusion at the level(s) to be treated.

WARNINGS

The surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.

2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.

3. All instruments must be cleaned and sterilized prior to surgery.

4. Do not reuse implants/devices. While an implant/device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant/device.

5. Do not treat patients with implants/devices that have been even momentarily placed in or used on a different patient.

6. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.

7. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

8. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

9. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system.

9. The Solitaire-C Cervical Spacer System has not been evaluated for safety and Compatibility in the MR environment. The Solitaire-C Cervical Spacer System has not been tested for heating or migration in the MR environment.

STERILIZATION

Unless supplied sterile, devices must be sterilized prior to surgical use. Product provided sterile is sterilized by exposure to a minimum dose of 2.5 Megarads (25kGy) gamma radiation. Where specified, do not use implants after expiration date. Re-sterilization is not recommended.

For product supplied non-sterile, all packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended:

U.S. Sterilization Parameters:
Cycle: Pre-vacuum Steam
Temperature: 270°F/132°C
Time: 4 minutes
Drying Time: 30 minutes
Note: Allow for cooling

FDA cleared sterilization wraps should be used to maintain sterility after processing.

European Union Sterilization Parameters:

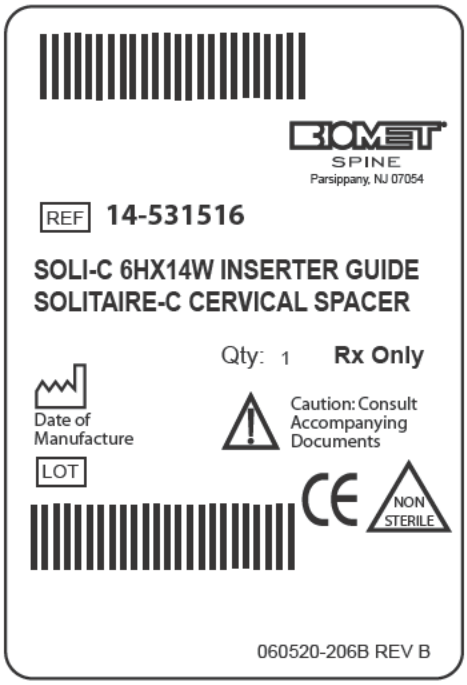
Cycle: Pre-vacuum Steam
Temperature: 275°F/135°C
Time: 3 minutes
Drying Time: 30 minutes
Note: Allow for cooling

Biomet does not recommend stacking of trays during the sterilization process.
Individuals or hospitals not using the recommended method, temperature, and time are advised to validate any alternative methods or cycles using an approved method or standard.

Additional information about instrumentation (including assembly/disassembly) may be found in the system surgical technique, reference guide and/or associated package inserts.

Refer to the Biomet Non-sterile Instrument IFU for full processing instructions for instruments.

Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
(973) 299 9300, (800) 526 2579
www.biometspine.com



Attachment 13-5
Draft Package Insert - Instruments

INTRODUCTION

Biomet Spine provides instruments and instrument trays that are generally manufactured from stainless steel, aluminum and polymeric materials. Biomet Spine instruments and instrument trays are not intended for use with other manufacturer's instruments, implants or instrument trays. Instruments should be placed in the intended location as indicated on the instrument tray.

Reusable surgical instruments and instrument trays must be cleaned and sterilized prior to use. The following steps apply to the cleaning of instruments and instrument trays:

PRECLEANING AT THE POINT OF USE

1. Soil should be wiped from the device with a sponge or towel moistened with water.
2. Cannulated instruments should be flushed to prevent drying of debris inside.
3. To prevent blood and/or debris from drying, devices should be placed in a container and covered with a towel that has been moistened with water.

CLEANING INSTRUCTIONS

1. All Instrument components should be disassembled and rinsed with tap water. The inner shaft of the instruments should be disassembled prior to cleaning.
2. Prepare solution of enzymatic surgical detergent and tap water by adding 2 oz. Of Enzol (Enzymatic Detergent, Johnson& Johnson) to 1 gallon of warm tap water (72ºF/22ºC to 109ºF/43ºC). Instrument components should be immersed in solution for 5 minutes.
3. Scrub components with soft brushes and rinse with a brisk stream of tap water (72ºF/22ºC to 109ºF/43ºC) until all visual soil is removed.
4. Using an ultrasonic cleaner, sonicate all components in the same enzymatic solution (see step # 2) for 10 minutes.
5. Manually clean all components with soft brushes and repeat step # 3 until all visual soil is removed. This step should be repeated until there are no signs of soil or residue remaining. Instruments and trays should be visually clean prior to further processing.
6. Dry components with a soft gauze cloth.
7. Inspect cleaned instrument for wear, loose screws and pins, clamp alignment, cracks and other irregularities. If instruments are discolored, show evidence of corrosion, have loose screws/pins, are out of alignment, are cracked or have other irregularities, **Do Not Use.**

CARE AND HANDLING

• All torque wrenches should be re-calibrated every 6 months.

• Please refer to ASTM standard F1744, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.

• Prior to use, instruments should be visually inspected for wear and function should be tested to assure instruments are functioning properly. If instruments are discolored, show evidence of corrosion, have loose screws/pins, are out of alignment, are cracked or have other irregularities, **Do Not Use.** Instrumentation that appears damaged should be returned to the manufacturer**.**

STERILIZATION
All packaging materials must be removed prior to sterilization. All instrument components should be sterilized in a loosened state such that components may move freely. The following steam sterilization parameters are recommended:

U.S. Sterilization Parameters:
Cycle: Pre-vacuum Steam
Temperature: 270°F/132°C
Time: 4 minutes
Drying Time: 30 minutes
Note: Allow for cooling

FDA cleared sterilization wraps should be used to maintain sterility after processing.

European Union Sterilization Parameters:
Cycle: Pre-vacuum Steam
Temperature: 275°F/135°C
Time: 3 minutes
Drying Time: 30 minutes
Note: Allow for cooling

Biomet does not recommend stacking of trays during the sterilization process. Individuals or hospitals not using the recommended method, temperature, and time are advised to validate any alternative methods or cycles using an approved method or standard.

Additional information about instrumentation (including assembly/disassembly) may be found in the system surgical technique, and/or reference guide.

INFORMATION
For further information, please contact the Customer Service Department at:
Biomet
100 Interpace Parkway
Parsippany, NJ 07054
973-299-9300
800-526-2579
www.biometspine.com

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend, South Wales

CF31 3XA UK

CE

Key to Label Symbols:

Rx Only

By prescription only

Do not reuse

REF

Reference Number

Caution, consult accompanying documents

Date of Manufacture

Batch Code

Section 14

Sterilization and Shelf Life

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Section 15

Biocompatibility

Materials and Biocompatibility:

The Solitaire®-C spacer is manufactured from implant grade PEEK (Polyetheretherketone polymer), titanium alloy (Ti-6Al-4V-ELI) and Unalloyed Tantalum per the standards listed in the table below. The bone screws for the system are also fabricated from titanium alloy (Ti-6Al-4V- ELI).

The Form FDA 3654 for each standard referenced below per the FDA Guidance Document "Recognition and Use of Consensus Standards" can be found in Section 9.

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Section 16

Software

The subject of this submission does not contain software; therefore, this section does not apply.

Section 17

Electromagnetic Compatibility and Electrical Safety

(b)(4) CCI

[redacted]

Section 18

Performance Testing - Bench

The mechanical testing performed to characterize the performance of the Solitaire-C Cervical spacer system follows on the next page.

MECHANICAL TESTING REPORT

Solitaire-C
Cervical Spacer System

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MECHANICAL TESTING REPORT

(b)(4) CCI

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APPENDIX B
MECHANICAL TESTING REPORT

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III. Results & Observations[2]

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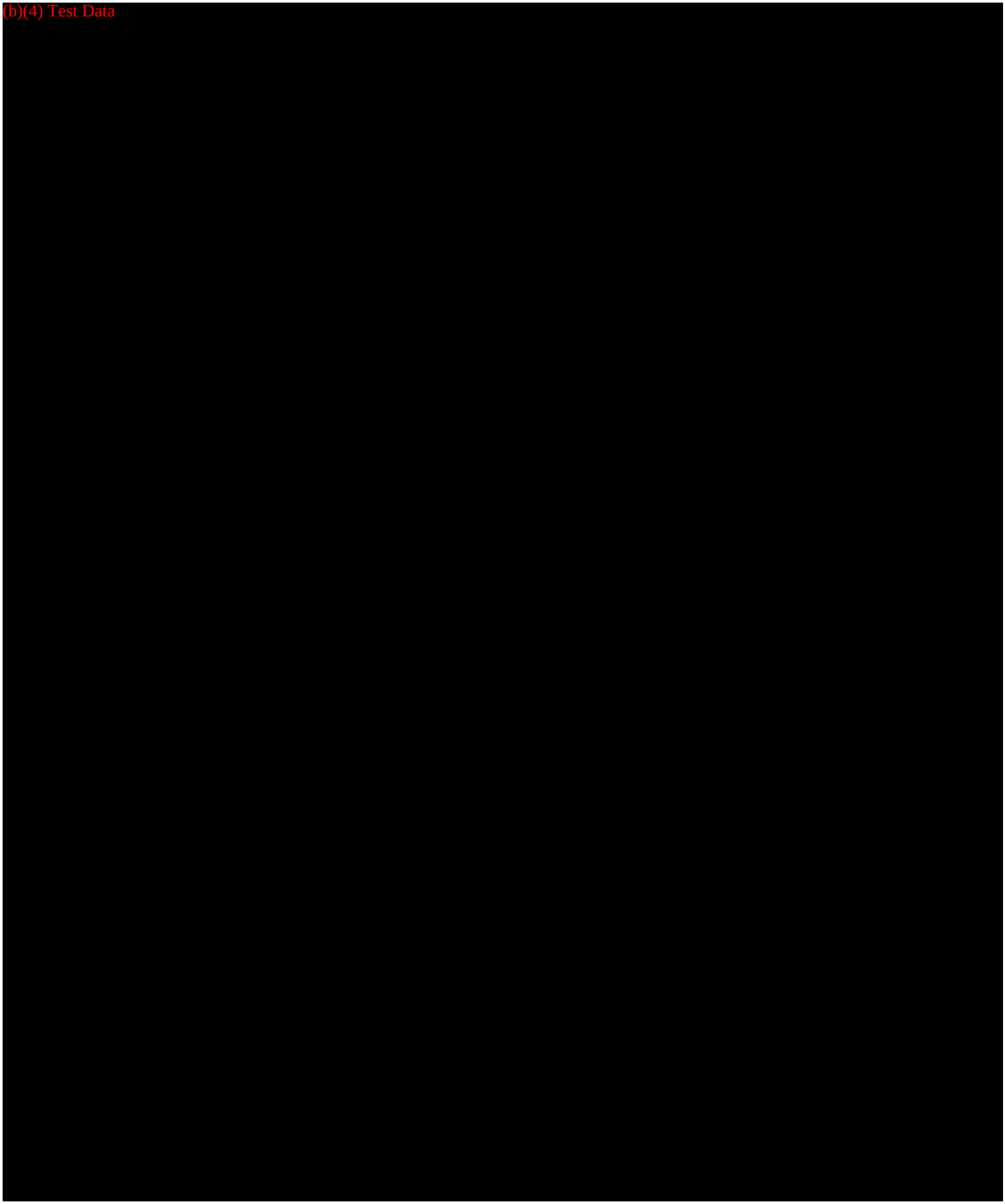

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Appendices

Appendix A. Figures

Figure 1. Solitaire-C System: Untested Parts

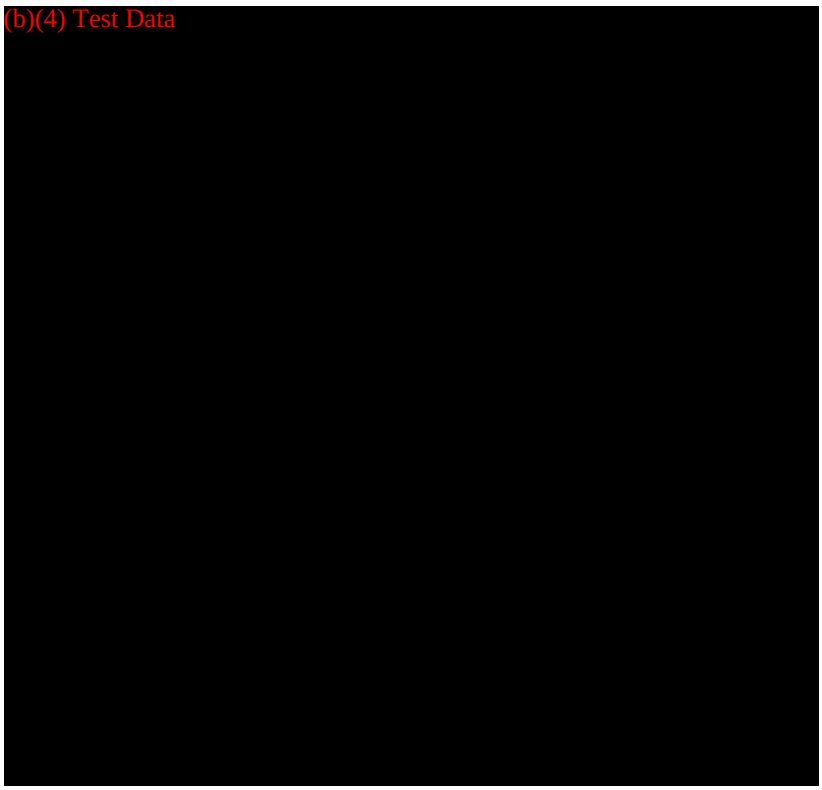

Figure 3. Static Test Blocks – Subsidence Foam

Figure 4. Static Test Blocks – Expulsion Foam

Figure 5. Dynamic Test Blocks – Stainless Steel

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Figure 9. Solitaire-C System (Static AC/SC/TR Specimen): Lateral View

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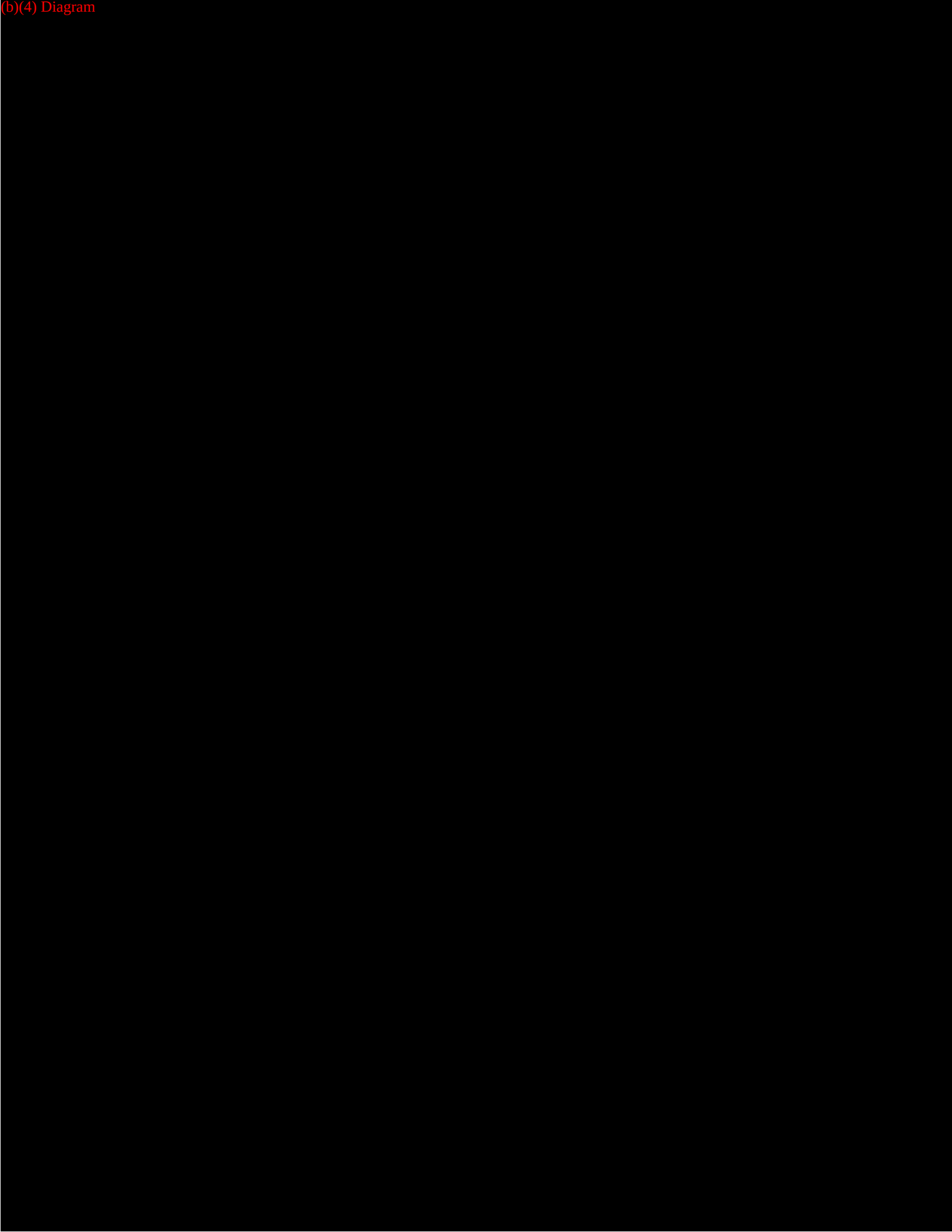
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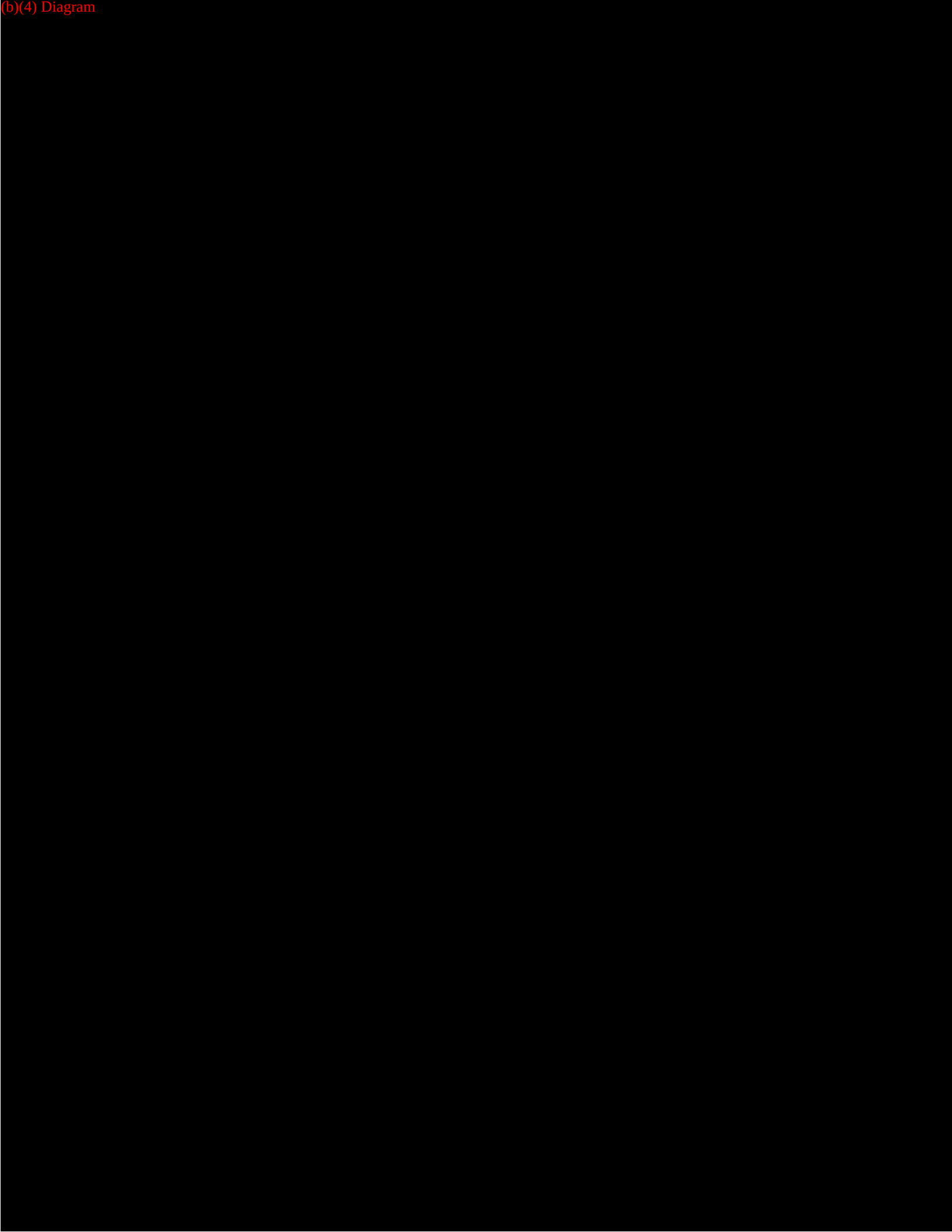
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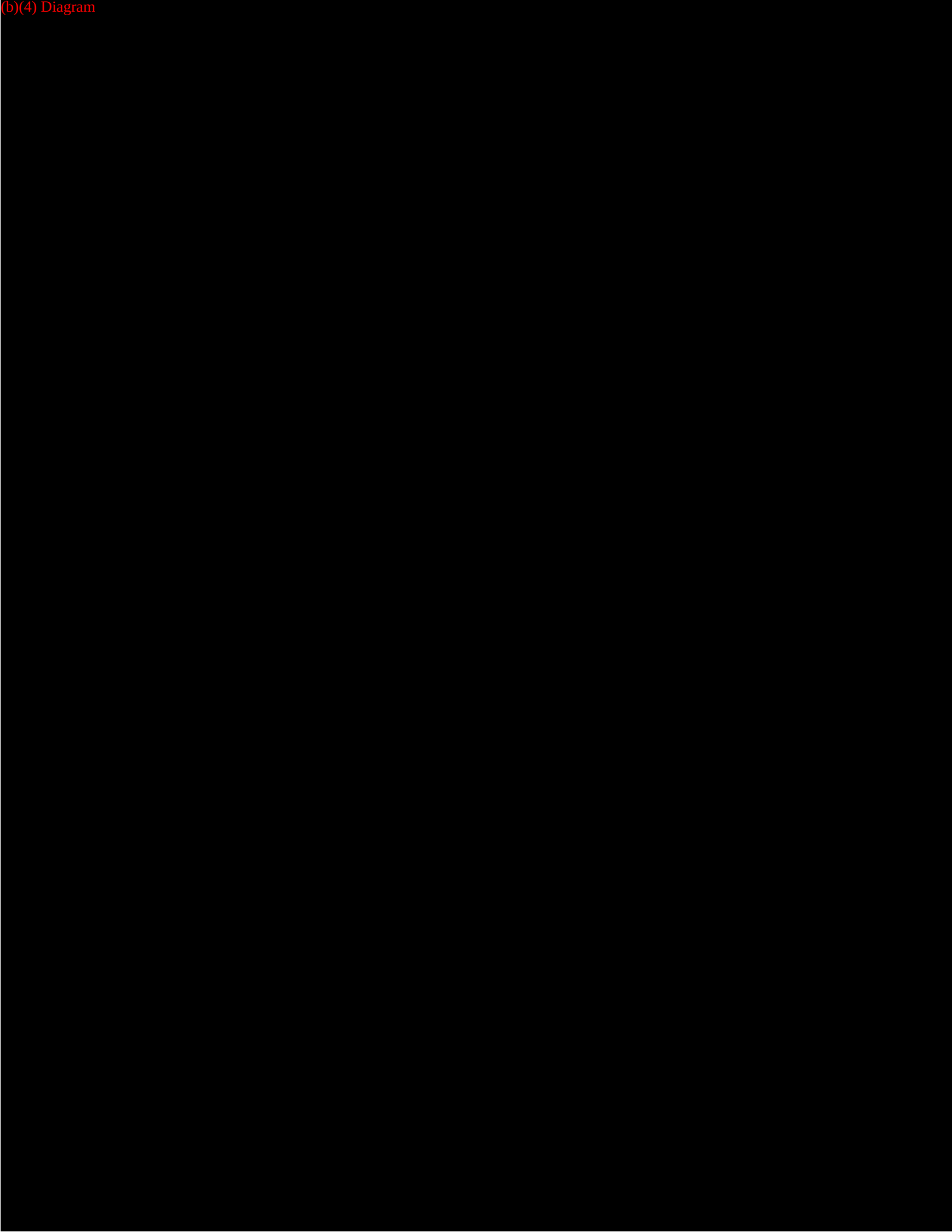
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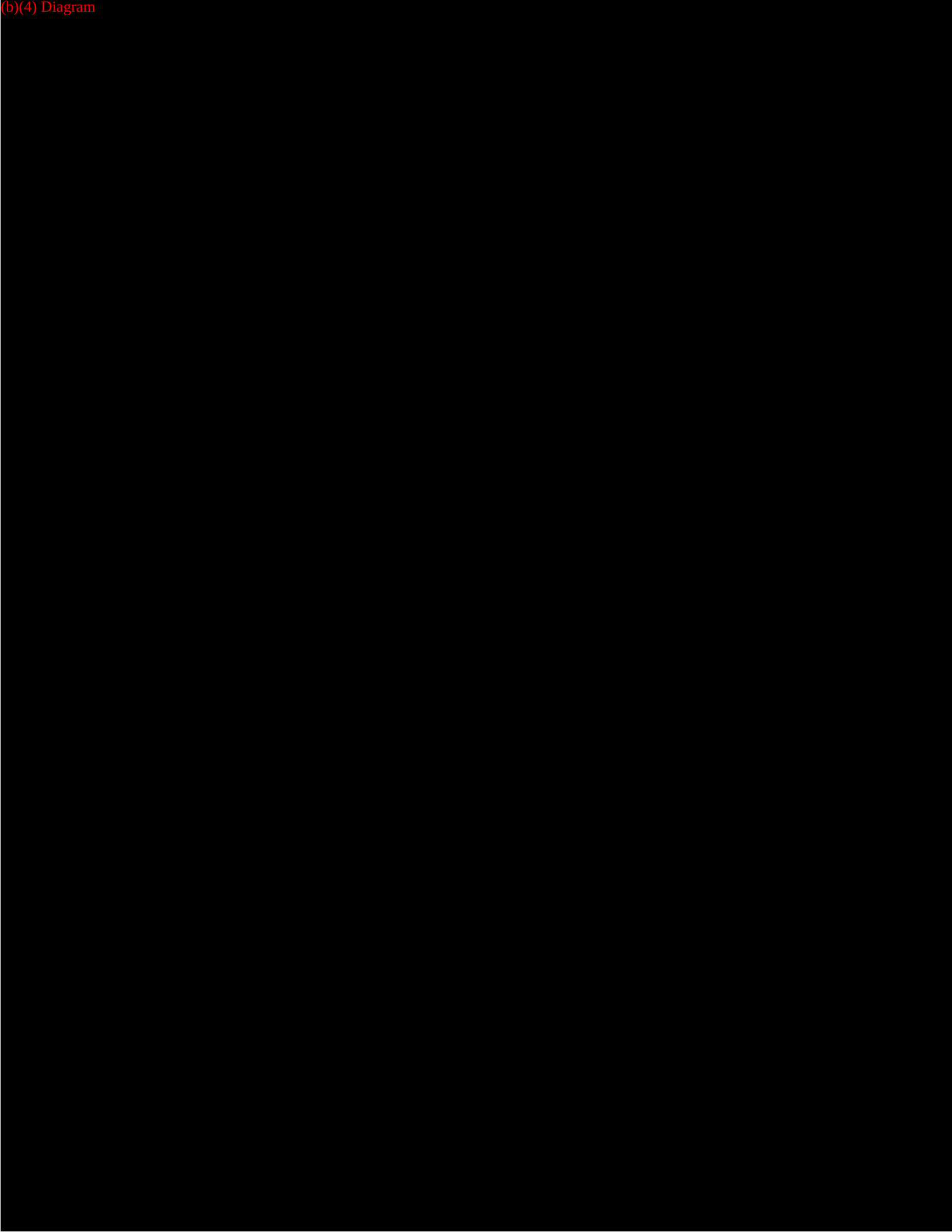
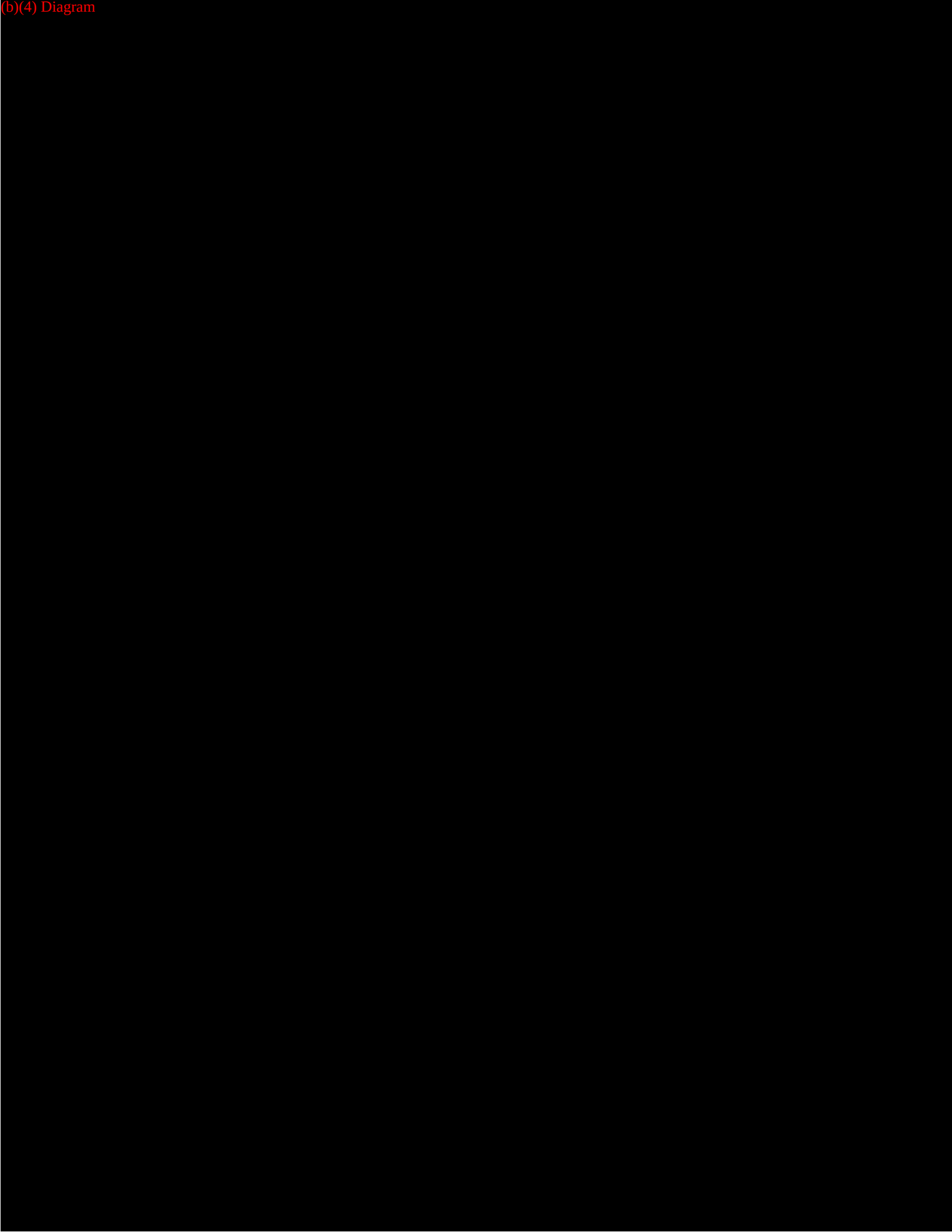

(b)(4) Diagram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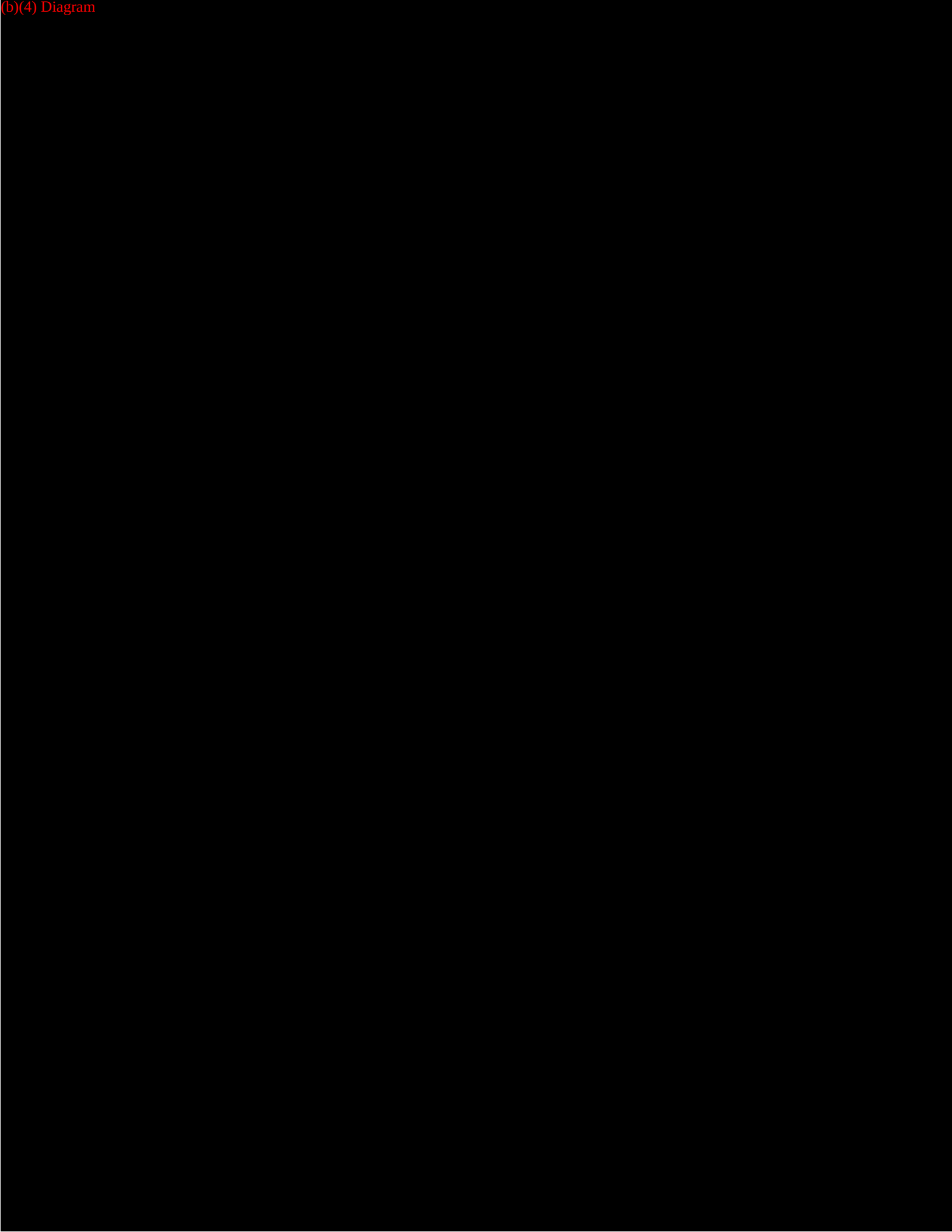
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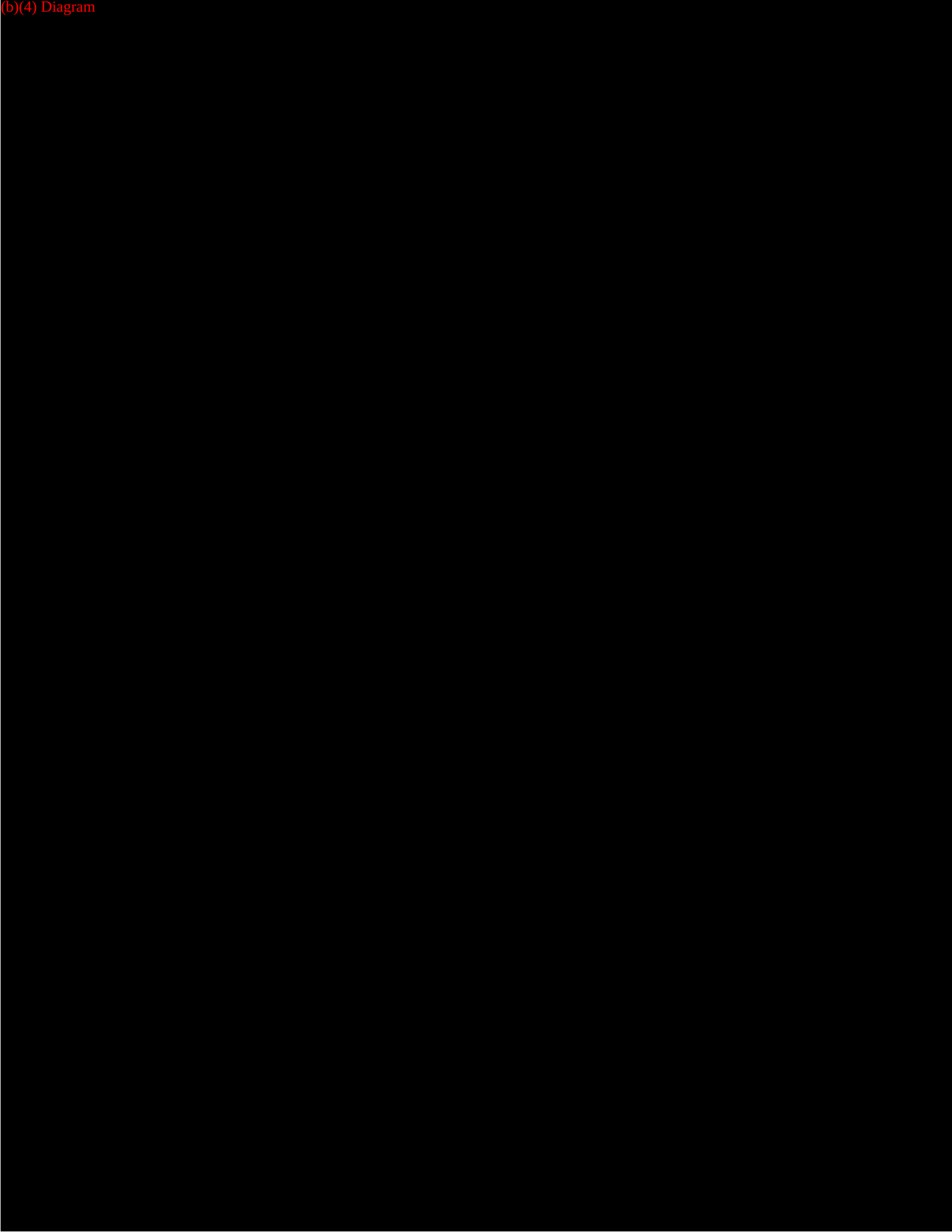
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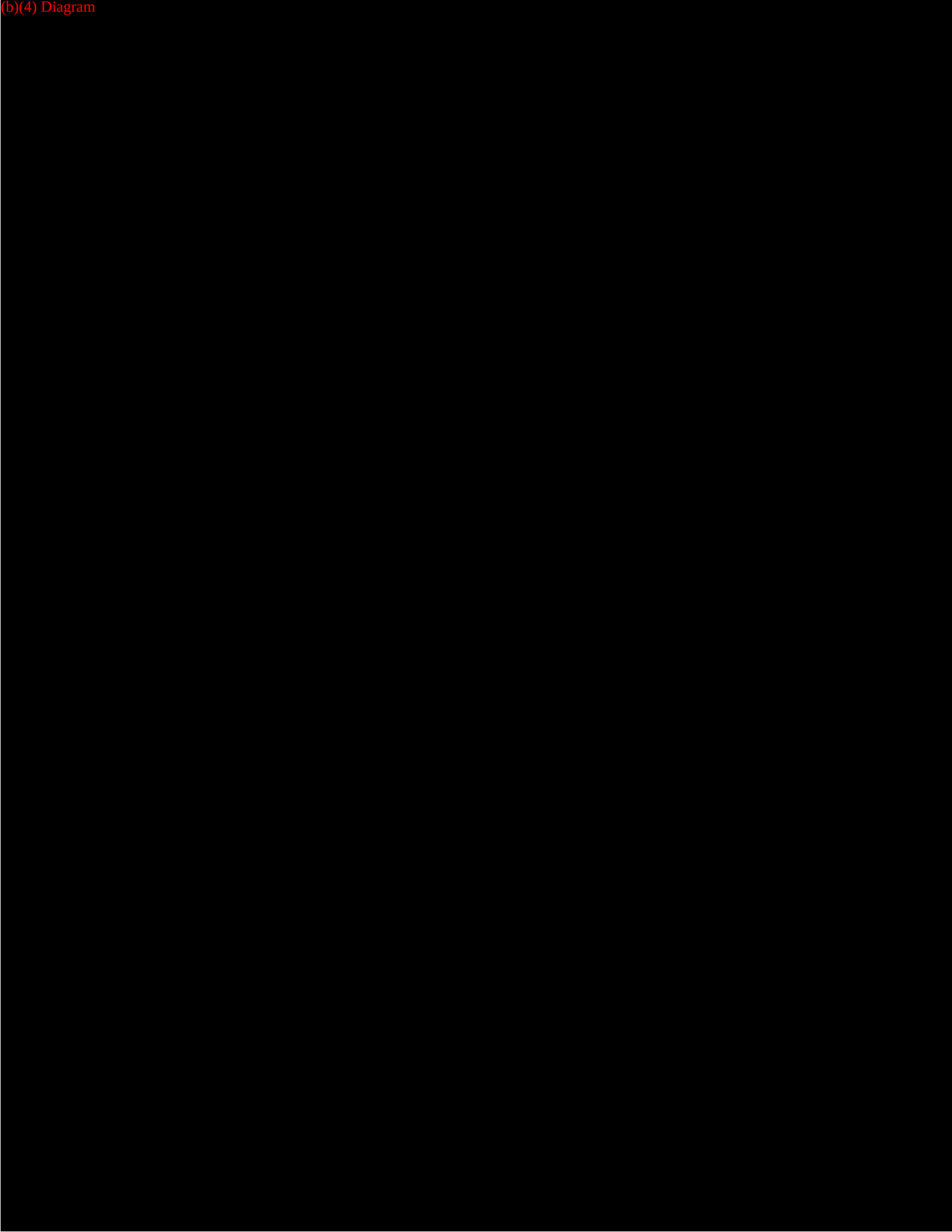
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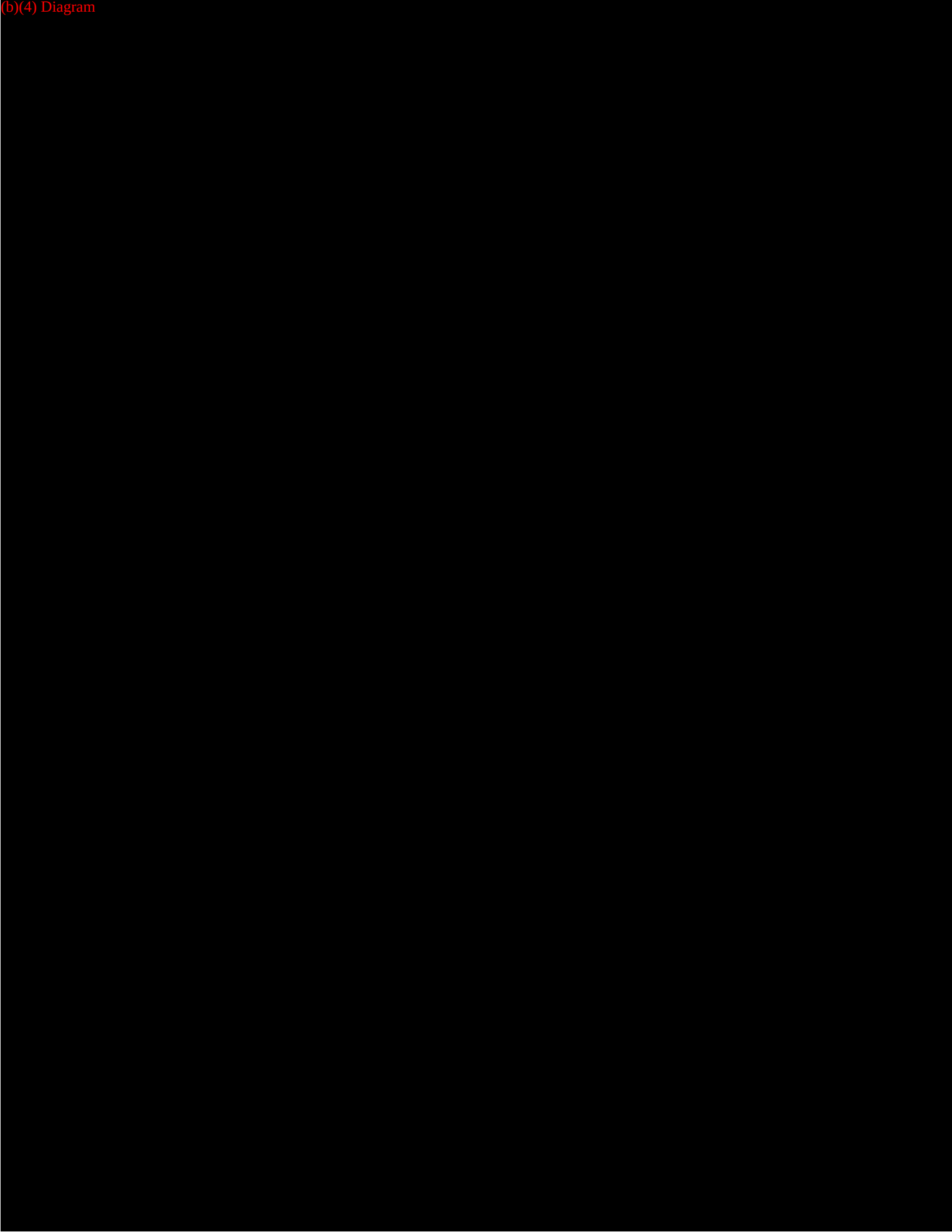
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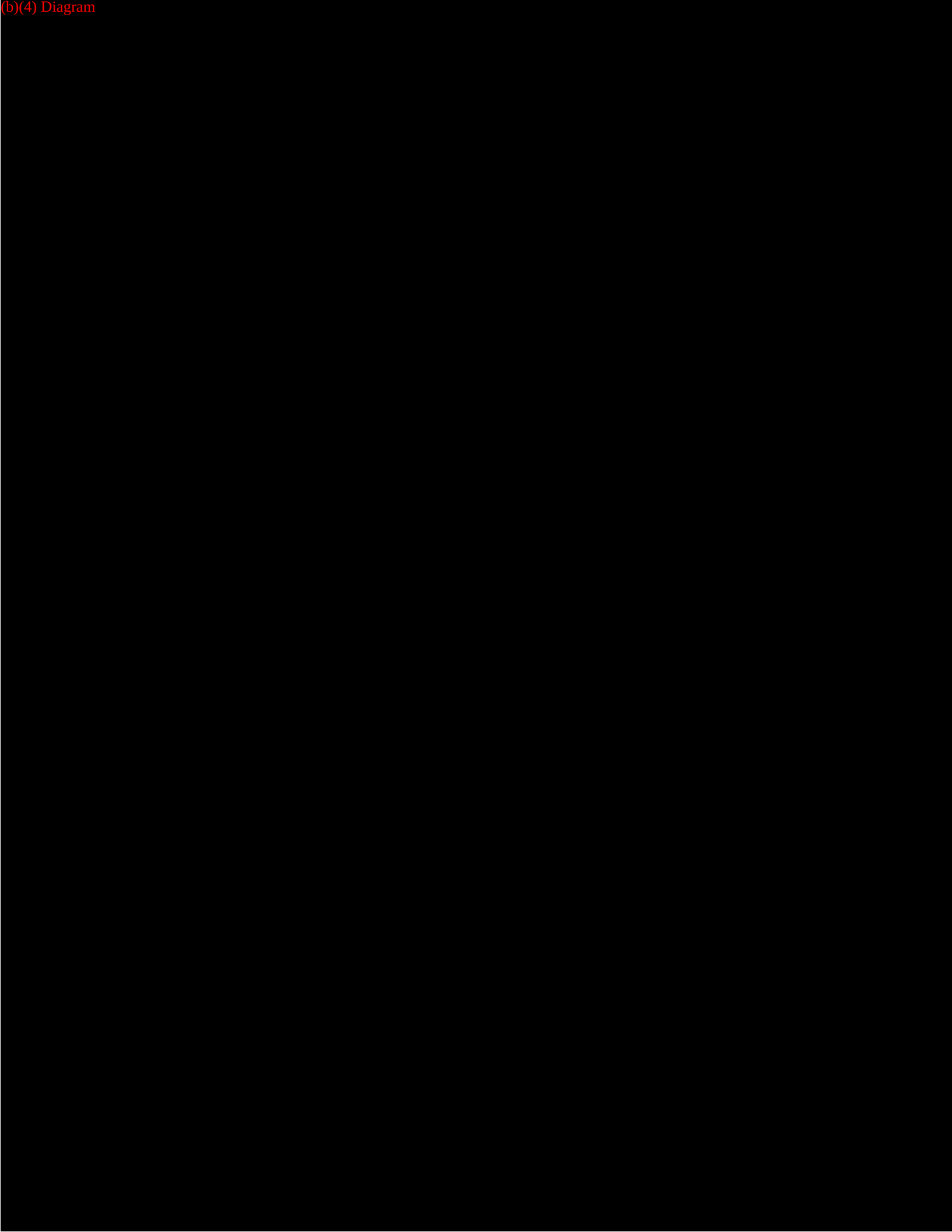
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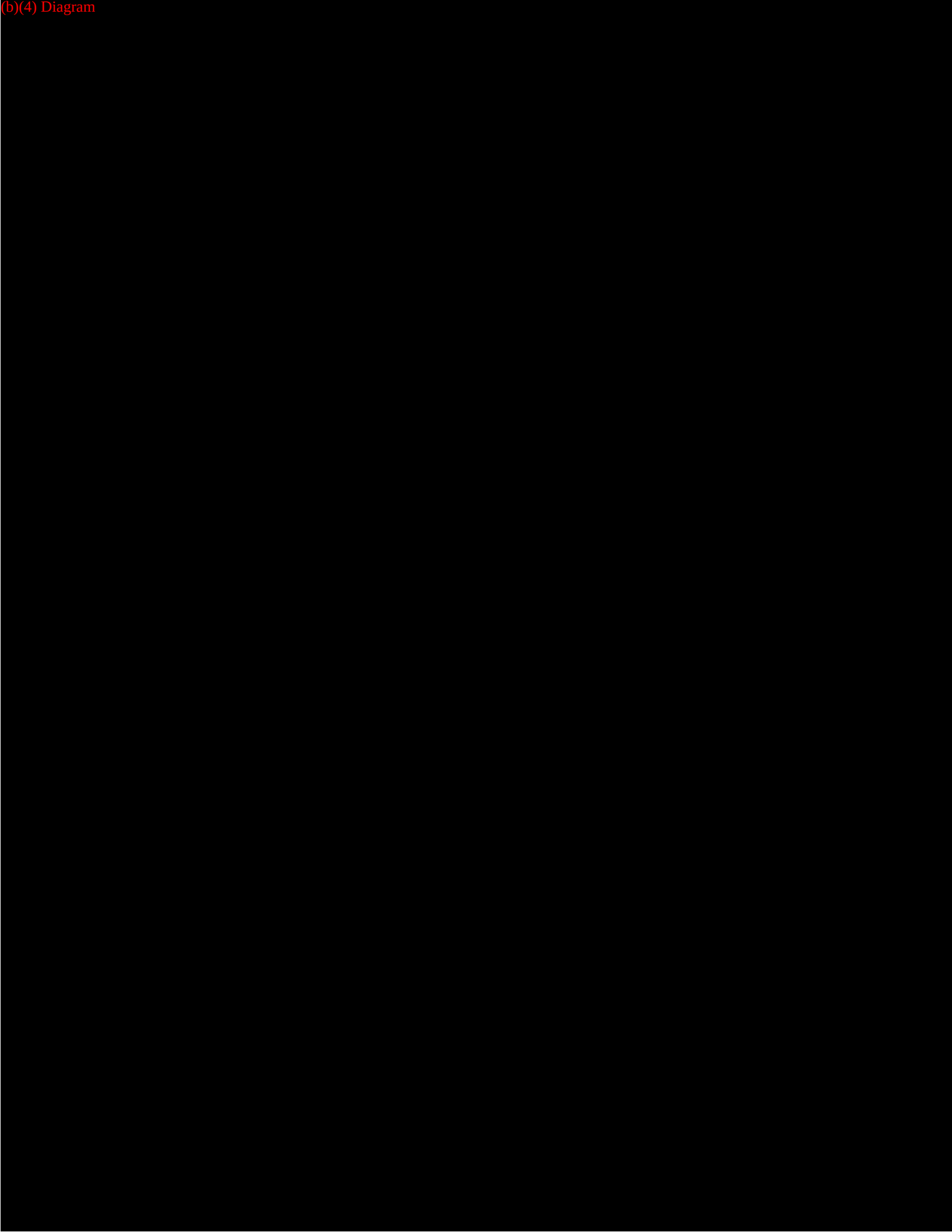
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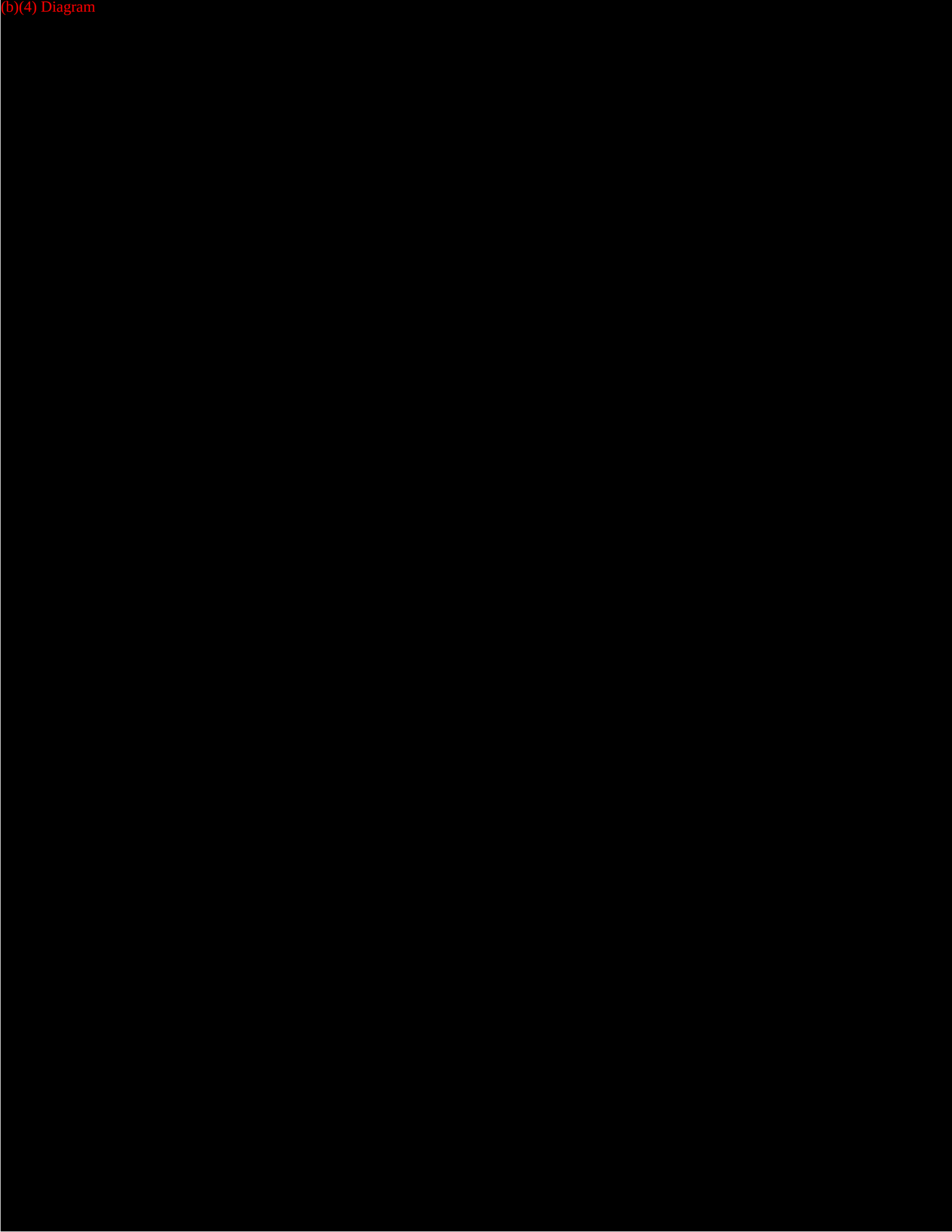
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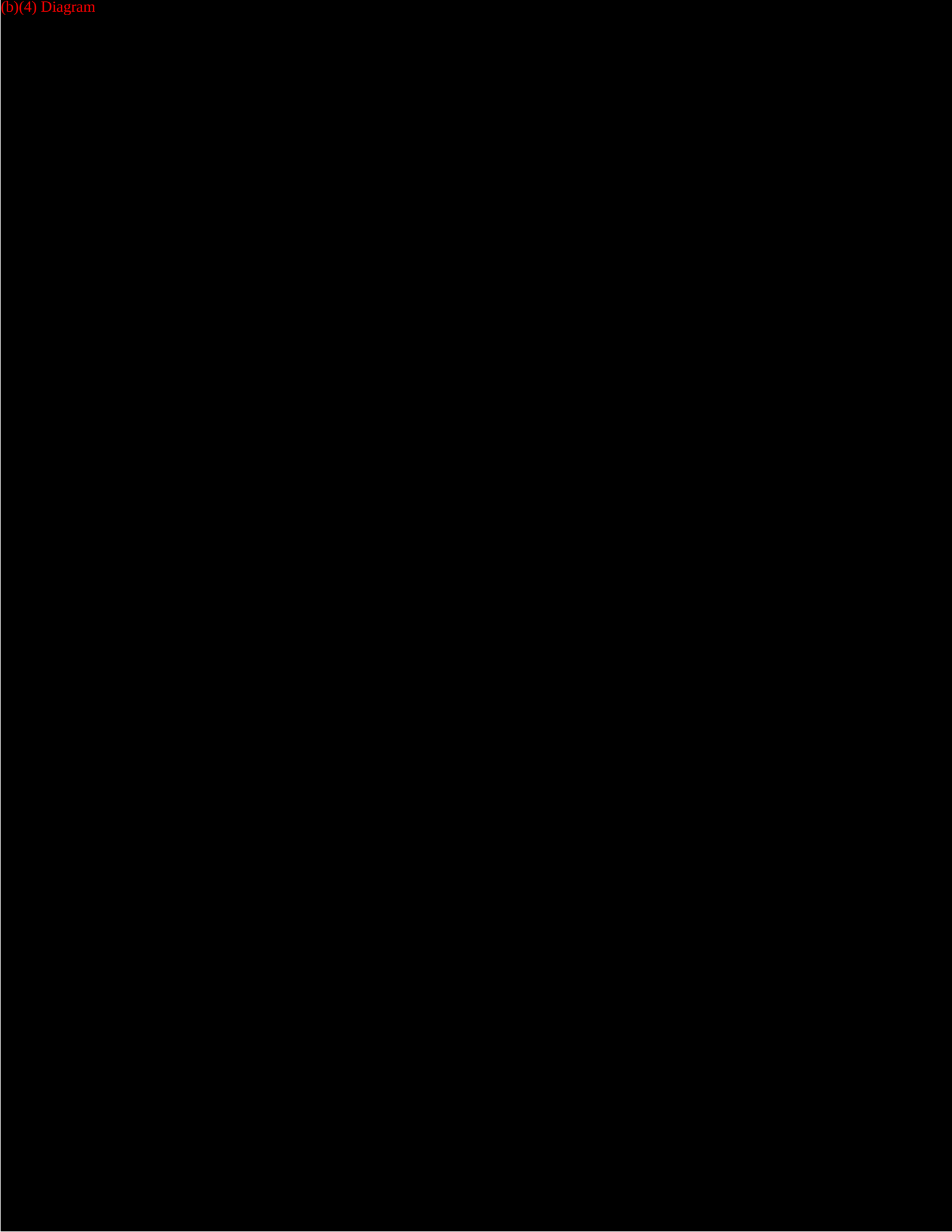
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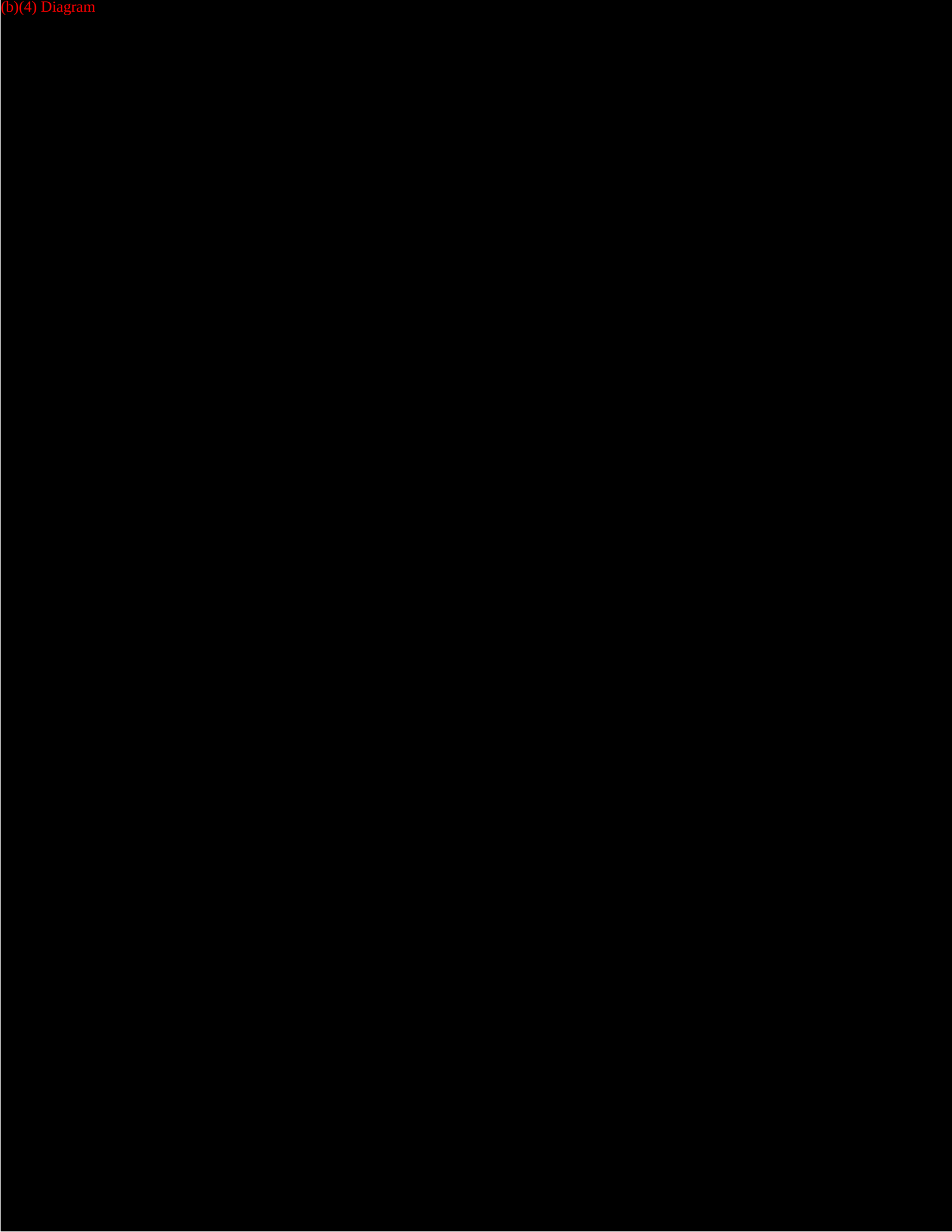
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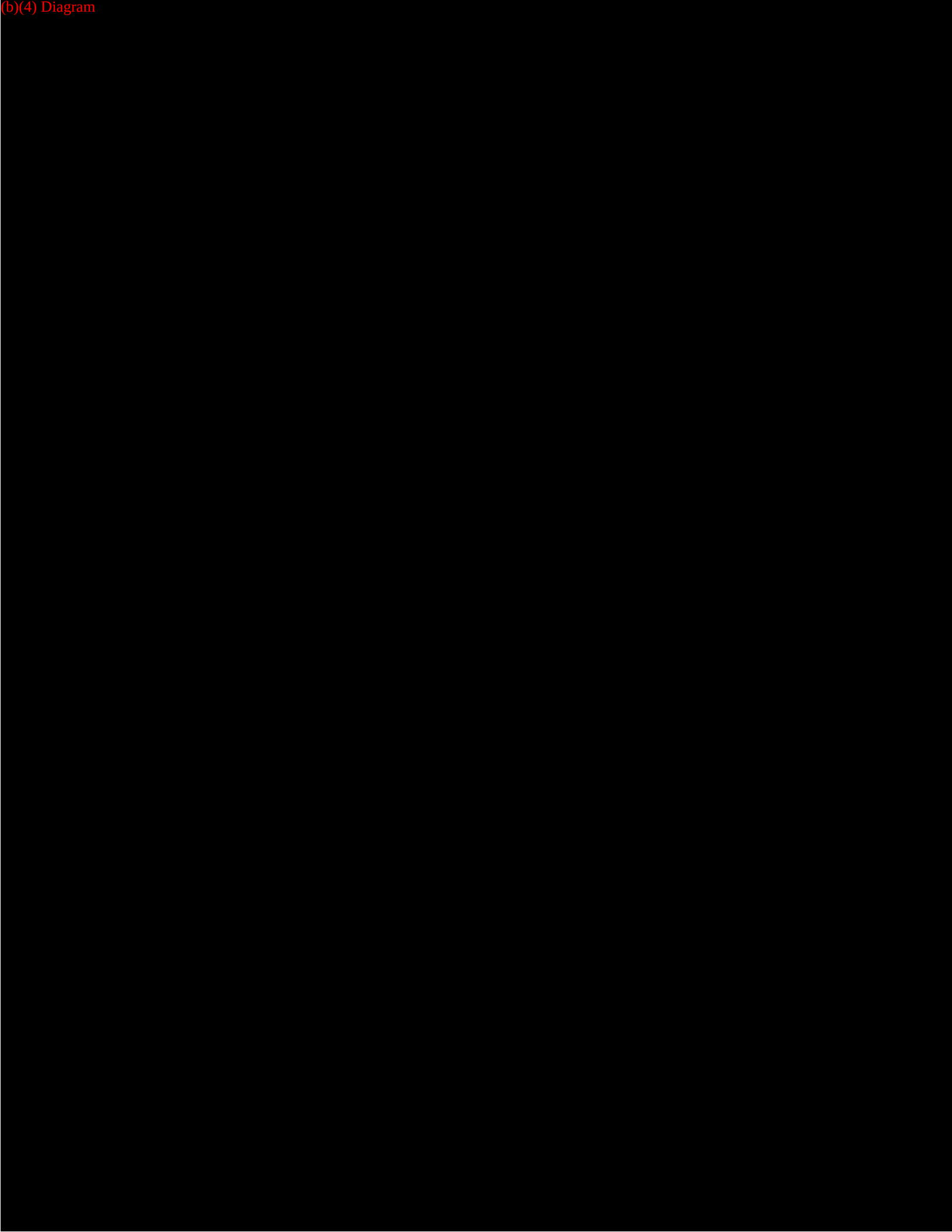
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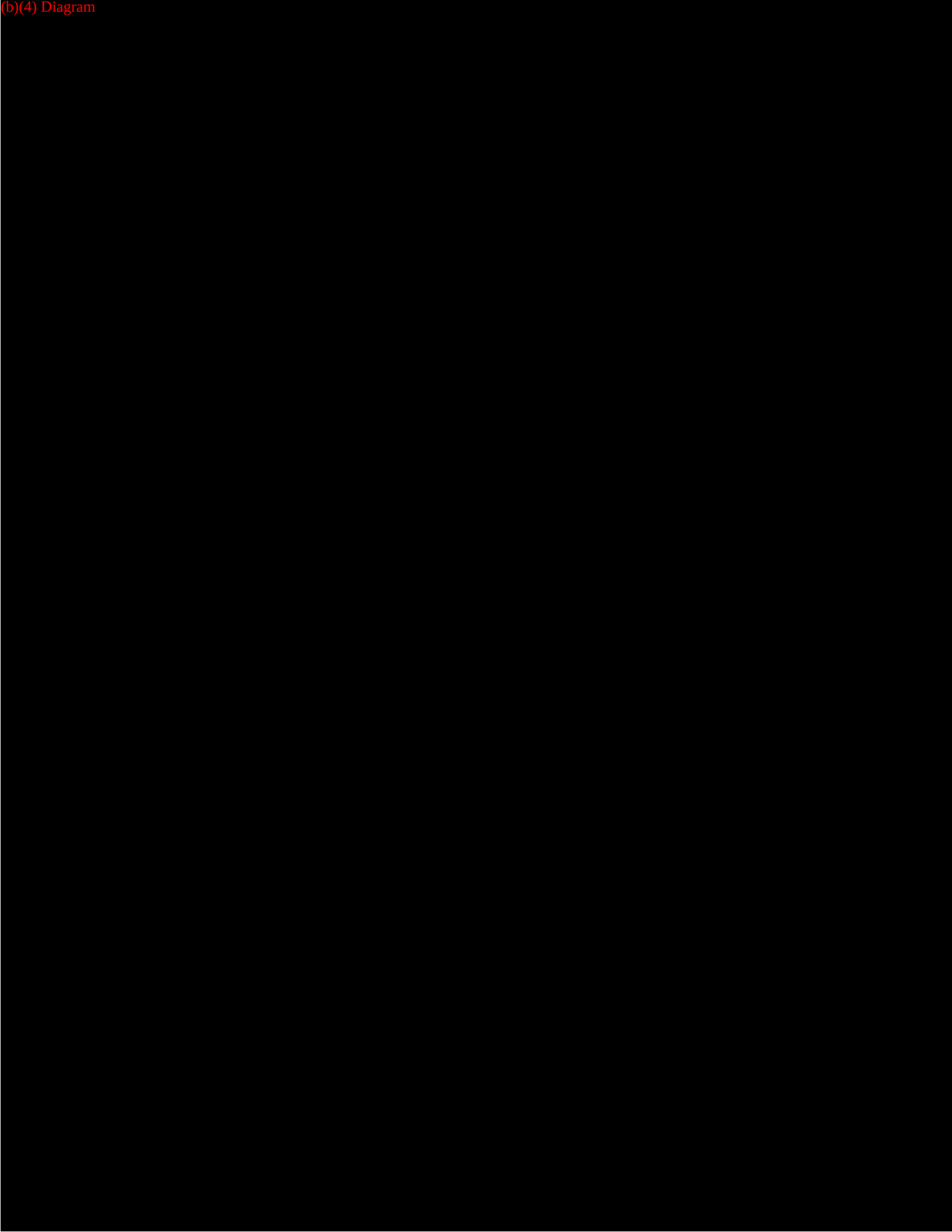
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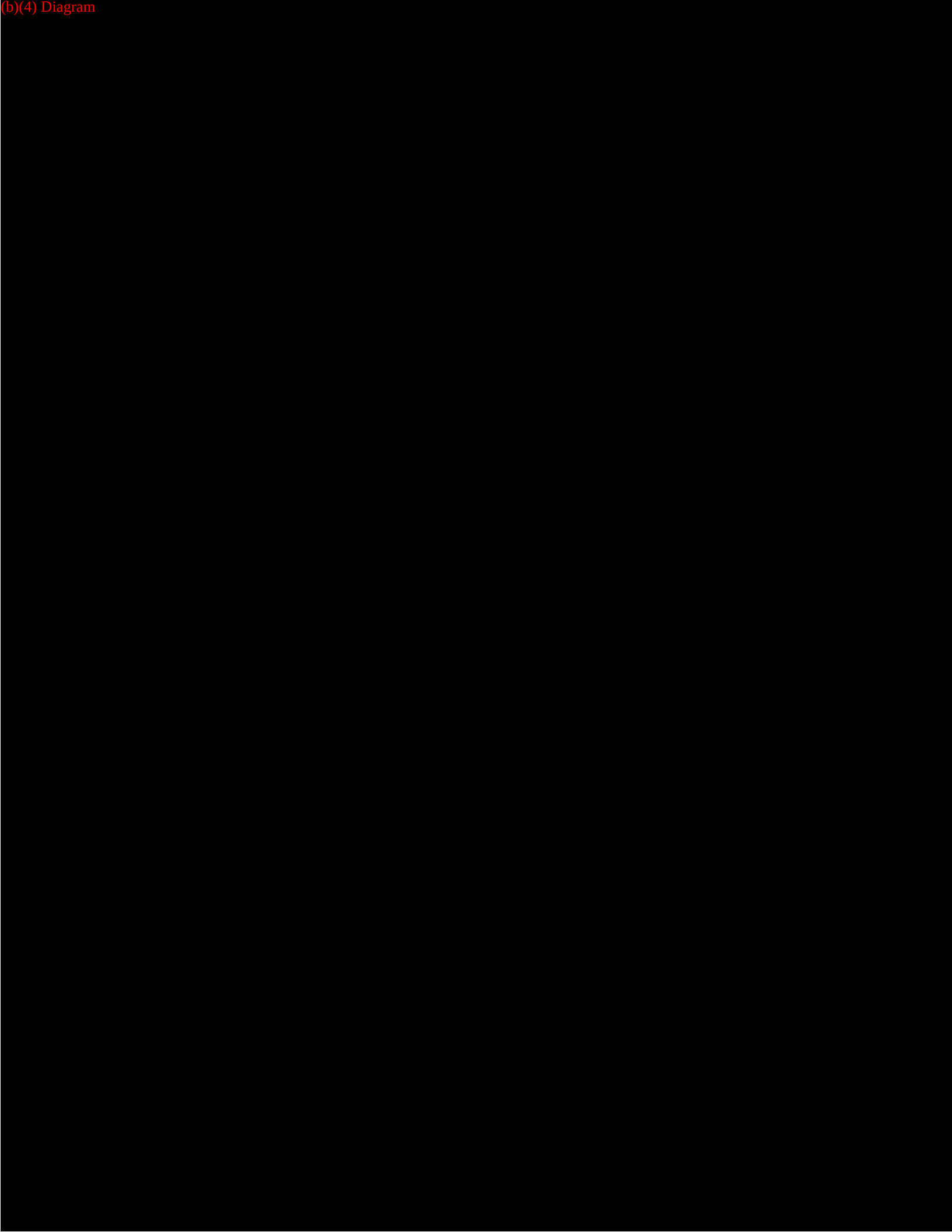
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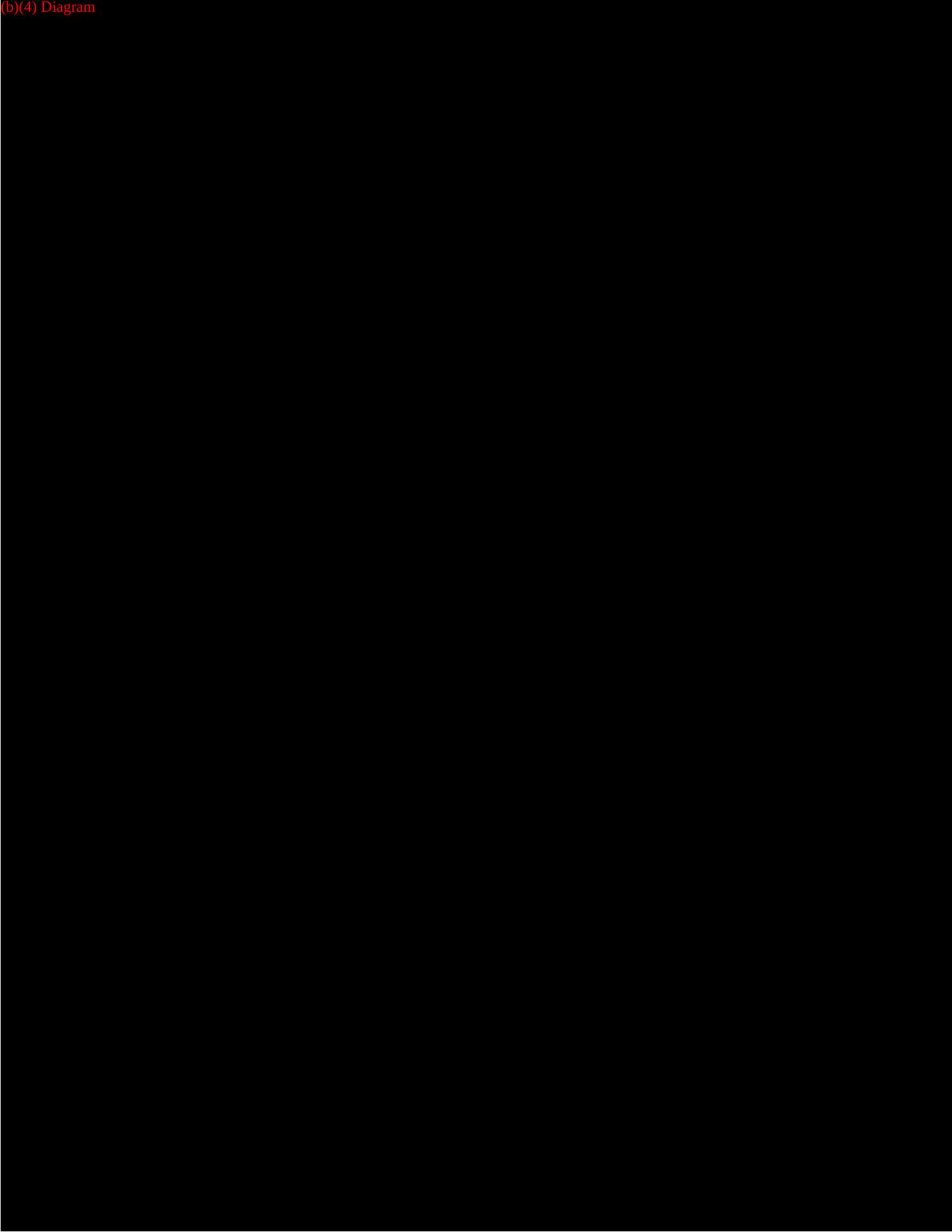
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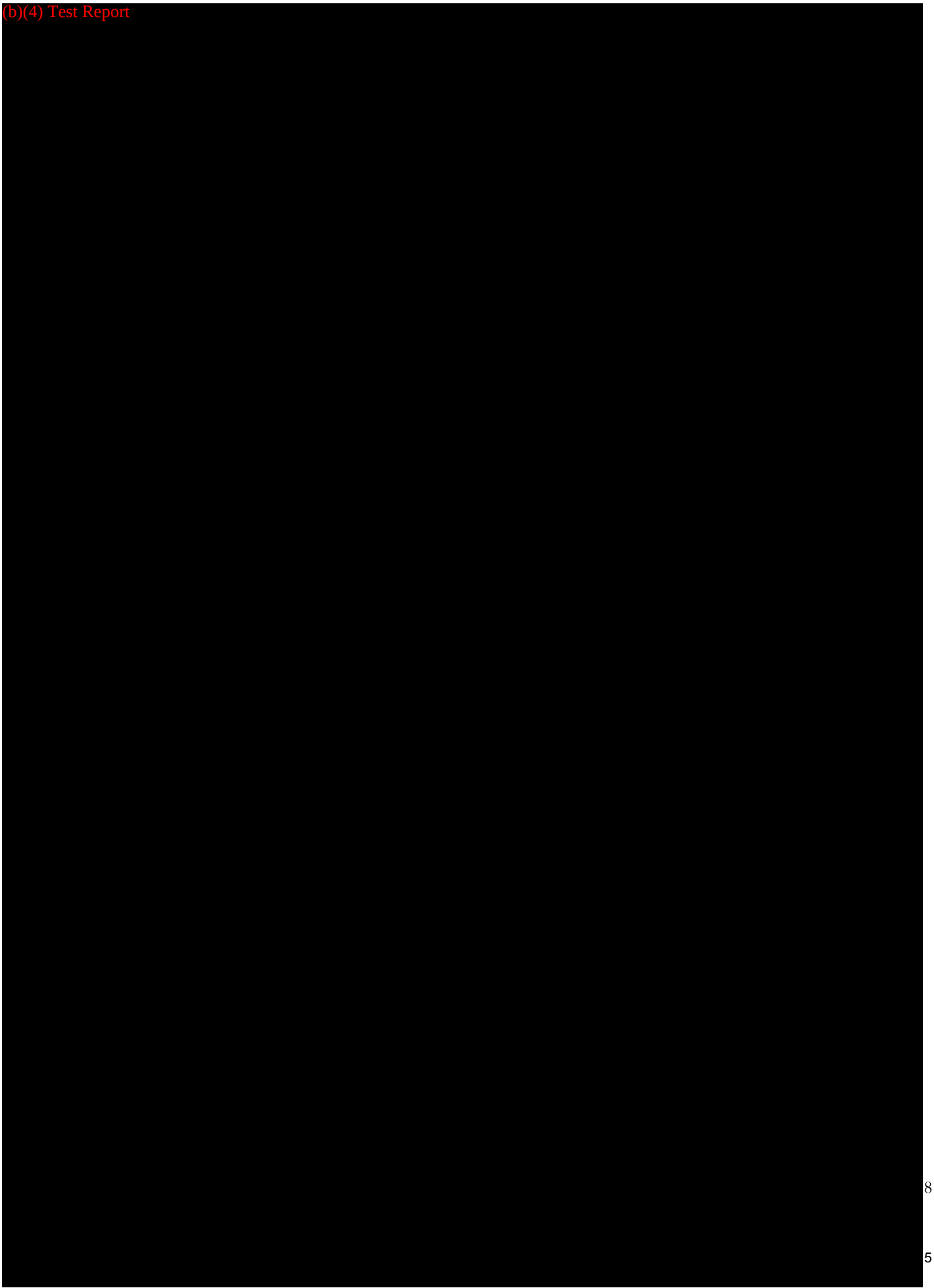
Appendix E. Test Specifications Summary Sheet

(b)(4) Test Report

[redacted]

(b)(4) Test Report



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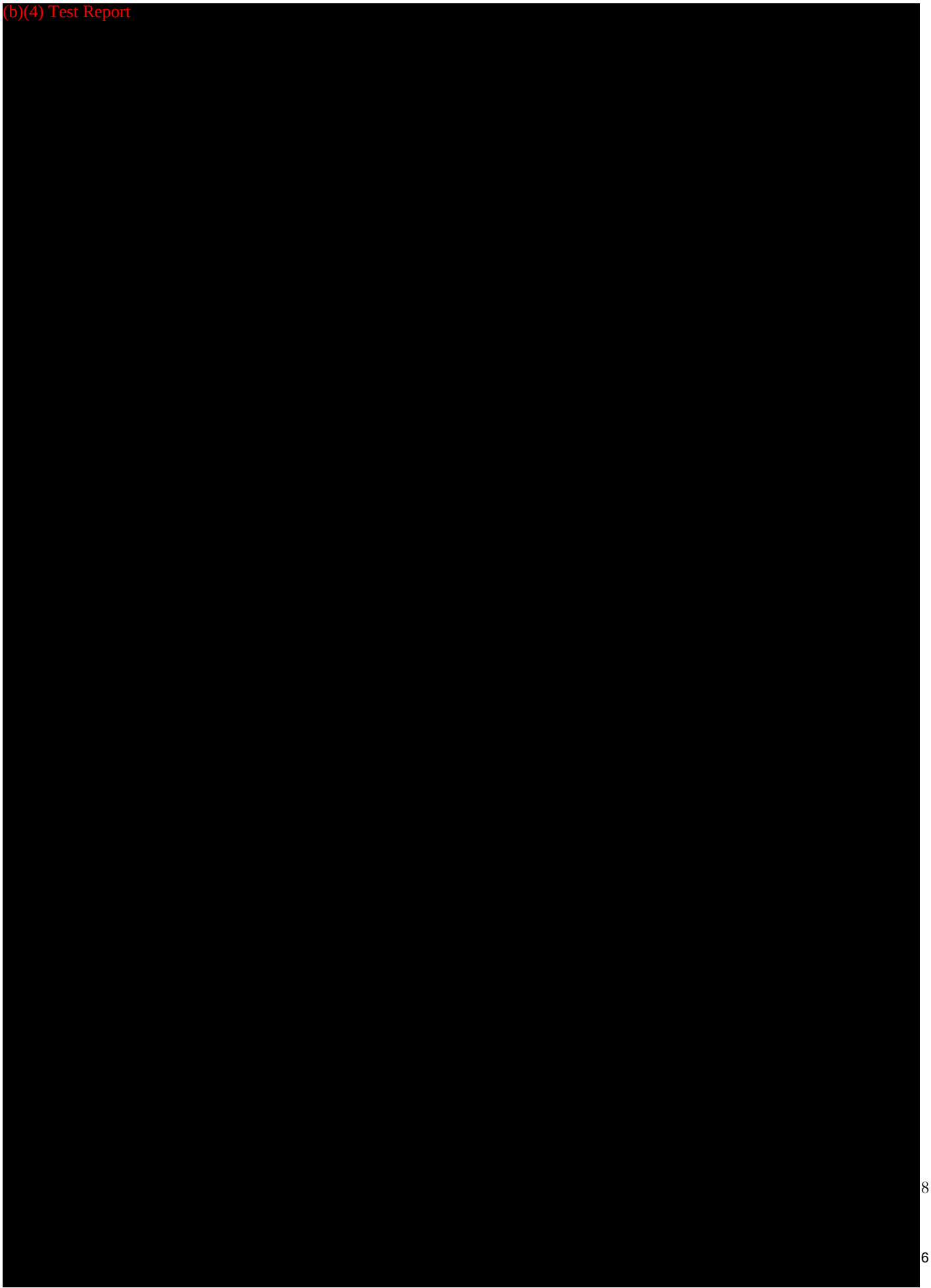

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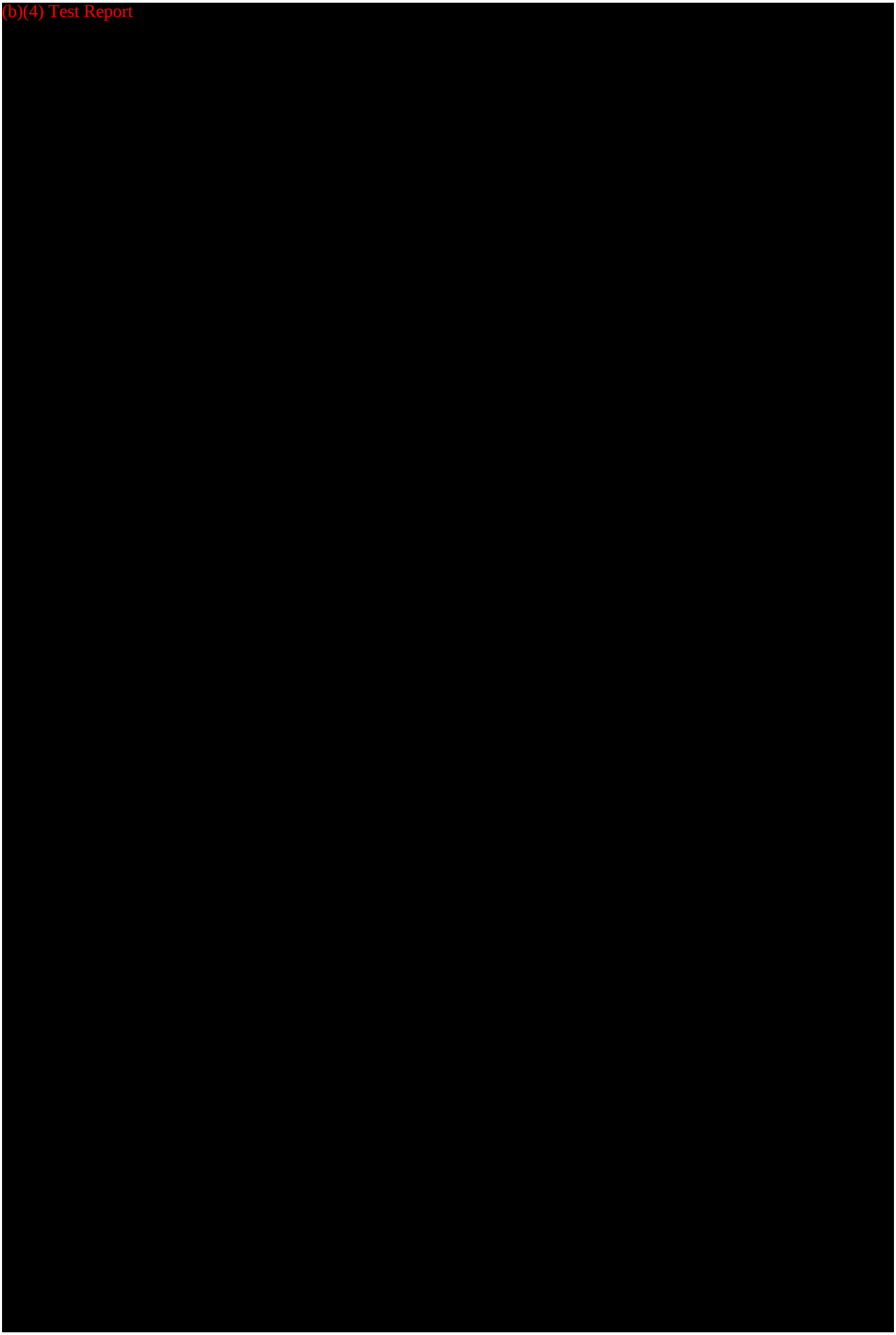

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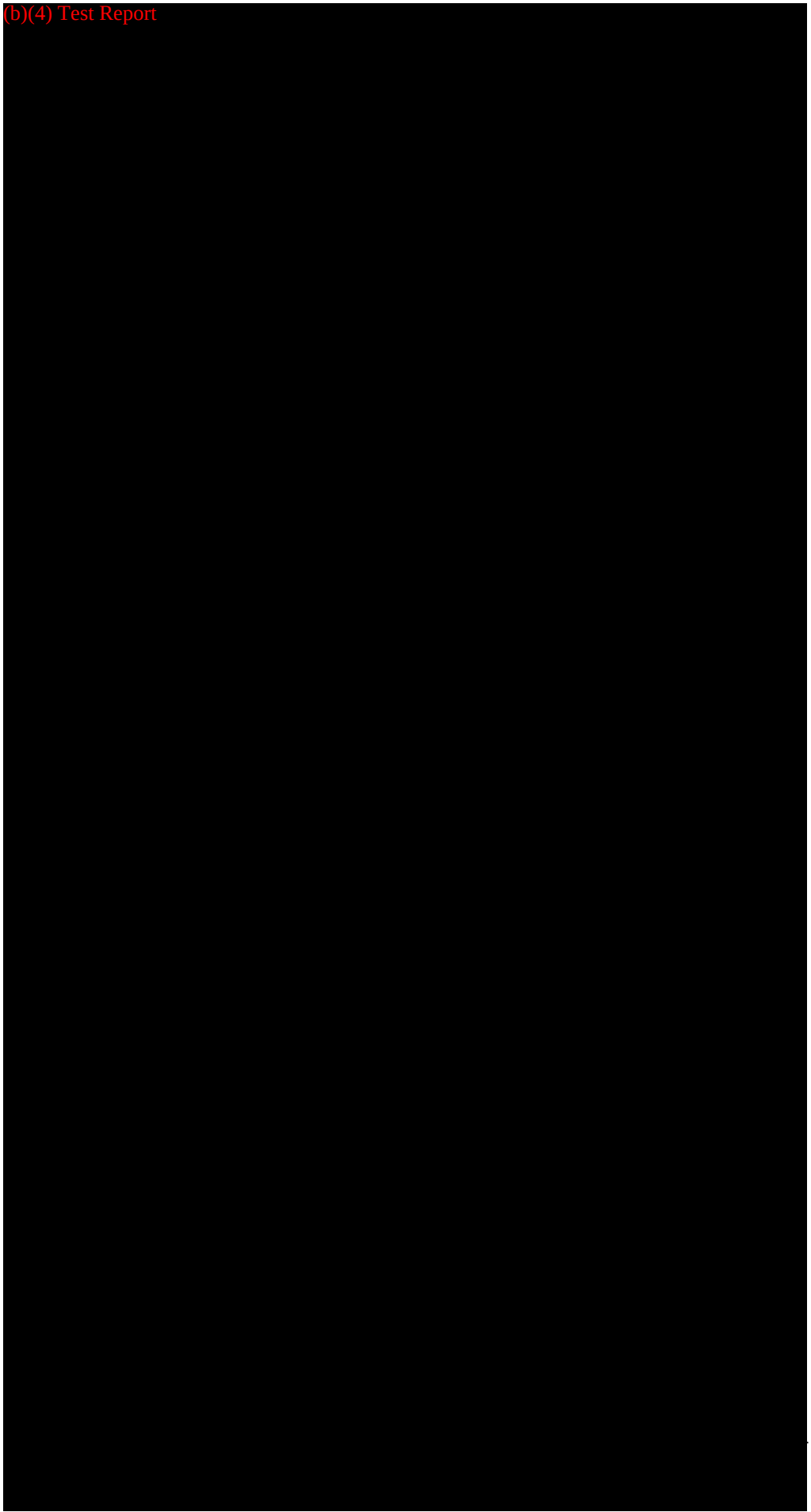
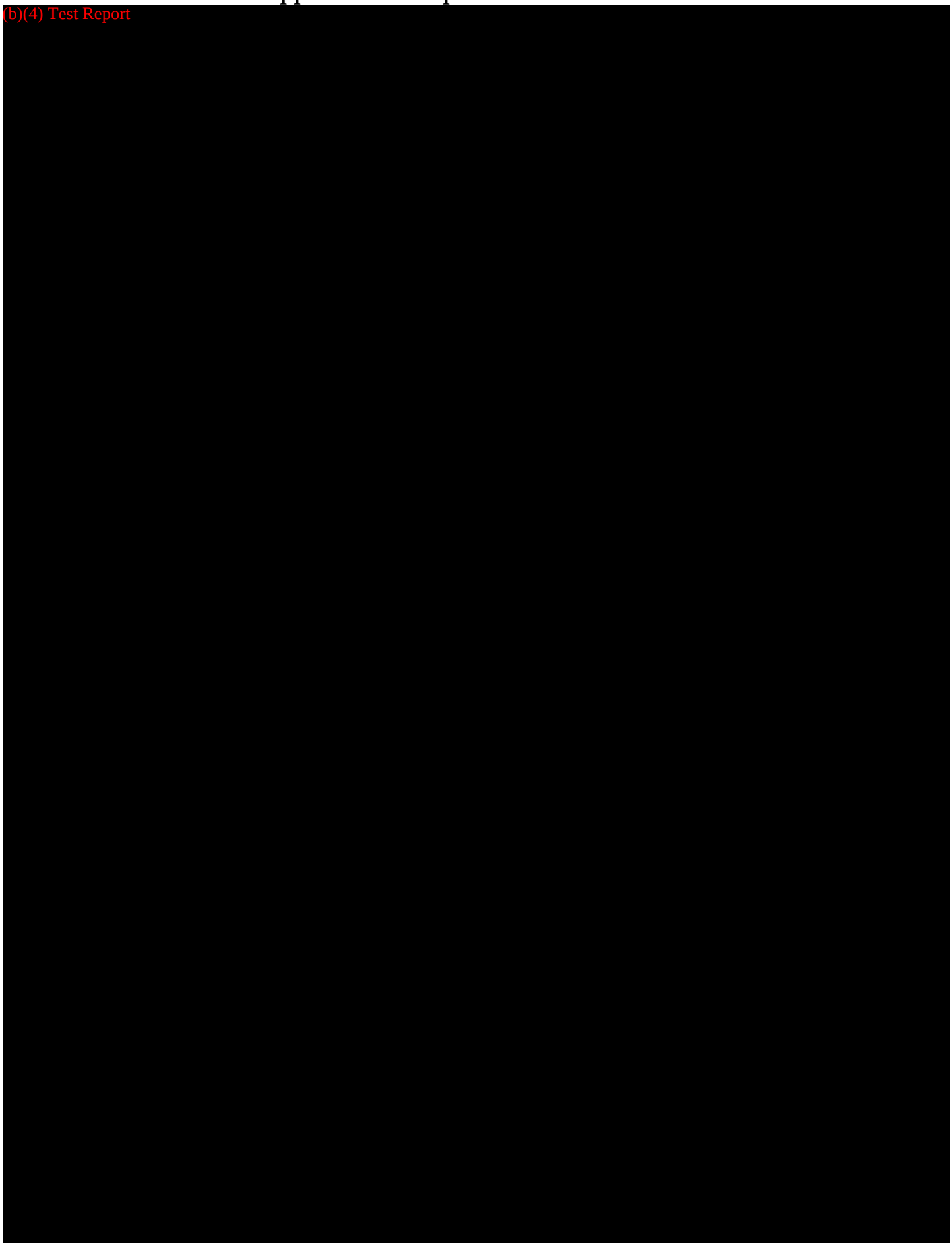


(b)(4) Test Report

Appendix F. Scope of Accreditation

(b)(4) Test Report



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[redacted]

(b)(4) Test Report

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Appendix G. References

(b)(4) Test Report

Appendix H. Glossary

(b)(4) Test Report

[redacted]

(b)(4) Test Report

[redacted]

Appendix I. Revision History

(b)(4) Test Report

[redacted]

APPENDIX C
MECHANICAL TESTING REPORT

Biomet Spine & Bone Healing Technologies

Compression Fatigue
Compression Shear Fatigue
Screw Back Out Testing
Screw Push Through Testing
Torsion Connection Testing

Project Description:	Solitaire-C Cervical Spacer System
Project #:	0318
Author:	Laurie Sanders
Date:	December 22, 2011

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(b)(4) Test Report

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Section 19

Performance Testing – Animal

(b)(4) Test Report

[redacted]

Section 20

Performance Testing – Clinical

(b)(4) Test Report

See OMB Statement on Reverse. Form Approved: OMB No. 0910-0616, Expiration Date: 06-30-2008

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
Biomet Spine (aka EBI, LLC)

2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES
12/22/2011

3. ADDRESS *(Number, Street, State, and ZIP Code)*
100 Interpace Parkway
Parsippany, NJ 07054

4. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 973-299-9300
(Fax) 973-257-0232

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)

Solitaire-C Cervical Spacer System

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 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 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)
Margaret F Crowe

12. NAME AND TITLE OF THE PERON WHO SIGNED IN NO. 11
(Name) Margaret F. Crowe
(Title) Regulatory Affairs Project Manager

13. ADDRESS *(Number, Street, State, and ZIP Code) (of person identified in No. 11 and 12)*
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054

14. TELEPHONE AND FAX NUMBER *(Include Area Code)*
(Tel.) 973-299-9300, ext. 2260
(Fax) 973-257-0232

15. DATE OF CERTIFICATION
12/20/2011

FDA-3674 (1/08) (FRONT)

PSC Graphics: (301) 443-1090 EF

Instructions for Completion of Form FDA 3674

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))
Form 3674 must accompany an application/submission, including amendments, supplements, and resubmissions, submitted under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.

1. **Name of Sponsor/Applicant/Submitter -** This is the name of the sponsor/applicant/submitter of the drug/biologic/device application/ submission which the certification accompanies. The name must be identical to that listed on the application/submission.

2. **Date -** This is the date of the application/submission which the certification accompanies.

3. **& 4. -** Provide complete address, telephone number and fax number of the sponsor/applicant/submitter.

5. **Product Information - For Drugs/Biologics:** Provide the established, proprietary name, and/or chemical/biochemical/blood product/ cellular/gene therapy name(s) for the product covered by the application/submission. Include all available names by which the product is known. **For Devices:** Provide the common or usual name, classification, trade or proprietary or model name(s), and/or model number(s). Include all available names/model numbers by which the product is known.

6. **Type of Application/Submission -** Identify the type of application/submission which the certification accompanies by checking the appropriate box. If the name of the type of application/submission is not identified, check the box labeled "Other."

7. **IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/Other Number -** If FDA has previously assigned a number associated with the application/ submission which this certification accompanies, list that number in this field. For example, if the application/submission accompanied by this certification is an IND protocol amendment and the IND number has already been issued by FDA, that number should be provided in this field.

8. **Serial Number -** In some instances a sequential serial number is assigned to the application. If there is such a serial number, provide it in this field.

9. **Certification -** This section contains three different check-off boxes.
   Box A should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply because no clinical trials are included, relied upon, or otherwise referred to, in the application/ submission which the certification accompanies.

   Box B should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply at the time of submission to any clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do not apply to any of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

   Box C should be checked if the sponsor/applicant/submitter has concluded that the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, do apply at the time of submission to some or all of the clinical trials that are included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. This means that, at the time the application/ submission is being made, the requirements of 42 U.S.C. § 282(j), section 402(j) of the Public Health Service Act, apply to one or more of the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies.

10. **National Clinical Trial (NCT) Numbers -** If you have checked Box C in number 9 (Certification), provide the NCT Number obtained from www.ClinicalTrials.gov for each clinical trial that is an "applicable clinical trial" under 42 U.S.C. § 282(j)(1)(A)(i), section 402(j)(1)(A)(i) of the Public Health Service Act, and that is included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies. Type only the number, as NCT will be added automatically before number. Include any and all NCT numbers assigned to the clinical trials included, relied upon, or otherwise referred to, in the application/submission which this certification accompanies. Multiple NCT numbers may be required for a particular certification, depending on the number of "applicable clinical trials" included, relied upon, or otherwise referred to, in the application/submission which the certification accompanies.

11. **Signature of Sponsor/Applicant/Submitter or an Authorized Representative -** The person signing the certification must sign in this field.

12. **Name and Title of Person Who Signed in number 11. -** Include the name and title of the person who is signing the certification. If the person signing the certification is not the sponsor/applicant/submitter of the application/submission, he or she must be an authorized representative of the sponsor/applicant/submitter.

13. **& 14. -** Provide the full address, telephone and fax number of the person who is identified in number 11 and signs the certification in number 11.

15. Provide the date the certification is signed. This date may be different from the date provided in number 2.

Paperwork Reduction Act Statement

Public reporting burden for this collection of information is estimated to average 15 minutes and 45 minutes (depending on the type of application/submission) per response, including time for reviewing instructions. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to the applicable address below.

Food and Drug Administration
Center for Drug Evaluation and Research
Central Document Room
Form No. FDA 3674
5901-B Ammendale Road
Beltsville, MD 20705-1266

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
Center for Devices and Radiological Health
Program Operations Staff (HFZ-403)
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 number.

FDA-3674 (1/08) (BACK)

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

COVER SHEET MEMORANDUM

From: Reviewer Name Caroline Rhim

Subject: 510(k) Number K113796/S1

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/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
☐	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)		✓	
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			✓

Questions concerning FORM FDA 3674 to CDRH-3674Mail@cdrh.fda.gov or 301-796-5118

Rev. 2/29/12

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**
21 CFR 888.3080	II	OVE

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

Additional Product Codes: —

Review: _____ OSDB 04/26/2012
(Branch Chief) (Branch Code) (Date)

Final Review: _____ 4/26/12
(Division Director) (Date)

5

DEPARTMENT OF HEALTH AND HUMAN SERVICES **MEMORANDUM**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K113796 / S1

Date: April 25, 2012
To: The Record
From: Caroline Rhim, Biomedical Engineer

Office: ODE
Division: DSORD/OSDB

510(k) Holder: Biomet Spine (aka EBI, LLC)
Device Name: Solitaire-C Cervical Spacer System
Contact: Ms. Margaret F. Crowe
Regulatory Affairs Project Manager
Address: 100 Interpace Parkway
Parsippany, NJ 07054
Phone: (973) 299-9300
Fax: (973) 257-0232
Email: margaret.crowe@biomet.com

Recommendation: SUBSTANTIALLY EQUIVALENT (SE)

I. Purpose and Submission Summary

(b)(4) CCI

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(b)(4) CCI

[redacted]

II. Administrative Requirements

		Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	Section 4	✓		
Truthful and Accuracy Statement	Section 6	✓		
510(k) Summary or 510(k) Statement	Section 5	✓		
Standards Form	Section 9	✓		

Reviewer Comments:

(b)(4) CCI

[redacted]

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		✓	
Is the device an implant (implanted longer than 30 days)?	✓		
Does the device design use software?		✓	
Is the device sterile?	✓	✓	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		✓	

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(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

9

(b)(4) CCI

Figure 1. Schematic of Subject Solitaire-C Cervical Spacer (6mm x 14mm x 12mm)

Figure 2. Solitaire-C Bone Screw

(b)(4) CCI

Figure 3. Schematic of Friction Fit Locking Mechanism

Materials

(b)(4) CCI

Predicates

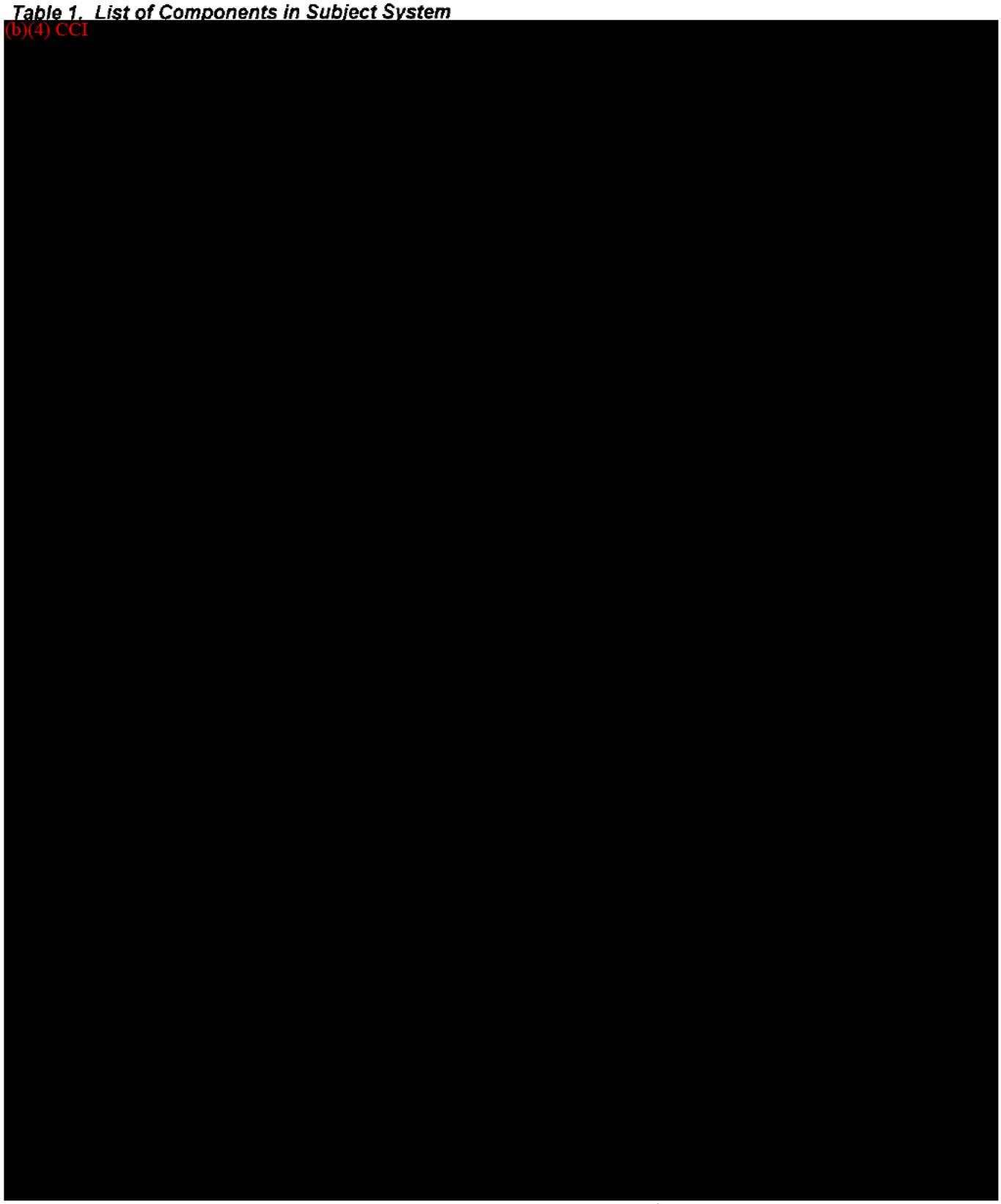
The proposed predicates for the subject device are the Biomet Spine Solitaire PEEK Anterior Spinal System (K081395, K093629), Globus Medical Coalition Spacer (K083389), Stryker Spine AVS Anchor-C Spacer (K102606), Synthes Zero-P Cervical Spacer (K072981, K093762), Biomet Spine C-Thru Spacer System (K092336), and Expandable PEEK Spacer (K082406). The sponsor also referenced the following predicates in the Mechanical Testing report (Section 18 of the original submission): DePuy Spine Uniplate Anterior Cervical Plating System (K042544), Biomet Spine SpineLink Anterior Cervical Spinal System (K973923), and Synthes Cervical Spine Locking Plate (K945700).

Engineering Drawings

Engineering drawings of the subject devices are provided in Attachment 11-2. A list of subject device components was provided in Attachment 11-1 of the original submission and also provided in Table 1 below for reference.

Table 1. List of Components in Subject System

(b)(4) CCI



(b)(4) CCI

[redacted]

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(b)(4) CCI

Reviewer Comments:

(b)(4) CCI

13

(b)(4) Deficiencies-Comments

[redacted]

(b)(4) Deficiencies-Comments

[redacted]

15

(b)(4) Deficiencies-Comments

[redacted]

IV. Indications for Use

(b)(4) Deficiencies-Comments

[redacted]

Reviewer Comments:

(b)(4) Deficiencies-Comments

[redacted]

Round 1, Deficiency #6:

(b)(4) Deficiencies-Comments [redacted]

Sponsor's Response to Round 1, Deficiency #6: *The sponsor modified the Indications for Use statement, 510(k) Summary, draft Instructions for use, and the draft surgical technique manual to reflect the use of the titanium screws. The appropriate documents were provided in Attachment C.*

(b)(4) Deficiencies-Comments [redacted]

V. Predicate Device Comparison

(b)(4) Deficiencies-Comments [redacted]

(b)(4) Deficiencies-Comments [redacted]

Table 2. Substantial Equivalence Table (Provided by Sponsor)

Device	Solitaire-C	Solitaire Lumbar	Coalition	AVS Anchor-C	Synthes Zero-P	C-Thru Spacer
Manufacturer						
	Biomet Spine	Biomet Spine	Globus Medical	Stryker Spine	Synthes Spine	Biomet Spine
Device Information						
510(k) Number	(b)(4)					
Product Codes						
Intended Use						
Stand-alone cervical interbody fusion						
Material						
Design						
Styles						
Heights						
Footprints (mm) Width x Depth						
Bone Screws						
Locking Mechanism						
Operational Principle						
Stand-alone Spacer						
Use with autograft						

(b)(4)

Reviewer Comments:

(b)(4) Deficiencies-Comments

[redacted]

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(b)(4) Deficiencies-Comments

[redacted]

VI. Labeling

Draft labeling (outer label, package insert, and surgical technique manual) was provided in Section 13 of the original submission.

(b)(4) Deficiencies-Comments

[redacted]

Reviewer Comments:

(b)(4) Deficiencies-Comments

[redacted]

VII. Sterilization/Shelf Life/Reuse

(b)(4) Deficiencies-Comments

[redacted]

21

Table 3. Sterilization Information for Subject System

1. Sterilant:	YES	NO
a. **Sterilization method** description (e.g., Steam (moist heat), EO, Radiation):	(b)(4) Deficiencies-Comments	
b. **Dose**, for radiation (e.g., 25 – 50 kGy):		
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals*," do not include measurement of ethylene glycol residuals);		
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),		
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))		
4. Is it labeled "Pyrogen Free"?		
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):		

(b)(4) Deficiencies-Comments

Table 4. Sterilization Parameters For Non-sterile Devices

(b)(4) Deficiencies-Comments

Reviewer Comments:

(b)(4) Deficiencies-Comments

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VIII. Biocompatibility

(b)(4) Deficiencies-Comments

[redacted]

IX. Software

(b)(4) Deficiencies-Comments [redacted]

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

(b)(4) Deficiencies-Comments

[redacted]

Reviewer Comments:

(b)(4) Deficiencies-Comments [redacted]

XI. Performance Testing – Bench

(b)(4) Deficiencies-Comments

[redacted]

Table 6. Performance Bench Testing Results (Reviewer-Generated)

Performance Bench Testing	Subject Solitaire®-C Cervical Cage	Sponsor's Stated Predicates	Early Bird Values & Lanx Cervical SA Cage (K112388)*
Static Compression	(b)(4) Deficiencies-Comments [redacted]		
Static Compression Shear			
Static Torsion			
Dynamic Compression			
Dynamic Compression Shear**			
Dynamic Torsion			

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Subsidence	(b)(4) Deficiencies-Comments [redacted]
Expulsion	
Screw Back-Out Testing	
Screw Push-Through Testing	
Torsion Interconnection Testing	

(b)(4) Deficiencies-Comments [redacted]

Table 7. Testing Details and Failure Modes for Subject Device

Performance Bench Test	Testing Details	Failure Mode(s)
Static Axial Compression	(b)(4) Deficiencies-Comments [redacted]	
Dynamic Axial Compression		
Static Compression Shear		

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Dynamic Compression Shear†	(b)(4) Deficiencies-Comments [redacted]
Static Torsion	
Dynamic Torsion	
Subsidence	
Expulsion	
Screw Backout Testing	
Screw Push Through Testing	
Torsion Connection Testing	

(b)(4) Deficiencies-Comments [redacted]

Reviewer Comments:

(b)(4) Deficiencies-Comments [redacted]

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(b)(4) Deficiencies-Comments

[redacted]

3.2 Features that change as height varies include:

(b)(4) Deficiencies-Comments

[redacted]

(b)(4) Deficiencies-Comments

[redacted]

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(b)(4) Deficiencies-Comments

[redacted]

(b)(4) Deficiencies-Comments

[redacted]

(b)(4) Deficiencies-Comments

[redacted]

(b)(4) Deficiencies-Comments

[redacted]

Round 1, Deficiency #1:

(b)(4) Deficiencies-Comments

[redacted]

(b)(4) Deficiencies-Comments

[redacted]

Sponsor's Response to Round 1, Deficiency #1: (b)(4) Deficiencies-Comments

[redacted]

(b)(4) Deficiencies-Comments

[redacted]

(b)(4) Deficiencies-Comments

[redacted]

31

(b)(4) Deficiencies-Comments

[redacted]

Round 1, Deficiency #2:

(b)(4) Deficiencies-Comments

[redacted]

Sponsor's Response to Round 1, Deficiency #2*: The sponsor stated that the wear debris analysis*

(b)(4) Deficiencies-Comments

[redacted]

(b)(4) Deficiencies-Comments

[redacted]

Wear Results Summary for Compression Fatigue Run-Outs

(b)(4) Deficiencies-Comments

[redacted]

32-

(b)(4) Deficiencies-Comments

(b)(4) Deficiencies-Comments

Interactive Deficiency (communicated to sponsor via telephone call on 04/24/2012): The (b)(4) Deficiencies-Comments

XII. Performance Testing – Animal

(b)(4) Deficiencies-Comments

Reviewer Comments:

(b)(4) Deficiencies-Comments

XIII. Performance Testing – Clinical

(b)(4) Deficiencies-Comments

Reviewer Comments:

(b)(4) Deficiencies-Comments

XIV. 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: **SE**

Note: See http://eroom.fda.gov/eRoomReg/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

1. Explain how the new indication differs from the predicate device's indication: N/A
2. Explain why there is or is not a new effect or safety or effectiveness issue: N/A
3. Describe the new technological characteristics: N/A
4. Explain how new characteristics could or could not affect safety or effectiveness: N/A
5. Explain how descriptive characteristics are not precise enough: *Please see Section XI of this memorandum. Performance bench testing (per ASTM F2077 and ASTM F2267) are necessary to determine substantial equivalence.*
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new: N/A
7. Explain why existing scientific methods can not be used: N/A
8. Explain what performance data is needed: *N/A*
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: *Please see Section XI of this memorandum. The subject devices are found to be substantially equivalent to other predicate devices in terms of performance bench testing per ASTM F2077 and ASTM F2267 as well as additional tests that were not performed to a specific standard (for feature characterization).*

X. First Round Deficiencies

1. (b)(4) Deficiencies-Comments

2. (b)(4) Deficiencies-Comments

3. (b)(4) Deficiencies-Comments

4. (b)(4) Deficiencies-Comments

5. (b)(4) Deficiencies-Comments

6. (b)(4) Deficiencies-Comments

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(b)(4) Deficiencies-Comments

7. The following deficiencies relate to your draft labeling (Section 13 of your 510(k) submission):

   a. (b)(4) Deficiencies-Comments

   b. (b)(4) Deficiencies-Comments

8. (b)(4) Deficiencies-Comments

XI. Contact History

02/02/2012	First round deficiencies sent to sponsor. The sponsor acknowledged receipt.
02/06/2012	Sponsor requested conference call.
02/15/2012	Conference call with sponsor with discussions regarding first round deficiencies.
02/16/2012	Sponsor sent meeting minutes from conference call.
02/22/2012	Email to sponsor clarifying safety factor of dynamic compression shear testing.
04/24/2012	(b)(4)
04/25/2012	(b)(4)

XII. Recommendation

SUBSTANTIALLY EQUIVALENT (SE)

Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE

Reviewer — Date: 04/25/2012

Branch Chief — Date: 04/26/2012

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Rhim, Caroline

·om: Crowe, Margaret [Margaret.Crowe@biomet.com]
ent: Monday, February 06, 2012 1:10 PM
To: Rhim, Caroline
Cc: Sanders, Laurie; Dougherty-Shah, Gretchen; Bing, Debra; Kelly, Vivian
Subject: RE: K113796 - First Round Deficiencies

Sensitivity: Confidential

Follow Up Flag: Follow up
Flag Status: Completed

Hi Dr. Rhim,

Representatives from Product Development and I would like to talk with you for some additional information regarding the questions on([redacted] b)

If possible, we would like to speak with you at some point on Tuesday, February 7th. If you could provide us with some times that would be good for you, we would greatly appreciate it. If that day does not work, please provide us with some alternate dates/times that would be good for you.

Thanks very much for your help.

Margaret

argaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
973-299-9300, ext. 2260 (Telephone)
973-257-0232 (Fax)

-----Original Message-----
From: Rhim, Caroline [mailto:Caroline.Rhim@fda.hhs.gov]
Sent: Friday, February 03, 2012 4:00 PM
To: Crowe, Margaret
Subject: RE: K113796 - First Round Deficiencies
Sensitivity: Confidential

Dear Ms. Crowe,

Thank you for your confirmation. Please do contact me if any further questions arise.

Best regards,
Caroline R.

-----Original Message-----
From: Crowe, Margaret [mailto:Margaret.Crowe@biomet.com]
Sent: Thursday, February 02, 2012 3:14 PM
To: Rhim, Caroline
Subject: RE: K113796 - First Round Deficiencies
Sensitivity: Confidential

ear Dr. Rhim,

I have received your deficiency regarding K113796. We may need to discuss some of the questions with you. If so, I will contact you to set up some time.

Thank you for your prompt attention to this submission.

Sincerely,

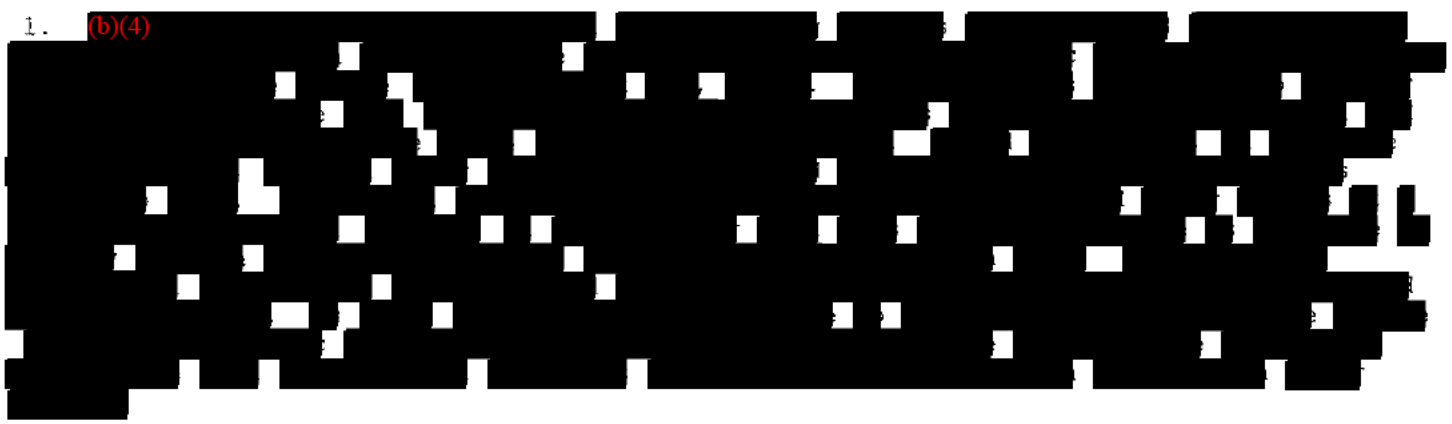
Margaret Crowe
Regulatory Affairs Project Manager

From: Rhim, Caroline [Caroline.Rhim@fda.hhs.gov]
Sent: Thursday, February 02, 2012 2:19 PM
To: Crowe, Margaret
Subject: K113796 - First Round Deficiencies

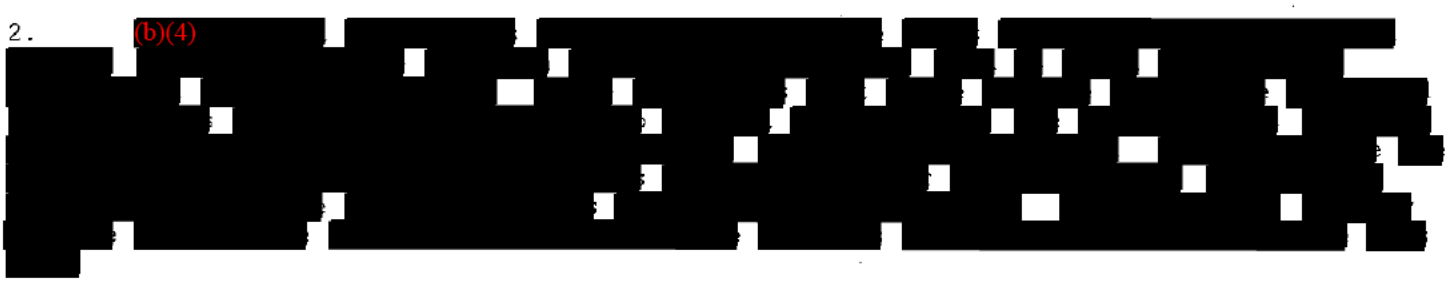
Dear Ms. Crowe,

We have reviewed your Traditional 510(k) premarket notification of intent to market the Solitaire-C Cervical Spacer System (K113796). We cannot determine if the device is substantially equivalent to a legally marketed predicate device with the information provided. To complete the review of your submission, we require that you address the following deficiencies:

1. (b)(4)

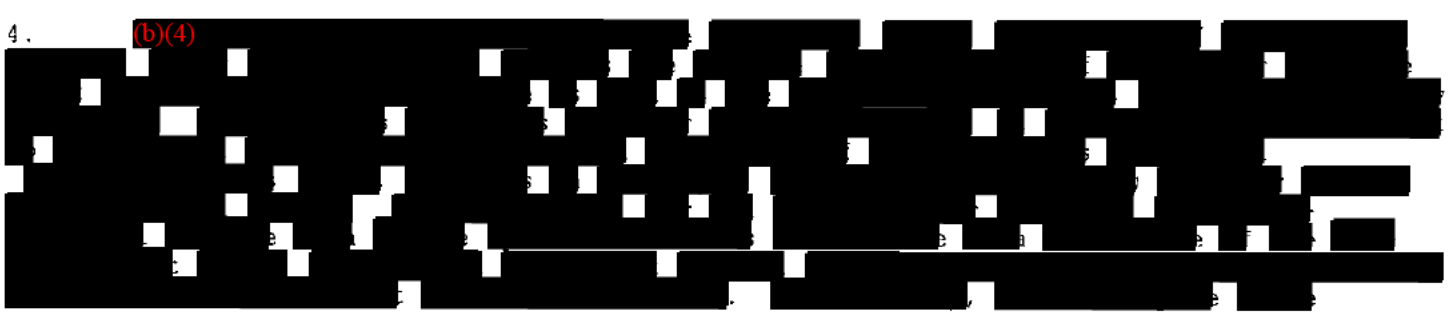


2. (b)(4)



3. (b)(4)

4. (b)(4)



parameters to those of valid predicates.

5. (b)(4) [redacted]

6. (b)(4) [redacted]

7. The following deficiencies relate to your draft labeling (Section 13 of your 510(k) submission):

1. (b)(4) [redacted]

b. (b)(4) [redacted]

8. (b)(4) [redacted]

Please note that I have placed your file on telephone hold, which will remain effective until the Document Mail Center receives all of the responses to the deficiencies above. As always, please do not hesitate to contact me with any questions, comments, or concerns.

Sincerely,
Caroline Rhim

Caroline Rhim, Ph.D.
Biomedical Engineer
U.S. Food and Drug Administration
Orthopedic Spine Devices Branch (OSDB)
Center for Devices and Radiological Health
Document Mail Center - WO66 Room 1443
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Phone: (301) 796-6432
Email: caroline.rhim@fda.hhs.gov

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This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time. It does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

Rhim, Caroline

From: Crowe, Margaret [Margaret.Crowe@biomet.com]
Sent: Thursday, February 16, 2012 6:02 PM
To: Rhim, Caroline
Cc: (b)(4) [redacted]
Subject: (b)(4) [redacted]
Follow Up Flag: Follow up
Flag Status: Red
Attachments: K113796 Deficiency Response FEB-2012 - meeting minutes from call 2 15 12 final.docx

Hi Dr. Rhim,

Attached please find the minutes from our phone conversation. Please let me know if I need to make any changes.

Thanks again for your time.

Margaret

Margaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
973-299-9300, ext. 2260 (Telephone)
973-257-0232 (Fax)

(b)(4)

[redacted]

The following questions from the deficiency were discussed. The summary of the discussion appears after the cited question.

1. (b)(4)

[redacted]

. **Discussion:**

(b)(4)

[redacted]

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(b)(4)

4. (b)(4)

Discussion:

(b)(4)

5. (b)(4)

Discussion:

(b)(4)

4U

(b)(4)

8. (b)(4)

Discussion:

(b)(4)

Rhim, Caroline

From: Peck, Jonathan H
Sent: Wednesday, April 18, 2012 11:50 AM
To: Rhim, Caroline
Subject: FW: K113796 - Solitaire C Cervical Spacer system
Attachments: K113796 - Deficiency 3 Response 30-Mar-2012.pdf

Is this the email?

Thanks again for trading!!!

From: Jean, Ronald P
Sent: Friday, March 30, 2012 2:36 PM
To: Peck, Jonathan H
Subject: FW: K113796 - Solitaire C Cervical Spacer system

FYI...

Ronald P. Jean, Ph.D. ronald.jean@fda.hhs.gov
Chief, Orthopedic Spine Devices Branch
U.S. Food & Drug Administration
Tel: (301) 796-5650 Fax: (301) 847-8117

From: Crowe, Margaret [mailto:Margaret.Crowe@biomet.com]
Sent: Friday, March 30, 2012 2:23 PM
To: Jean, Ronald P
Subject: RE: K113796 - Solitaire C Cervical Spacer system

Hi Dr. Jean,

(b)(4) [redacted]

Thanks for your help with this.

Best regards,

Margaret

Margaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
973-299-9300, ext. 2260 (Telephone)
973-257-0232 (Fax)

From: Jean, Ronald P [mailto:Ronald.Jean@fda.hhs.gov]
Sent: Friday, March 30, 2012 1:00 PM
To: Crowe, Margaret
Subject: RE: K113796 - Solitaire C Cervical Spacer system

Dear Ms. Crowe,

If you have an electronic copy of the updated materials (even just the affected section), please send that to me directly, and I can expedite the passage of the information to the assigned reviewer.

Thanks,

Ronald

Ronald P. Jean, Ph.D. ronald.jean@fda.hhs.gov
Chief, Orthopedic Spine Devices Branch
U.S. Food & Drug Administration
Tel: (301) 796-5650 Fax: (301) 847-8117

From: Crowe, Margaret [mailto:Margaret.Crowe@biomet.com]
Sent: Friday, March 30, 2012 11:21 AM
To: Jean, Ronald P
Subject: K113796 - Solitaire C Cervical Spacer system

Hi Dr. Jean,

(b)(4) [redacted]

Margaret

Margaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
973-299-9300, ext. 2260 (Telephone)
973-257-0232 (Fax)

3. (b)(4) [redacted]

Biomet Response:

(b)(4) [redacted]

Explanation of the Solitaire-C Spacer Assembly

(b)(4) [redacted]

(b)(4)

1. (b)(4)

2. (b)(4)

(b)(4)

	Solitaire-C Implant Prior to Band Assembly	Solitaire-C Implant Following Band Assembly
Axial View	(b)(4)	
Lateral View		
3D View		

(b)(4)

(b)(4)

How the Spacer Changes when Spacer Width, Depth, and Height are Modified

(b)(4)

(b)(4)

Anatomic Directions Relative to Human Body	Anatomic Directions Relative to the Solitaire-C Cervical Spacer

SO

3.1 Features that remain unchanged as implant height, width, or depth vary include:

(b)(4)

[redacted]

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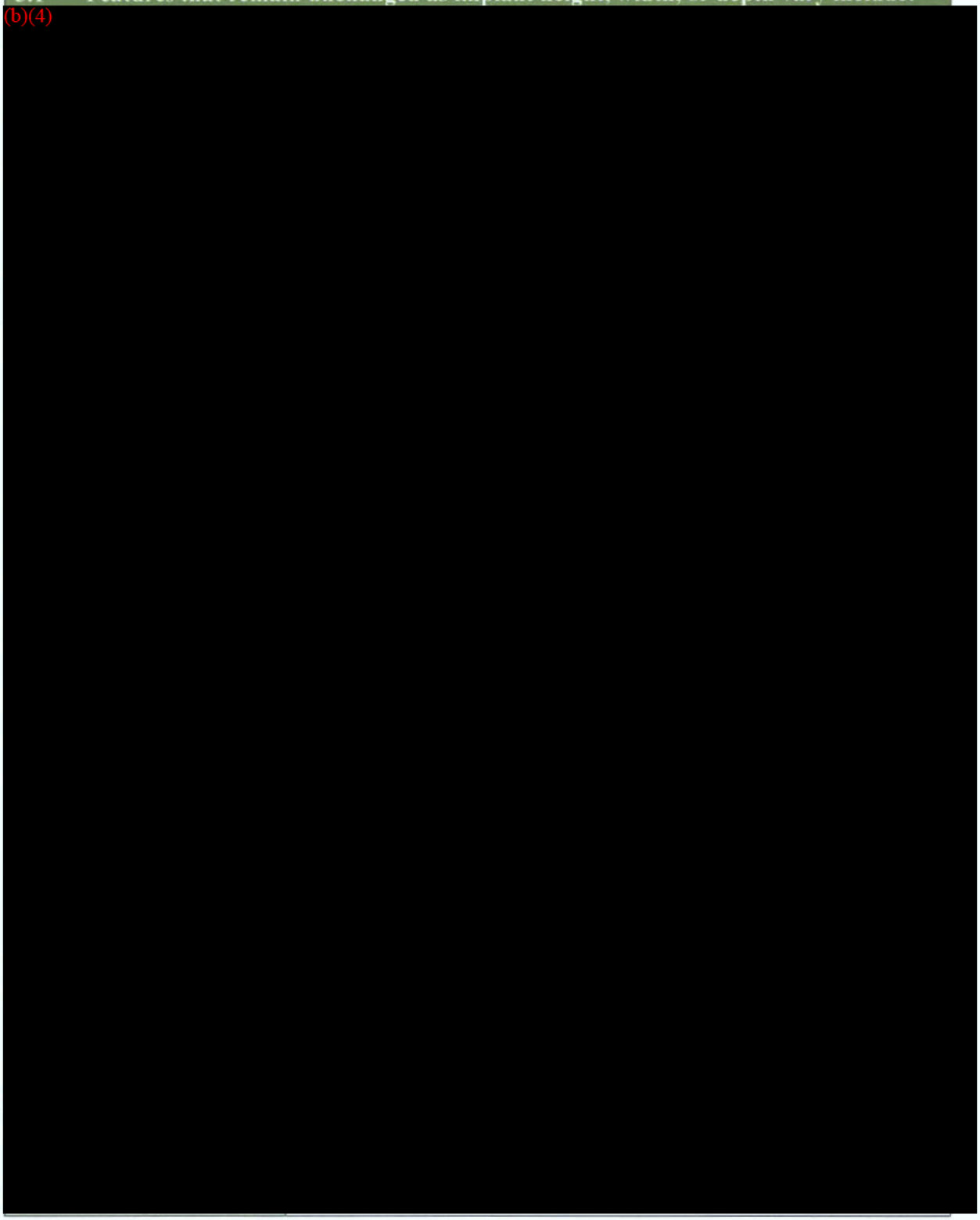
3.1 Features that remain unchanged as implant height, width, or depth vary include:

(b)(4)



52

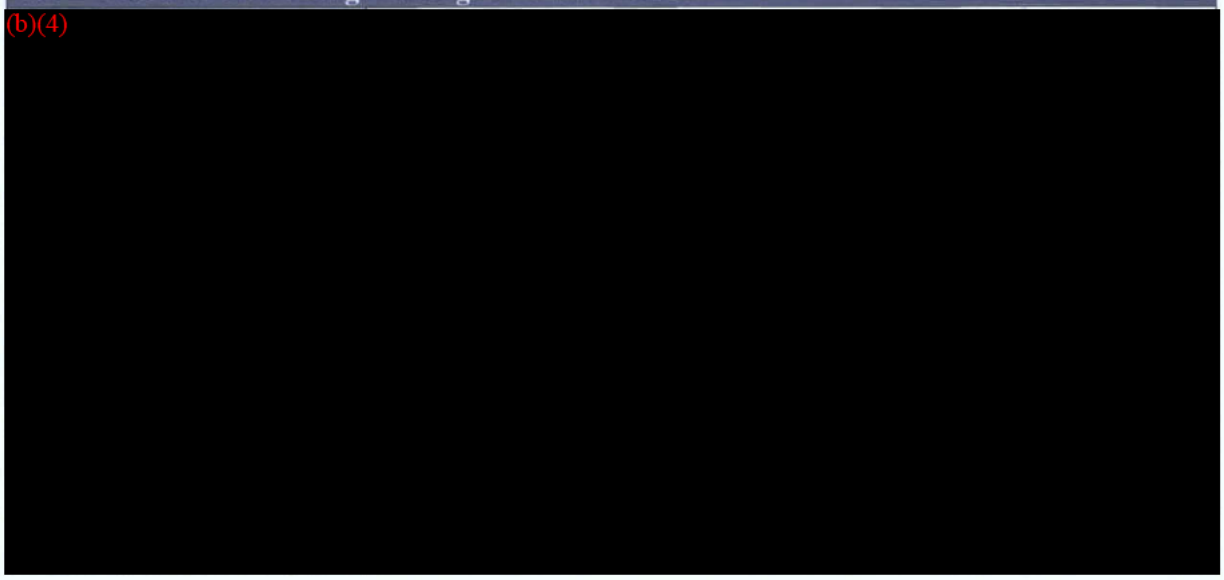
3.2 Features that change as height varies include:

(b)(4)

[redacted]

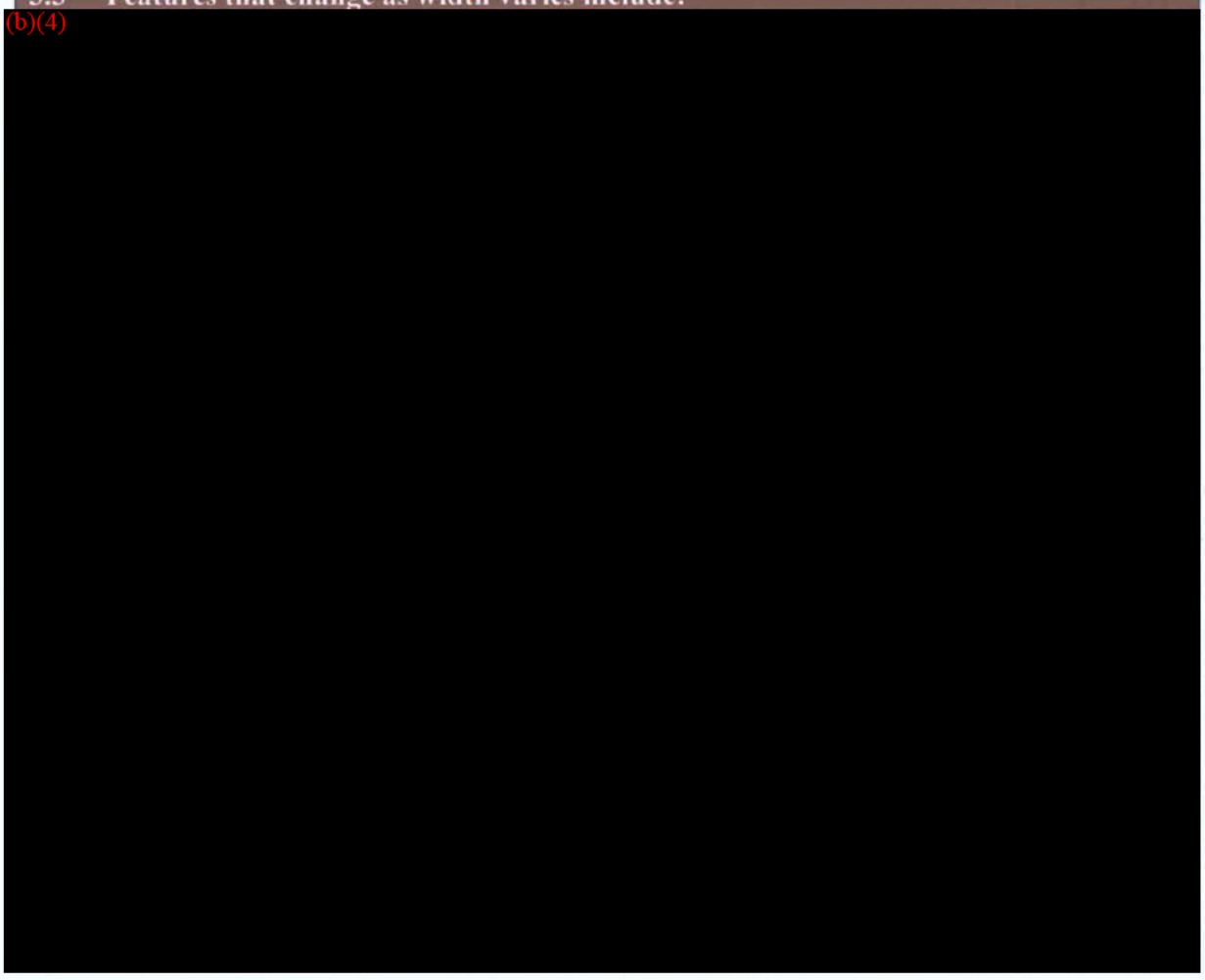
3.2 Features that change as height varies include:

(b)(4)



3.3 Features that change as width varies include:

(b)(4)



S4

3.4 Features that change as depth varies include:

(b)(4)

[redacted]

55

Worst-Case Rationale for Compression

(b)(4)

(b)(4)

- Titanium Faceplate – (b)(4)

- PEEK Body – (b)(4)

- Titanium Band – [redacted] (b)(4)

(b)(4) [redacted]

Worst Case Rationale for Compression Shear

(b)(4) [redacted]

(b)(4) [redacted]

(b)(4) [redacted]

57

(b)(4)

- Titanium Faceplate – (b)(4)
- PEEK Body – (b)(4)
- Titanium Band – (b)(4)

(b)(4)

(b)(4)

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Worst Case Rationale for Torsion

(b)(4)

[redacted]

(b)(4)

[redacted]

- Titanium Faceplate – (b)(4)

[redacted]

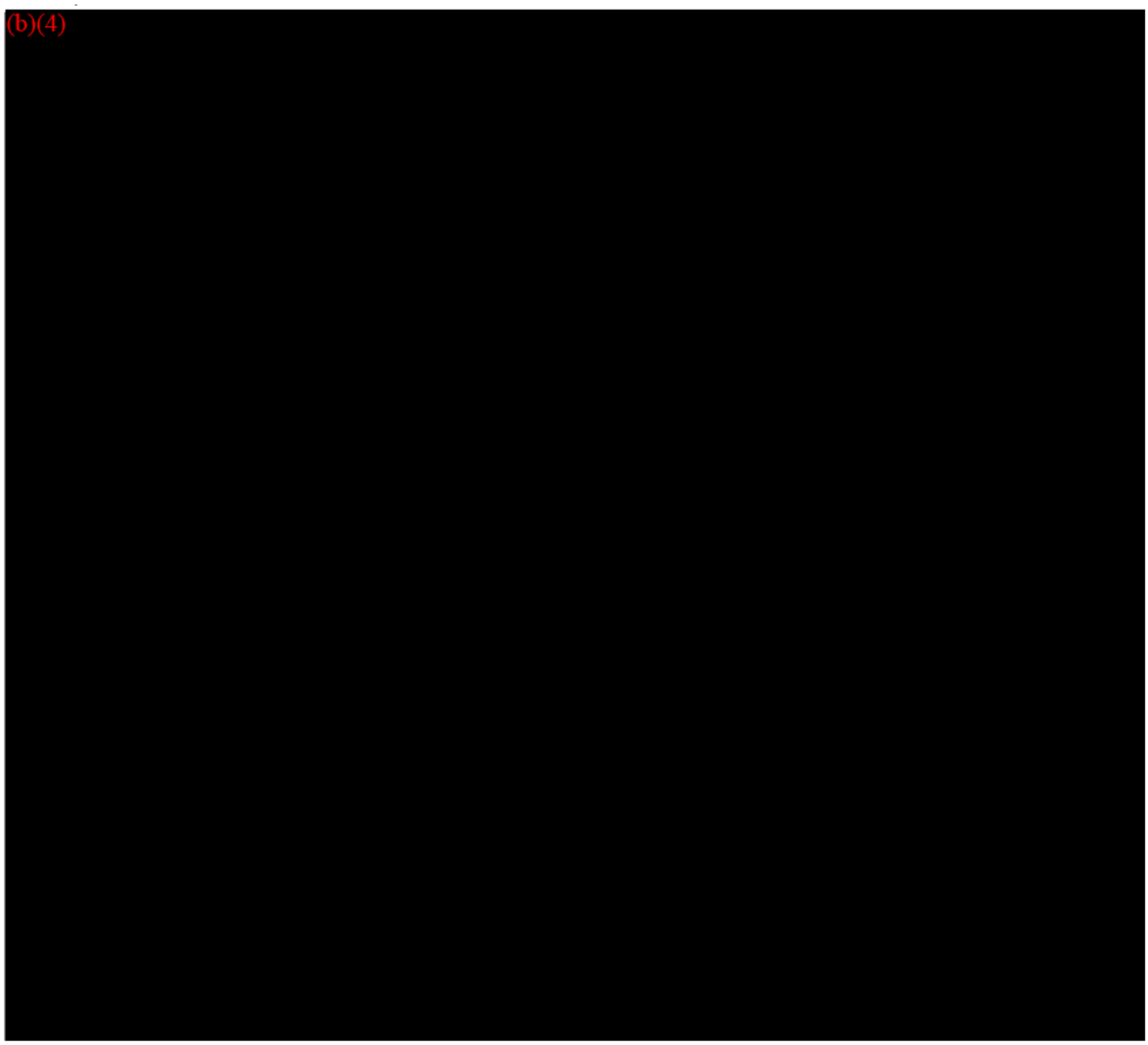
(b)(4)

[redacted]

59

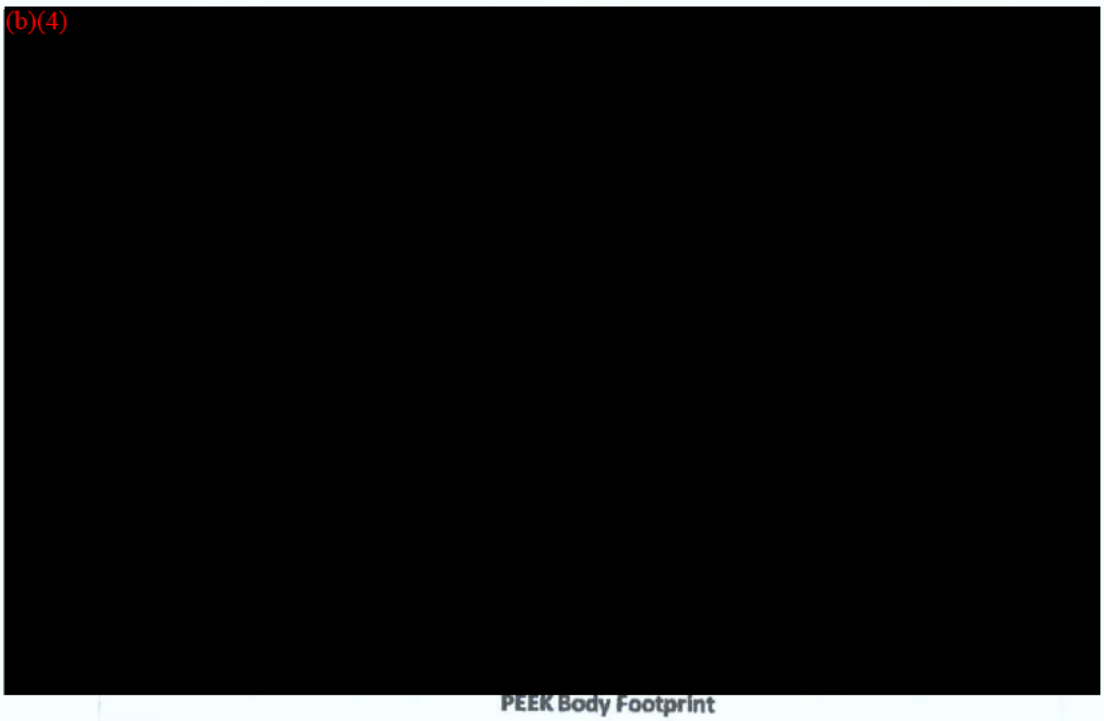
(b)(4)

(b)(4)



b 6

(b)(4)



PEEK Body Footprint

(b)(4)

(b)(4)

- Titanium Band – (b)(4)

6 (

(b)(4)

[redacted]

Conclusion

(b)(4)

[redacted]

b 2

Rhim, Caroline

From: Crowe, Margaret [Margaret.Crowe@biomet.com]
Sent: Tuesday, April 24, 2012 1:23 PM
To: Rhim, Caroline
Subject: (b)(4)
Attachments: (b)(4)

Hi Dr. Rhim,

(b)(4)

I hope this addresses your questions adequately. Please let me know if need anything else, and if the (b)(4)

I appreciate the help.

Margaret

Margaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
973-299-9300, ext. 2260 (Telephone)
973-257-0232 (Fax)

From: (b)(4)]
Sent: Tuesday, April 24, 2012 1:07 PM
To: Crowe, Margaret
(b)(4)

Hello Margaret
(b)(4)

Please do not hesitate to contact me if there are any other clarifications, questions etc we can help you with.
Best Regards
Nadim

Nadim Hallab, PhD

(b)(4)

[redacted]

From: Crowe, Margaret [mailto:Margaret.Crowe@biomet.com]
Sent: Tuesday, April 24, 2012 11:35 AM
To: (b)(4) [redacted]
Subject: (b)(4) [redacted]
Importance: (b) [redacted]

Hi (b)(4) [redacted],

(b)(4)

[redacted]

Thanks very much.

Margaret Crowe

Margaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
973-299-9300, ext. 2260 (Telephone)
973-257-0232 (Fax)

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

Rhim, Caroline

From: Crowe, Margaret [Margaret.Crowe@biomet.com]
Sent: Wednesday, April 25, 2012 11:16 AM
To: Rhim, Caroline
Subject: K113796 - Revised 510(k) Summary
Attachments: 510(k) Summary revised 4 25 12.pdf

Hi Dr. Rhim,

I think this is correct – please see the revised 510(k) summary. Thanks very much.

Margaret

Margaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
973-299-9300, ext. 2260 (Telephone)
973-257-0232 (Fax)

Section 5

510(k) Summary

30

BIOMET SPINE

510(k) Summary

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

Preparation Date:	April 25, 2012
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Margaret F. Crowe Phone: 973-299-9300, ext. 2260 Fax: 973-257-0232
Trade name:	Solitaire®-C Cervical Spacer System
Common Name:	Cervical interbody fusion device with integrated fixation
Classification Name (Product Code):	Intervertebral Body Fusion Device (OVE)
Device Panel - Regulation No.:	Orthopedics - 21 CFR 888.3080

Device Description:

The purpose of this submission is to gain market clearance for the Solitaire-C Cervical Spacer System. The Solitaire®-C Cervical Spacer System consists of spacers and bone screws for stand-alone cervical intervertebral body fusion. The Solitaire®-C spacer will be available in a variety of sizes, angles and footprints.
This cervical spacer has a PEEK main body (PEEK-Optima LT1 per ASTM F-2026) with a titanium faceplate and band (Ti-6Al-4V ELI alloy per ASTM F-136), and tantalum markers (unalloyed tantalum per ASTM F-560). This device accepts titanium bone screws that are available in two diameters and multiple lengths.

Indications for Use:

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer is to be used with autograft and implanted via an anterior approach. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the Solitaire-C Cervical Spacer System is the same as, or similar to, the predicate devices. Examples of predicate devices include:

- Solitaire PEEK Anterior Spinal System (Biomet Spine - K081395, K093629)
- Coalition Spacer (Globus Medical – K083389)
- AVS-C Spacer (Stryker Spine – K102606)
- Synthes Zero-P Cervical Spacer (Synthes Spine – K072981, K093762)
- C-Thru Spacer System (Biomet Spine – K092336)

Performance Data

Mechanical testing recommended in the special controls guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was conducted. The testing conducted, along with the ASTM standard, are listed below:

1) Static Axial Compression (ASTM F-2077)
2) Dynamic Axial Compression (ASTM F-2077)
3) Static Compression-Shear (ASTM F-2077)
4) Dynamic Compression-Shear (ASTM F-2077)
5) Static Torsion (ASTM F-2077)
6) Dynamic Torsion (ASTM F-2077)
7) Subsidence (ASTM F-2267 and ASTM F-2077)
8) Expulsion (ASTM Draft F-04.25.02.02)

Additional mechanical testing was conducted to evaluate screw back out, screw push through, and interconnection testing between the spacer body and the faceplate. Wear debris analysis was also presented.

Mechanical testing shows that the mechanical strength of the subject device is sufficient for its intended use.

Substantial Equivalence:

The Solitaire-C Cervical Spacer System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. The predicates listed above are distributed for similar indications, and/or have similar design features.

Rhim, Caroline

From: Crowe, Margaret [Margaret.Crowe@biomet.com]
Sent: Wednesday, April 25, 2012 2:44 PM
To: Rhim, Caroline
Subject: (b)(4) CCI [redacted]

Dear Dr. Rhim,

(b)(4) CCI [redacted]

I hope this information, and the revised 510(k) summary, is adequate. Please let me know if you need any other information.

Thanks very much.

Margaret

Margaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
973-299-9300, ext. 2260 (Telephone)
973-257-0232 (Fax)

From: Rhim, Caroline [mailto:Caroline.Rhim@fda.hhs.gov]
Sent: Tuesday, April 24, 2012 4:22 PM
To: Crowe, Margaret
Subject: (b)(4) CCI [redacted]

Hello Ms. Crowe,

(b)(4) CCI [redacted]

Thank you,
Caroline R.

From: Crowe, Margaret [mailto:Margaret.Crowe@biomet.com]
Sent: Tuesday, April 24, 2012 1:23 PM
To: Rhim, Caroline
Subject: (b)(4) CCI [redacted]

Hi Dr. Rhim,

(b)(4) CCI [redacted]

I hope this addresses your questions adequately. Please let me know if need anything else, and if the (b)(4) CCI

I appreciate the help.

Margaret

Margaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
973-299-9300, ext. 2260 (Telephone)
973-257-0232 (Fax)

From: (b)(4) CCI
Sent: Tuesday, April 24, 2012 1:07 PM
To: Crowe, Margaret
(b)(4) CCI

Hello Margaret

(b)(4) CCI

Please do not hesitate to contact me if there are any other clarifications, questions etc we can help you with.
Best Regards
Nadim

(b)(4) CCI

[redacted] (b)(4) CCI [redacted]

From: Crowe, Margaret [mailto:Margaret.Crowe@biomet.com]
Sent: Tuesday, April 24, 2012 11:35 AM
To: nhallab@bioengineeringsolutions.com
(b)(4) [redacted]
CC [redacted]

(b)(4) CCI [redacted]

(b)(4) CCI [redacted]

Thanks very much.

Margaret Crowe

Margaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
973-299-9300, ext. 2260 (Telephone)
973-257-0232 (Fax)

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

COVER SHEET MEMORANDUM

From: Reviewer Name Caroline Rhim

Subject: 510(k) Number K113796

To: The Record

Please list CTS decision code TH

☐ 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
☐	NP	NSE for lack of performance data
☐	NC	NSE call for PMAs
☐	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/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC			
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			
Is this device intended for pediatric use only?			
Is this a prescription device? (If both prescription & OTC, check both boxes.)			
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?			
Is clinical data necessary to support the review of this 510(k)? 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**

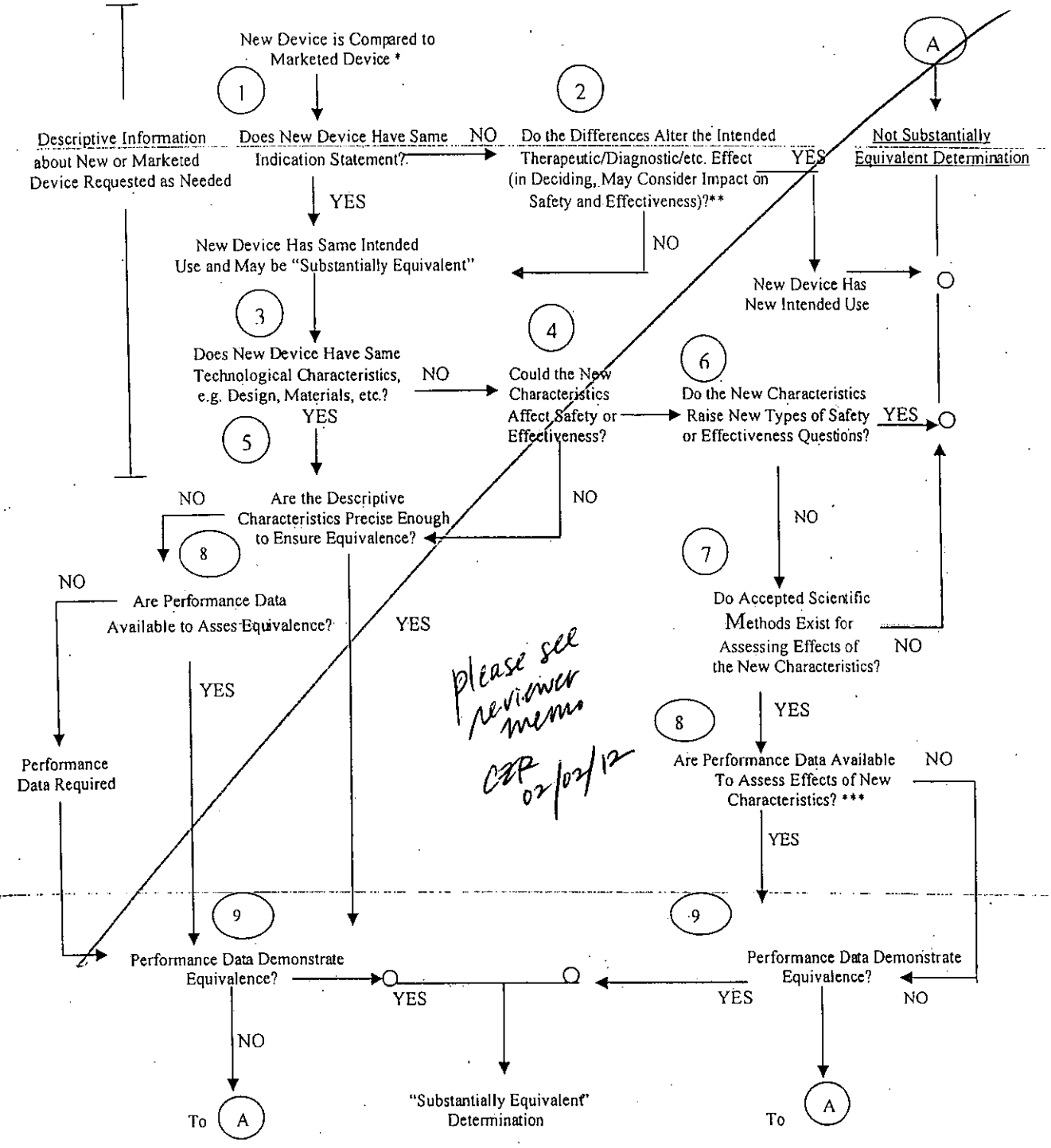
(*If unclassified, see 510(k) Staff)

Additional Product Codes:

Review: _____ OSDB 02/02/2012
(Branch Chief) (Branch Code) (Date)

Final Review: _____ for 02/02/2012
(Division Director) (Date)

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 **M E M O R A N D U M**

Food and Drug Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Premarket Notification [510(k)] Review
Traditional

K113796

Date: February 2, 2012
To: The Record
From: Caroline Rhim, Biomedical Engineer

Office: ODE
Division: DSORD/OSDB

510(k) Holder: Biomet Spine (aka EBI, LLC)
Device Name: Solitaire-C Cervical Spacer System
Contact: Ms. Margaret F. Crowe
Regulatory Affairs Project Manager
Address: 100 Interpace Parkway
Parsippany, NJ 07054
Phone: (973) 299-9300
Fax: (973) 257-0232
Email: margaret.crowe@biomet.com

Recommendation: TELEPHONE HOLD (TH)

I. Purpose and Submission Summary

(b)(4) CCI

[redacted]

II. Administrative Requirements

		Yes	No	N/A
Indications for Use page (Indicate if: Prescription or OTC)	Section 4	✓		
Truthful and Accuracy Statement	Section 6	✓		
510(k) Summary or 510(k) Statement	Section 5	✓		
Standards Form	Section 9	✓		

Reviewer Comments:

(b)(4) CCI

[redacted]

III. Device Description

	Yes	No	N/A
Is the device life-supporting or life sustaining?		✓	
Is the device an implant (implanted longer than 30 days)?	✓		
Does the device design use software?		✓	
Is the device sterile?	✓	✓	
Is the device reusable (not reprocessed single use)? Are "cleaning" instructions included for the end user?		✓	

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

(b)(4) CCI

(b)(4) CCI

Figure 1. Schematic of Subject Solitaire-C Cervical Spacer (6mm x 14mm x 12mm)

(b)(4) CCI

Figure 2. Solitaire-C Bone Screw

Figure 3. Schematic of Friction Fit Locking Mechanism

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Materials

(b)(4) CCI [redacted]

Predicates

The proposed predicates for the subject device are the Biomet Spine Solitaire PEEK Anterior Spinal System (K081395, K093629), Globus Medical Coalition Spacer (K083389), Stryker Spine AVS Anchor-C Spacer (K102606), Synthes Zero-P Cervical Spacer (K072981, K093762), Biomet Spine C-Thru Spacer System (K092336), (b)(4) CCI [redacted].

Engineering Drawings

Engineering drawings of the subject devices are provided in Attachment 11-2. A list of subject device components was provided in Attachment 11-1 of the original submission and also provided in Table 1 below for reference.

Table 1 List of Components in Subject System

(b)(4) CCI [redacted]

(b)(4) CCI

[redacted]

202

(b)(4) CCI

[redacted]

Reviewer Comments:

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

Round 1 Deficiency #4:

(b)(4) CCI

[redacted]

IV. Indications for Use

The indications for use supplied by the sponsor (Section 4 of original submission) is as follows:

"The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer System is to be used with autograft and implanted via an anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment."

Reviewer Comments:

(b)(4) CCI

[redacted]

204

(b)(4) CCI

[redacted]

V. Predicate Device Comparison

The proposed predicates for the subject device are as follows:

- Biomet Spine Solitaire PEEK Anterior Spinal System (K081395, K093629)
- Globus Medical Coalition Spacer (K083389)
- Stryker Spine AVS Anchor-C Spacer (K102606)
- Synthes Zero-P Cervical Spacer (K072981, K093762)
- Biomet Spine C-Thru Spacer System (K092336)
- Biomet Spine Expandable PEEK Spacer (K082406).

(b)(4) CCI

[redacted]

Table 2. Substantial Equivalence Table (Provided by Sponsor)

Device	Solitaire-C	Solitaire Lumbar	Coalition	AVS Anchor-C	Synthes Zero-P	C-Thru Spacer
Manufacturer						
	(b)(4) CCI [redacted]					
Device Information						
510(k) Number						
Product Codes						
Intended Use						
Stand-alone cervical interbody fusion						
Material						
Design						
Styles						
Heights						
Footprints (mm) Width x Depth						
Bone Screws						
Locking Mechanism						
Operational Principle						
Stand-alone Spacer						
Use with autograft						

(b)(4) CCI [redacted]

Reviewer Comments:

(b)(4) CCI

[redacted]

Round 1, Deficiency #5:

(b)(4) CCI

[redacted]

VI. Labeling

Draft labeling (outer label, package insert, and surgical technique manual) was provided in Section 13 of the original submission.

(b)(4) CCI

[redacted]

207

(b)(4) CCI

Reviewer Comments:

(b)(4) CCI

Round 1, Deficiency #7:

(b)(4) CCI

VII. Sterilization/Shelf Life/Reuse

(b)(4) CCI

Table 3. Sterilization Information for Subject System

	YES	NO
1. Sterilant:	(b)(4) CCI	
a. **Sterilization method** description (e.g., Steam (moist heat), EO, Radiation):		
b. **Dose**, for radiation (e.g., 25 – 50 kGy):		
c. **Sterilant residuals** remaining on the device: For EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: not to include ethylene glycol residual level because the standards that have been, or currently are recognized, "ANSI/AAMI/ISO 10993-7:1995 and 2008 *Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals*," do not include measurement of ethylene glycol residuals);		
2. A description of the Validation Method for the sterilization cycle (not data): (Full citation of an FDA recognized standard is recommended including date (e.g., ANSI/AAMI/ISO 11135:2007)),		
3. Sterility assurance level (SAL): (e.g., 10^{-6} for all devices (except 10^{-3} for devices that contact intact skin))		
4. Is it labeled "Pyrogen Free"?		
If so, a description of the method: (e.g., LAL (*Limulus* Amebocyte Lysate test))		
5. A description of the packaging (not including package integrity test data):		

(b)(4) CCI

Reviewer Comments:

(b)(4) CCI

VIII. Biocompatibility

(b)(4) CCI

[redacted]

IX. Software

(b)(4) CCI [redacted]

X. Electromagnetic Compatibility and Electrical, Mechanical and Thermal Safety

(b)(4) CCI

[redacted]

Reviewer Comments:

(b)(4) CCI

[redacted]

XI. Performance Testing – Bench

(b)(4) CCI

[redacted]

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Table 6. Performance Bench Testing Results (Reviewer-Generated)

Performance Bench Testing	Subject Solitaire®-C Cervical Cage	Sponsor's Stated Predicates	Early Bird Values & Lanx Cervical SA Cage (K112388)*
Static Compression	(b)(4) CCI		
Static Compression Shear			
Static Torsion			
Dynamic Compression			
Dynamic Compression Shear			
Dynamic Torsion			
Subsidence			

DLI

	Stiffness of System (K_s(N/mm))	469 ± 43 N/mm	Not provided	183 N/mm (K072991)
Expulsion	(b)(4) CCI			
Screw Back-Out Testing				
Screw Push-Through Testing				
Torsion Interconnection Testing				

(b)(4) CCI

Table 7. Testing Details and Failure Modes for Subject Device

Performance Bench Test	Testing Details	Failure Mode(s)
Static Axial Compression	(b)(4) CCI	
Dynamic Axial Compression		
Static Compression Shear		

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Dynamic Compression Shear	(b)(4) CCI [redacted]
Static Torsion	
Dynamic Torsion	
Subsidence	
Expulsion	
Screw Backout Testing	
Screw Push Through Testing	
Torsion Connection Testing	

Reviewer Comments:

(b)(4) CCI [redacted]

increasing heights. Based on this information, the sponsor's assessment of the worst-case may be correct, but it cannot be fully corroborated at this time. As such, the sponsor will be asked to clarify and justify their worst-case construct for different loading modes (e.g., axial compression, compression shear, and torsion).

Round 1, Deficiency #3:

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

214

Round 1, Deficiency #1:
(b)(4) CCI

Round 1, Deficiency #2:
(b)(4) CCI

XII. Performance Testing – Animal
(b)(4) CCI

Reviewer Comments:
(b)(4) CCI

XIII. Performance Testing – Clinical
(b)(4) CCI

Reviewer Comments:
(b)(4) CCI

215

XIV. 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?			Final Decision: **TH**

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: N/A
2. Explain why there is or is not a new effect or safety or effectiveness issue: N/A
3. Describe the new technological characteristics: N/A
4. Explain how new characteristics could or could not affect safety or effectiveness: N/A
5. Explain how descriptive characteristics are not precise enough: *Please see Section XI of this memorandum. Performance bench testing (per ASTM F2077 and ASTM F2267) are necessary to determine substantial equivalence.*
6. Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new: N/A
7. Explain why existing scientific methods can not be used: N/A
8. Explain what performance data is needed: *Please see Section XI of this memorandum. Additional justification for the performance bench test results is needed to determine substantial equivalence.*
9. Explain how the performance data demonstrates that the device is or is not substantially equivalent: N/A

X. First Round Deficiencies

1. (b)(4) CCI [redacted]

2. (b)(4) CCI [redacted]

3. (b)(4) CCI [redacted]

4. (b)(4) CCI [redacted]

5. (b)(4) CCI [redacted]

6. (b)(4) CCI [redacted]

217

(b)(4) CCI [redacted]

7. The following deficiencies relate[redacted]

   a. (b)(4) CCI [redacted]

   b. (b)(4) CCI [redacted]

8. (b)(4) CCI [redacted]

XI. Contact History

None at this time.

XII. Recommendation

Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE

Reviewer — Date: 02/02/2012

Branch Chief — Date: 02/02/2012

Rhim, Caroline

From: Rhim, Caroline
Sent: Thursday, February 02, 2012 2:19 PM
To: 'margaret.crowe@biomet.com'
Subject: K113796 - First Round Deficiencies

Importance: High
Sensitivity: Confidential

Dear Ms. Crowe,

We have reviewed your Traditional 510(k) premarket notification of intent to market the Solitaire-C Cervical Spacer System (K113796). We cannot determine if the device is substantially equivalent to a legally marketed predicate device with the information provided. To complete the review of your submission, we require that you address the following deficiencies:

1. (b)(4) CCI [redacted]
2. (b)(4) CCI [redacted]
3. (b)(4) CCI [redacted]
4. (b)(4) CCI [redacted]
5. (b)(4) CCI [redacted]
6. (b)(4) CCI [redacted]

219

(b)(4) CCI

7. The following deficiencies relate to (b)

   a. (b)(4) CCI

   b. (b)(4) CCI

8. (b)(4) CCI

Please note that I have placed your file on telephone hold, which will remain effective until the Document Mail Center receives all of the responses to the deficiencies above. As always, please do not hesitate to contact me with any questions, comments, or concerns.

Sincerely,
Caroline Rhim

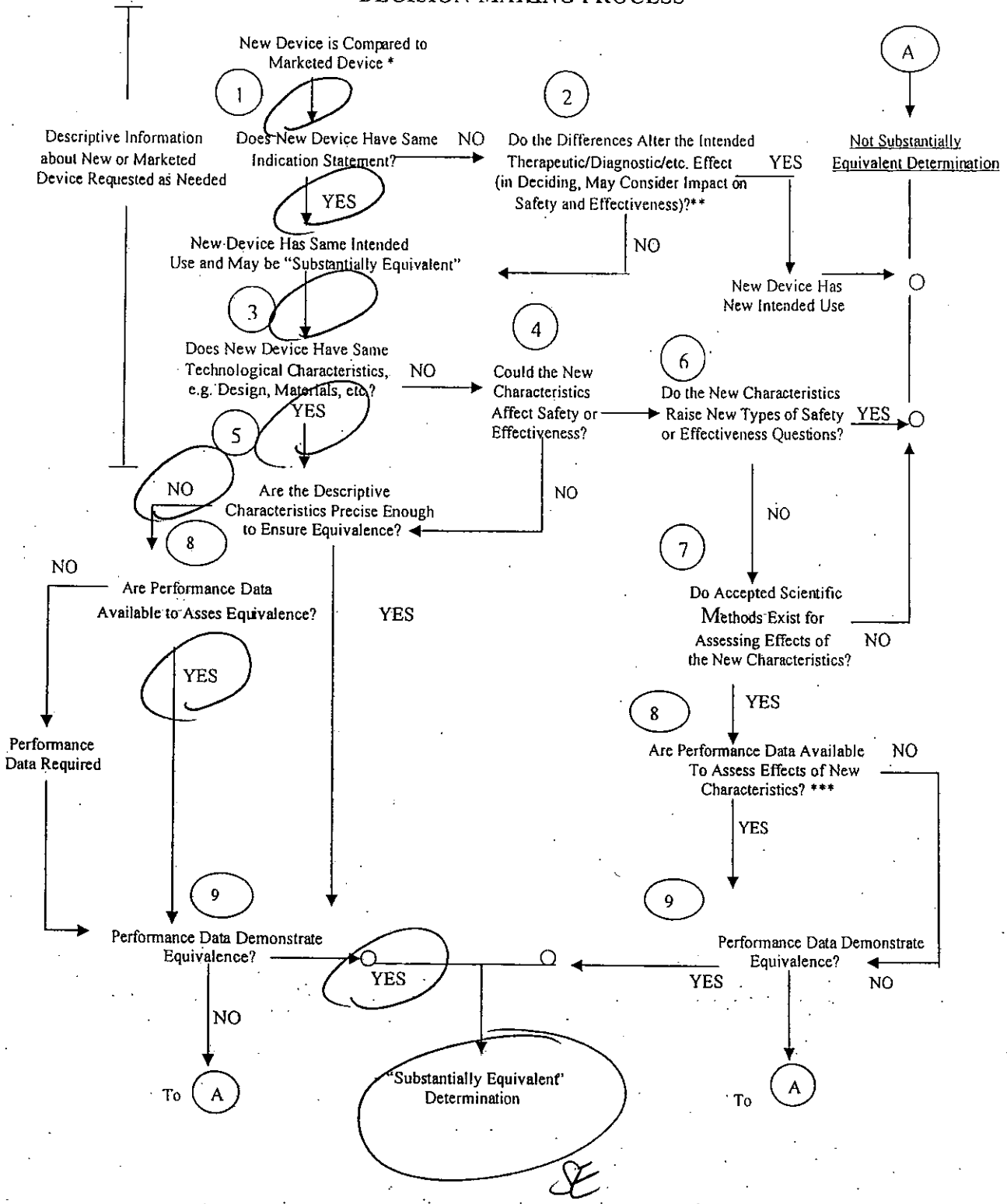
Caroline Rhim, Ph.D.
Biomedical Engineer
U.S. Food and Drug Administration
Orthopedic Spine Devices Branch (OSDB)
Center for Devices and Radiological Health
Document Mail Center – WO66 Room 1443
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Phone: (301) 796-6432
Email: caroline.rhim@fda.hhs.gov

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time. It does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

220

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 may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

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 16, 2012

EBI, LLC
100 INTERPACE PKWY.
PARSIPPANY, NEW JERSEY 07054
ATTN: MARGARET CROWE

510k Number: K113796

Product: SOLITAIRE-C CERVICAL SPACER SY

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

Mcdonald, Lisa *

From: Crowe, Margaret [Margaret.Crowe@biomet.com]
To: Mcdonald, Lisa *
Sent: Friday, March 16, 2012 12:02 PM
bject: Read: K113796 AI Letter

Your message was read on Friday, March 16, 2012 12:02:11 PM (GMT-05:00) Eastern Time (US & Canada).

87

K113796/S1

BIOMET SPINE

FDA CDRH DMC
MAR 16 2012 K42
Received

March 15, 2012

Caroline Rhim, Ph.D.
Biomedical Engineer
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Room – WO66 - G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: K113796 – Solitaire-C Cervical Spacer System

Dear Dr. Rhim:

Enclosed is Biomet Spine's response to your e-mail dated February 2, 2012 requesting additional information on the above referenced 510(k). The response is based on the outcome of the conference call with the FDA on February 15, 2012 per the documented minutes to address the deficiencies cited in the letter. FDA's request is highlighted in bold text followed by our response.

If any additional information is required, you may contact the undersigned by phone at 973-299-9300, Ext. 2260, fax at 973-257-0232 or via email at margaret.crowe@biomet.com.

Sincerely,

Margaret F Crowe

Margaret F. Crowe
Regulatory Affairs Project Manager
Biomet Spine

Submitted in Duplicate

EBI, LLC d/b/a
Biomet Spine & Bone Healing Technologies
100 Interpace Parkway
Parsippany, NJ 07054
Toll Free: 800.526.2579
Office: 973.299.9300
www.biomet.com

From: Rhim, Caroline [Caroline.Rhim@fda.hhs.gov]
Sent: Thursday, February 02, 2012 2:19 PM
To: Crowe, Margaret
Subject: K113796 - First Round Deficiencies

Dear Ms. Crowe,

We have reviewed your Traditional 510(k) premarket notification of intent to market the Solitaire-C Cervical Spacer System (K113796). We cannot determine if the device is substantially equivalent to a legally marketed predicate device with the information provided. To complete the review of your submission, we require that you address the following deficiencies:

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

7. The following deficiencies relate to your (b)(4) CCI :

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

Please note that I have placed your file on telephone hold, which will remain effective until the Document Mail Center receives all of the responses to the deficiencies above. As always, please do not hesitate to contact me with any questions, comments, or concerns.

Sincerely,
Caroline Rhim

Caroline Rhim, Ph.D.
Biomedical Engineer
U.S. Food and Drug Administration
Orthopedic Spine Devices Branch (OSDB)
Center for Devices and Radiological Health
Document Mail Center – WO66 Room 1443

10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Phone: (301) 796-6432
Email: caroline.rhim@fda.hhs.gov

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time. It does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

1. (b)(4) CCI

[redacted]

Biomet Response:

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

95

(b)(4) CCI

[redacted]

Results Summary for Compression Shear Fatigue

(b)(4) CCI

[redacted]

Solitaire-C Cervical Spacer System Compression Shear Fatigue Summary

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

Failure Modes

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

94

(b)(4) CCI

[redacted]

93

(b)(4) CCI [redacted]

(b)(4) CCI [redacted]

(b)(4) CCI [redacted]

Additionally, (b)(4) CCI [redacted]

(b)(4) CCI [redacted]

Finally, (b)(4) CCI [redacted]

Conclusion

(b)(4) CCI

[redacted]

97

2. (b)(4) CCI [redacted]

Biomet Response:

(b)(4) CCI [redacted]

GD

3. (b)(4) CCI [redacted]

Biomet Response:

(b)(4) CCI [redacted]

(b)(4) CCI [redacted]

99

(b)(4) CCI

1. (b)(4) CCI

2. (b)(4) CCI

(b)(4) CCI

100

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

(b)(4) CCI

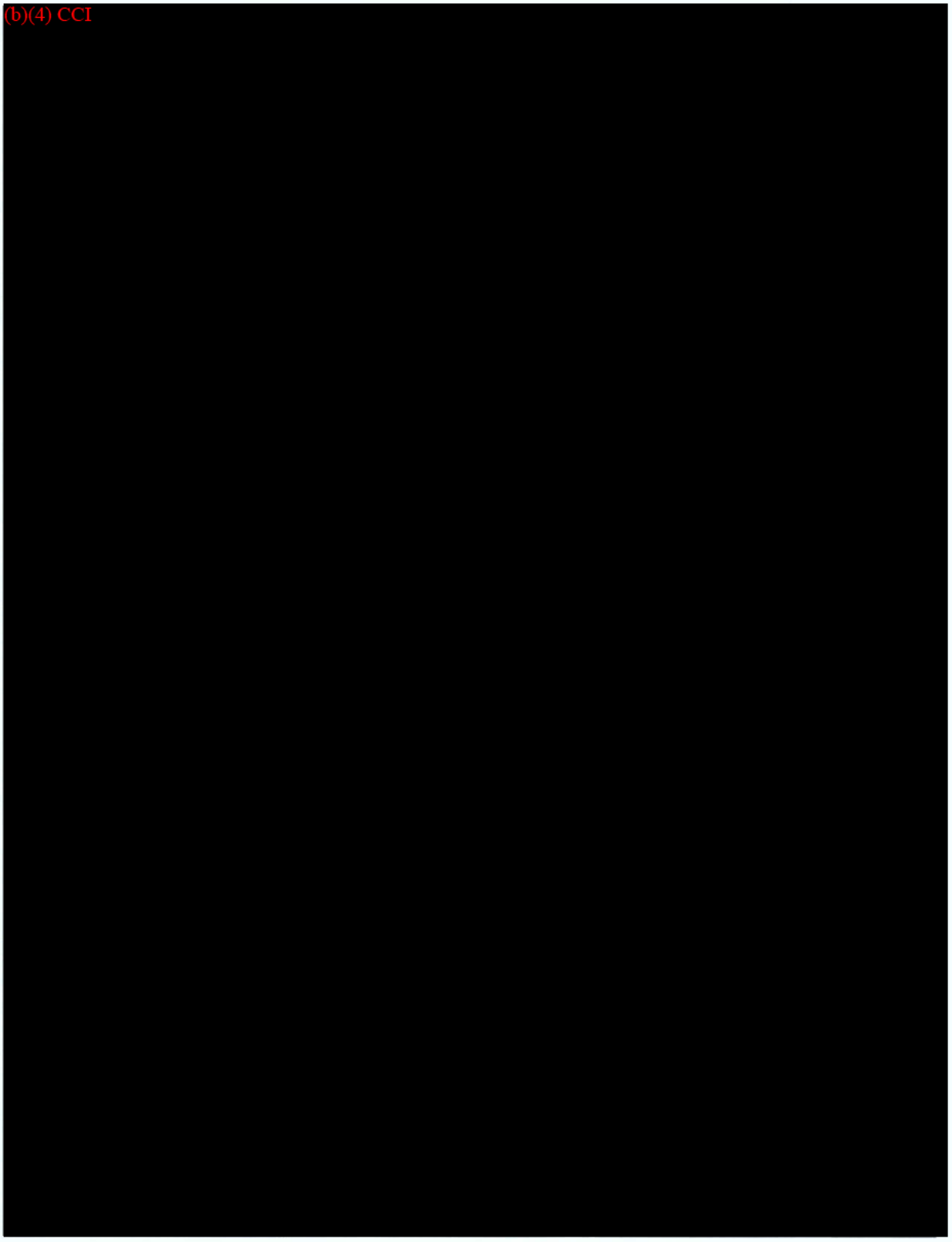
[redacted]

101

(b)(4) CCI

[redacted]

(b)(4) CCI

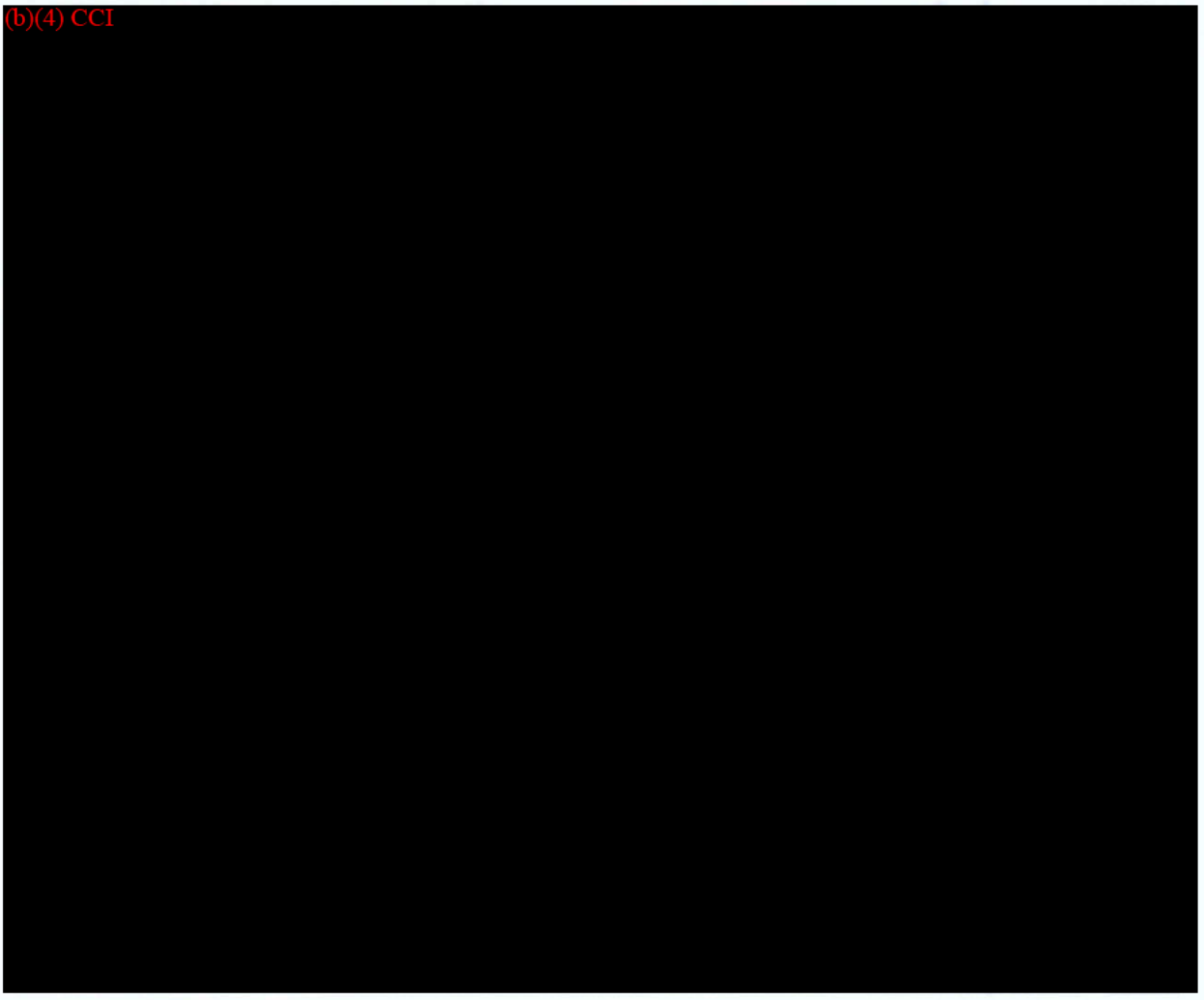


(b)(4) CCI

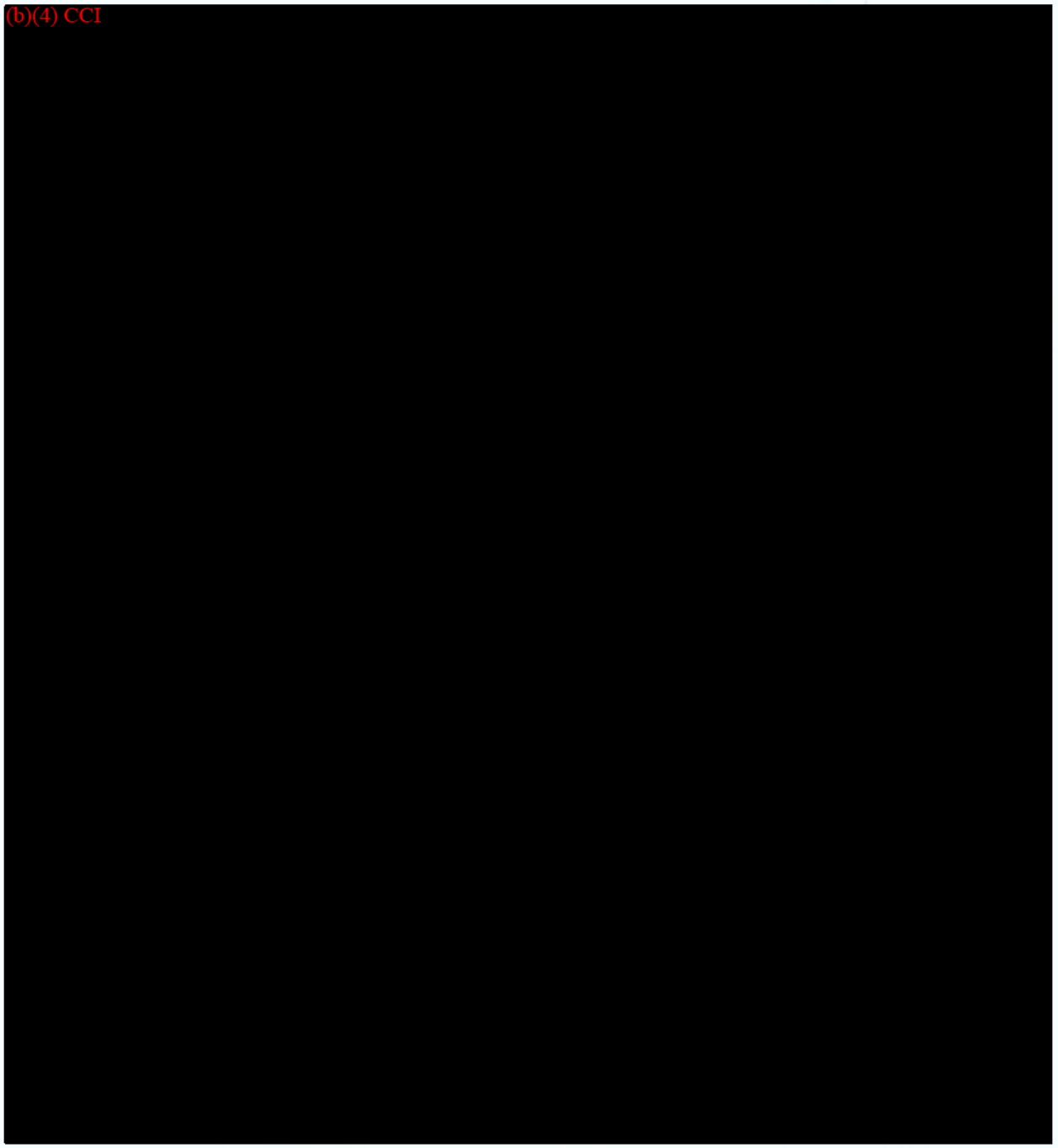
[redacted]

(b)(4) CCI

(b)(4) CCI



(b)(4) CCI



Worst-Case Rationale for Compression

(b)(4) CCI

(b)(4) CCI

- Titanium Faceplate (b)(4) CCI

- PEEK Body – (b)(4) CCI

- Titanium Band – (b)(4) CCI

(b)(4) CCI

Worst Case Rationale for Compression Shear

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

- Titanium Faceplate – (b)(4) CCI
- PEEK Body – (b)(4) CCI
- Titanium Band – (b)(4) CCI

Additionally, (b)(4) CCI

(b)(4) CCI

Worst Case Rationale for Torsion

(b)(4) CCI

(b)(4) CCI

- Titanium Faceplate – (b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

110

(b)(4) CCI

- PEEK Body – (b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

- Titanium Band – (b)(4) CCI

112

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

Conclusion

(b)(4) CCI

4. (b)(4) CCI

[redacted]

Biomet Response:

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

115

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

(b)(4) CCI

ROI-C Bone Graft Volumes (cc)	
Footprint (width by depth)	Volume (cc)
(b)(4) CCI	
(b)(4) CCI	

5. (b)(4) CCI [redacted]

Biomet Response:

(b)(4) CCI [redacted]

Device	Solitaire-C	C-Thru	Coalition
(b)(4) CCI [redacted]			

(b)(4) CCI [redacted]

(b)(4) CCI

[redacted]

Vertebral Level	(b)(4) CCI [redacted]
Dimension (mm)	
Endplate Depth (upper)	
Endplate Depth (lower)	
Endplate Width (upper)	
Endplate Width (lower)	

(b)(4) CCI

[redacted]

(b)(4) CCI

[redacted]

6. (b)(4) CCI [redacted]

Biomet Response:

(b)(4) CCI [redacted]

120

7. **The following deficiencies relate to your** (b)(4) CCI [redacted]

a. (b)(4) CCI [redacted]

b. (b)(4) CCI [redacted]

Biomet Response:

(b)(4) CCI [redacted]

(b)(4) CCI [redacted]

121

8. (b)(4) CCI [redacted]

Biomet Response:

(b)(4) CCI [redacted]

Additional Information:

(b)(4) CCI [redacted]

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

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(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

(b)(4) Test Report

Cervical Human Vertebrae

Quantitative Three-Dimensional Anatomy of the Middle and Lower Regions

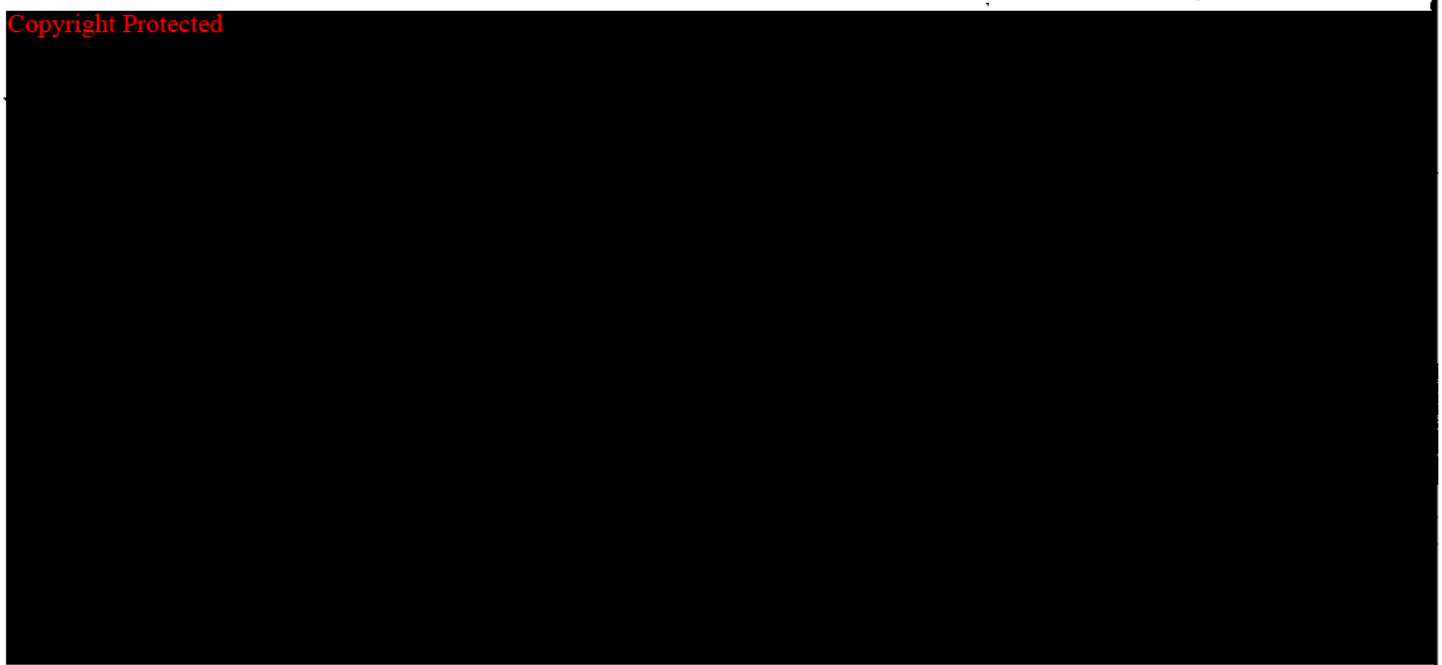
MANOHAR M. PANJABI, PhD,* JOANNE DURANCEAU, MS,* VIJAY GOEL, PhD,† THOMAS OXLAND, MASc,* and KOICHIRO TAKATA, MD‡

In this study, the three-dimensional quantitative anatom of middle and lower cervical vertebrae was determine The three-dimensional coordinates of various marke points on the surface of the vertebra were measured wi a specially designed morphometer instrument. Fro these coordinates, linear dimensions, angulations, ar areas of surfaces and cross-sections of most vertebr components were calculated. The results showed tw distinct transition regions: 1) toward the thoracic spi by the wider C7 vertebra but narrower spinal canal; and toward the upper cervical region with the larger pedic and spinous process of C2. Based on the study of human cervical vertebrae, mean and standard error of th mean values of some clinically important dimensions vertebral body, spinal canal, pedicles, transverse pr cesses, spinous process, and uncovertebral joints a given for C2–C7 vertebrae. The areas of the end plate spinal canal, and pedicles were modeled by elliptical ar triangular shapes, and results were compared with th actual measurements. [Key words: cervical spine, vert brae, anatomy, vertebral dimensions, spinal canal, pe cles]

From the *Department of Orthopaedics and Rehabilitation, Yale Univers School of Medicine, New Haven, Connecticut, the †Department of Biomed Engineering, University of Iowa, Iowa City, Iowa, and the ‡Department Orthopaedic Surgery, Tokushima University, Tokushima, Japan.

Support was provided in part by NIH Grant AR30361.
Accepted for publication November 8, 1990.
The authors thank Mr. Mark Price for his anatomic drawings.

[redacted]



152

ATTACHMENT C

- Revised Indications for Use Statement
- Revised 510(k) Summary
- Revised Draft Instructions for Use
- Revised Draft Surgical Technique

Section 4

Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Solitaire®-C Cervical Spacer System

Indications for Use:

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer System is to be used with autograft and implanted via an anterior approach. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Section 5

510(k) Summary

BIOMET SPINE

510(k) Summary

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

Preparation Date:	March 7, 2012
Applicant/Sponsor:	Biomet Spine 100 Interpace Parkway Parsippany, NJ 07054
Contact Person:	Margaret F. Crowe Phone: 973-299-9300, ext. 2260 Fax: 973-257-0232
Trade name:	Solitaire®-C Cervical Spacer System
Common Name:	Cervical interbody fusion device
Classification Name (Product Code):	Intervertebral Fusion Device with Integrated Fixation, Cervical (OVE)
Device Panel - Regulation No.:	Orthopedics - 21 CFR 888.3080

Device Description:

The purpose of this submission is to gain market clearance for the Solitaire-C Cervical Spacer System. The Solitaire®-C Cervical Spacer System consists of spacers and bone screws for stand-alone cervical intervertebral body fusion. The Solitaire®-C spacer will be available in a variety of sizes, angles and footprints.
This cervical spacer has a PEEK main body with a titanium faceplate and band, and tantalum markers. This device accepts titanium bone screws that are available in two diameters and multiple lengths.

Indications for Use:

The Solitaire®-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire®-C Cervical Spacer is to be used with autograft and implanted via an anterior approach. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Summary of Technologies:

The technological characteristics (material, design and sizing) of the Solitaire-C Cervical Spacer System is the same as, or similar to, the predicate devices. Examples of predicate devices include:

- Solitaire PEEK Anterior Spinal System (Biomet Spine - K081395, K093629)
- Coalition Spacer (Globus Medical – K083389)
- AVS-C Spacer (Stryker Spine – K102606)
- Synthes Zero-P Cervical Spacer (Synthes Spine – K072981, K093762)
- C-Thru Spacer System (Biomet Spine – K092336)
- Expandable PEEK Spacer (Biomet Spine – K082406)

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Performance Data

Mechanical testing recommended in the special controls guidance document entitled "Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" was conducted. The testing conducted, along with the ASTM standard, are listed below:

1) Static Axial Compression (ASTM F-2077)
2) Dynamic Axial Compression (ASTM F-2077)
3) Static Compression-Shear (ASTM F-2077)
4) Dynamic Compression-Shear (ASTM F-2077)
5) Static Torsion (ASTM F-2077)
6) Dynamic Torsion (ASTM F-2077)
7) Subsidence (ASTM F-2267 and ASTM F-2077)
8) Expulsion (ASTM Draft F-04.25.02.02)

Additional mechanical testing was conducted to evaluate screw back out, screw push through, and interconnection testing between the spacer body and the faceplate. Wear debris analysis was also presented.

Mechanical testing shows that the mechanical strength of the subject device is sufficient for its intended use.

Substantial Equivalence:

The Solitaire-C Cervical Spacer System is substantially equivalent to its predicate devices with respect to intended use and indications, technological characteristics, and principles of operation and do not present any new issues of safety or effectiveness. The predicates listed above are distributed for similar indications, and/or have similar design features.

Draft Package Insert

Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054

Solitaire-C Cervical Spacer System

060582-00
Rev B 2012-03

Attention Operating Surgeon

DEVICE DESCRIPTION

The Solitaire-C Cervical Spacer System consists of spacers and bone screws for stand-alone cervical intervertebral body fusion. The Solitaire-C spacer will be available in a variety of sizes, angles and footprints to accommodate variations in patient anatomy. The Solitaire-C spacer dimensions are designed to accommodate skeletally mature patients.

The main PEEK body is C-shaped, with walls to provide structural integrity. The top and bottom walls have a macrotextured surface to grip into the endplates of the vertebral body to reduce implant migration, while providing optimum surface contact with the vertebral body. The spacer is available in two styles- lordotic and parallel. The lordotic style will incorporate 7° of lordosis, while the parallel style will have flat superior and inferior surfaces.

The titanium faceplate is located on the anterior aspect of the spacer implant. The faceplate has two threaded holes for bone screw interference and accepts the Solitaire-C bone screws. The titanium alloy band sits in a groove on the exterior surface of the main PEEK body. This band attaches the PEEK spacer body to the titanium faceplate, and is designed to provide stability and strength to the spacer, as well as to aid in visualization of the implant on X-ray or fluoroscopy. Tantalum markers are present in the PEEK body to aid in visualization of the implant.

Bone screws will be available in two diameters and multiple lengths.

MATERIALS

The Solitaire-C Cervical Spacer System is fabricated from the following materials:

- PEEK-OPTIMA™ LT1 (PEEK-OPTIMA™ is a trademark of Invibio, Ltd.) per ASTM specification F-2026 (spacer body)
- Titanium alloy (Ti-6Al-4V-ELI) per ASTM specification F-136 (Titanium faceplate, band and bone screws)
- Unalloyed tantalum per ASTM specification F-560 (markers in spacer body)

INTENDED USE

The Solitaire-C Cervical Spacer System consists of spacers (with bone screws) of various sizes, angles and footprints, which can be inserted between two cervical vertebral bodies to give

support and correction during cervical interbody fusion procedures. The screws protrude through the spacer portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The large hollow geometry of the implant allows it to be packed with autogenous bone graft to facilitate fusion. The implant is contained within the excised disc space, and does not protrude past the anterior wall of the vertebral body. This feature is designed to reduce soft tissue irritation. The Solitaire-C Cervical Spacer System is designed to address the risk of adjacent level ossification by remaining 5mm or greater from the adjacent level disc spaces. The Solitaire-C system incorporates integrated fixation, so supplemental fixation is not required. The Solitaire-C Cervical Spacer System is intended to be implanted with Solitaire-C bone screws.

INDICATIONS FOR USE

The Solitaire-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire-C Cervical Spacer System is to be used with autograft and implanted via an anterior approach. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

INSTRUCTIONS FOR USE

Caution: The Solitaire-C Cervical Spacer System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgical techniques. Refer to the Solitaire-C Cervical Spacer System Surgical Technique for complete Instructions-for-Use. For a copy of the surgical technique, please contact your sales representative or customer service at the address provided below.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection, systemic, spinal or localized
2. Morbid obesity
3. Signs of local inflammation
4. Fever or leukocytosis
5. Metal sensitivity/allergies to the implant materials
6. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
7. Grossly distorted anatomy due to congenital abnormalities
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft)
9. Any case not needing a bone graft and fusion or where fracture healing is not required
10. Any patient having inadequate tissue coverage over the operative site

11. Any patient unwilling to cooperate with the postoperative instructions
12. Prior fusion at the level(s) to be treated.

WARNINGS
The surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.

2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.

3. All instruments must be cleaned and sterilized prior to surgery.

4. Do not reuse implants/devices. While an implant/device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant/device.

5. Do not treat patients with implants/devices that have been even momentarily placed in or used on a different patient.

6. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.

7. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

8. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

9. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system.

9. The Solitaire-C Cervical Spacer System has not been evaluated for safety and Compatibility in the MR environment. The Solitaire-C Cervical Spacer System has not been tested for heating or migration in the MR environment.

PRECAUTIONS
Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.

2. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.

3. Biomet Spine implants should not be used with implants or instruments from another manufacturer for reasons of metallurgy, mechanics and design.

Intraoperative:
1. Any instruction manuals should be carefully followed.

2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions. Bone grafts must be placed in the area to be fused.

Postoperative:
1. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

2. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening or breakage of the components is complications which can occur as a result of excessive or early weight-bearing or excessive muscular activity. The risk of bending, loosening, or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented, or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.

3. To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.

4. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.

5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the Solitaire-C

Cervical Spacer System components should ever be reused under any circumstances.

POTENTIAL ADVERSE EFFECTS AND COMPLICATIONS

Possible adverse effects include, but are not limited to:
1. Bending, loosening, migration or fracture of the implants or instruments
2. Loss of fixation
3. Sensitivity to a metallic foreign body, including possible tumor formation
4. Skin or muscle sensitivity in patients with inadequate tissue coverage over the operative site, which may result in skin breakdown and/or wound complications
5. Nonunion or delayed union
6. Infection
7. Nerve or vascular damage due to surgical trauma, including loss of neurological function, dural tears, radiculopathy, paralysis and cerebral spinal fluid leakage
8. Gastrointestinal, urological and/or reproductive system compromise, including sterility, impotency and/or loss of consortium
9. Pain or discomfort at the operative and/or bone graft donor site
10. Bone loss due to resorption or stress shielding, or bone fracture at, above or below the level or surgery (fracture of the vertebra)
11. Hemorrhage of blood vessels and/or hematomas
12. Misalignment of anatomical structures, including loss of proper spinal curvature, correction, reduction and/or height
13. Bursitis
14. Inability to resume activities of normal daily living
15. Reoperation
16. Death

STERILIZATION

Unless supplied sterile, devices must be sterilized prior to surgical use. Product provided sterile is sterilized by exposure to a minimum dose of 2.5 Megarads (25kGy) gamma radiation. Where specified, do not use implants after expiration date. Re-sterilization is not recommended.

For product supplied non-sterile, all packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended:

U.S. Sterilization Parameters:
Cycle: Pre-vacuum Steam
Temperature: 270°F/132°C
Time: 4 minutes
Drying Time: 30 minutes
Note: Allow for cooling

FDA cleared sterilization wraps should be used to maintain sterility after processing.

European Union Sterilization Parameters:

Cycle: Pre-vacuum Steam
Temperature: 275°F/135°C
Time: 3 minutes
Drying Time: 30 minutes
Note: Allow for cooling

Biomet does not recommend stacking of trays during the sterilization process.
Individuals or hospitals not using the recommended method, temperature, and time are advised to validate any alternative methods or cycles using an approved method or standard.

Additional information about instrumentation (including assembly/disassembly) may be found in the system surgical technique, reference guide and/or associated package inserts.

Refer to the Biomet Non-sterile Instrument IFU for full processing instructions for instruments.

CAUTION
Federal (USA) law restricts these devices to sale by or on the order of a licensed physician.

INFORMATION
For further information, please contact the Customer Service Department at:

Biomet Spine
100 Interpace Parkway
Parsippany, NJ 07054
(973) 299 9300, (800) 526 2579
www.biometspine.com

Key to label symbols:

By prescription only

Do not reuse

Date of Manufacture

Caution, consult accompanying documents

Batch Code

Sterilized using Gamma radiation

See Package Insert for Labeling Limitations

Draft Surgical Technique
Solitaire®-C Cervical Spacer System

Introduction

The Solitaire®-C Cervical Spacer System is used for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients. It offers several unique features including a large graft cavity, three footprint sizes (in both lordotic and parallel), a unique color-coded band around the implant for easier screw identification, and a sophisticated yet simple instrumentation system. The Solitaire®-C System also offers (2) locking screws (3.5mm & 3.75mm) and zero-profile.

Solitaire® – C Spacers:

All spacers are composed of a titanium alloy faceplate, PEEK body, tantalum markers, and a titanium alloy band. The titanium faceplates are color coded to denote height (see chart below). The titanium bands are color coded via titanium anodization to denote depth.

Spacer Height	Color
6mm	Dark Green
7mm	Light Magenta
8mm	Dark Blue
9mm	Gold
10mm	Bronze
11mm	Light Blue
12mm	Dark Magenta

Spacer Depth	Screw Length	Color
12mm	12mm	Light Green
14mm	14mm	Gold
15mm	15mm	Light Magenta

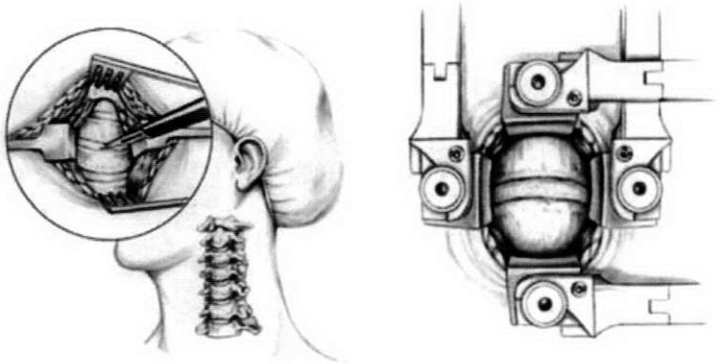
Screws:

Screws are placed at a fixed trajectory 35 degree cephalad/caudal and 7 degrees medial/lateral. The screw length is measured in the lateral view from the anterior face of the spacer to the tip of the screw. Screws are also color coded by length which is designed to match spacer depth. Two screws are intended to be placed into each spacer such that one screw attaches the spacer to the superior vertebral body of the affected level and the other screw attaches the spacer to the inferior vertebral body of the affected level. Screws lock to the titanium faceplate by way of a threaded, cam style locking mechanism that is torqued with a minimum of 14 in-lbs to lock the screws in place. Screws are manufactured from titanium alloy.

Note: Screw length is defined as the distance in the lateral view from the anterior face of the spacer to the tip of the screw. This means screw depth will be equivalent to spacer depth when corresponding sizes are used.

Surgical Approach/Technique

Using a standard surgical approach, expose the vertebral bodies to be fused. Traditional cervical retractors may be used. Prepare the fusion site following the appropriate technique for the specific indication.



Vertebral Body Distraction

If using distraction pins, place one distraction pin in the vertebral body superior to the affected level and the other distraction pin in the vertebral body inferior to the affected level. The Pin Distractor is placed over the Pins and opened as needed, to distract the vertebral bodies (being careful not to over-distract the segment).

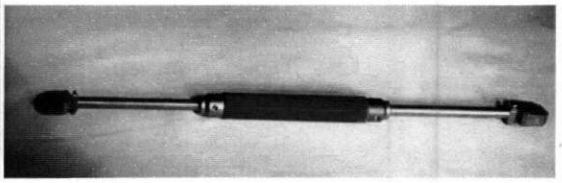
Discectomy & End-Plate Preparation

Using rongeurs, pituitaries and curettes, remove the intervertebral disc and osteophytes as needed. Rasps can also be used to prepare the endplates and expose bleeding bone.

The Solitaire®-C trials & rasps are double sided for efficiency. These instruments correspond to the implant footprints and are available in 5-12mm heights in 1mm increments similar to the implants. (Please note that there is a 5mm trial and rasp, but that height is not available in an implant).

Also, the rasps are designed so that the teeth cut on the backstroke as the instrument is being pulled away from the spinal cord.

CAUTION: Aggressive preparation of the endplate may remove excessive bone and weaken the endplate.



Implant Sizing

Using the double-sided rasps or trials, determine the appropriate implant size by sizing the disc space. When sizing, use incrementally larger sizes until a tight fit is achieved. A secure fit is desirable to maintain disc height and stabilize the segment, so there should be no gaps between the prepared site and trial or rasp.

The trials and rasps are both available with or without stops. The stops allow for a maximum of 2mm of countersink into the disc space.

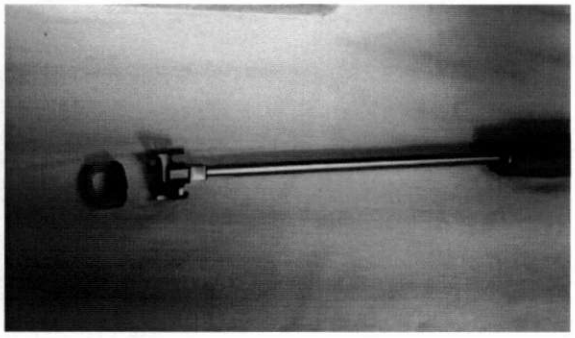
Once the desired disc height is determined, select the appropriate Solitaire-C implant. Rasps and trials have sleeves that are color-coded to match the height of the corresponding spacer.

Note: The trial, rasp and implant heights for each particular size are all equal. The implants are measured to the anterior/posterior surfaces of the titanium faceplate and peaks of the PEEK body macro-texture. Rasps are measured to the peaks of the teeth.

Inserter Guide Assembly

The Solitaire-C system offers inserter guides which attach to modular shafts/handles and facilitate screw hole preparation and screw insertion through the same instrument. Select the inserter guide that corresponds to the final implant size to be used. Each implant width and height has a corresponding guide tip which is color-coded to match a particular spacer height.

Attach the inserter guide to the modular shaft/handle by inserting the distal tip of the modular shaft/handle into the mating connection feature on the inserter guide. Now place the inner shaft down the modular shaft/handle and turn the knob at the proximal end of the inner shaft clockwise to capture the inner shaft in the modular shaft/handle. Once the inner shaft is in place the inserter guide cannot be disengaged from the assembly.



Implant Attachment

Fill the graft cavity in the implant with autograft and attach the implant to the inserter guide assembly by placing the anterior face of the implant against the mating distal end of the inserter guide assembly. Since the implant and inserter guide are both rotationally symmetric, the superior and inferior surfaces of both devices are interchangeable. Turn the knob at the proximal end of the inserter guide assembly clockwise to thread the inner shaft into the center fixation hole on the spacer.

OR Tip: Confirm proper orientation of guide to implant by inserting an awl or drill with centering sleeve or driver option down one of the inserter guide tubes. The instrument should easily seat into the guide with no manipulation.

Implant Insertion

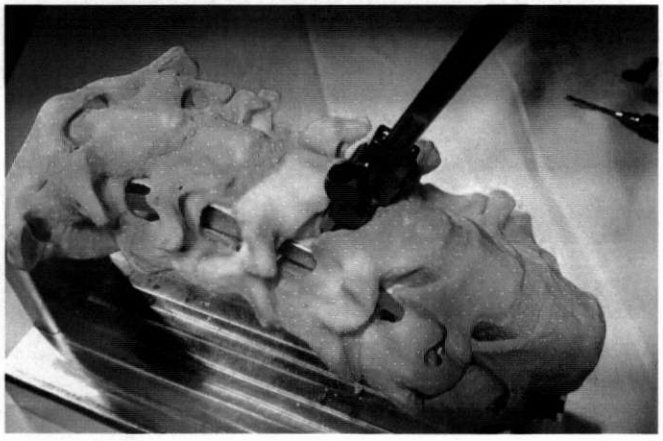
Impact the implant into the fusion site by striking the knob of the inserter guide assembly (the slide hammer with adapter could also be used).

The implant guide assemblies have stops which countersink the implant a maximum of 2mm into the disk space relative to the anterior face of the vertebral body.

Each implant contains two markers 1mm from the posterior wall of the implant that can be used as a reference when using fluoroscopy.

Additionally, the Solitaire-C spacer incorporates a uniquely designed titanium band around the spacer which assists with radiographic visualization at the fusion site.

Release any distractors in use to ensure implant is fully engaged with endplates.



Screw Hole Preparation:

A variety of drills, awls, and centering sleeves are available to aid in screw hole preparation to meet anatomical challenges.

Drill and Awl Options:

All awls and drills are available in 12mm, 14mm and 15mm lengths, and correspond to equivalent screw lengths. Just like the screws, drill depth is measured in the lateral view from the anterior face of the spacer to the tip of the drill or awl. Several guide options are available for drills and awls and are identified below.

Additionally, drills and awls have color coding to help aid in instrument identification and ensure proper depth. Straights drills and awls and angled awls are color coded to match screw length. However, angled drill bits have their own color coding schematic:

	12mm	14mm	15mm
Screws	Light Green	Gold	Light Magenta
Straight Drill	Light Green	Gold	Light Magenta
Straight Awl	Light Green	Gold	Light Magenta
Angled Awl	Light Green	Gold	Light Magenta
Angled Drill Bit	Silver	Gold	Dark Gray

The straight drill and awl and angled awl are designed to connect directly to the AO quick connect handle. The angled drill bit must be attached to the 45° fixed angled driver. This driver mates with the AO handle.

To attach the angled drill bit to the 45° fixed angled driver, line up the male square of the driver with the female square within the bit. When the squares are aligned the male square on the driver will sit deeper in the bit. Once the squares are aligned, apply force to seat the cantilever springs on the bit over of the retention bump on the driver.

Centering Sleeve Options:

Drill and awl options are not intended to be used by themselves and must be used with an appropriate centering sleeve option. All centering sleeves have an exterior hard stop that rests against the top surface of the inserter guide when fully seated.

The following combinations of drills, awls, and sleeves are available:

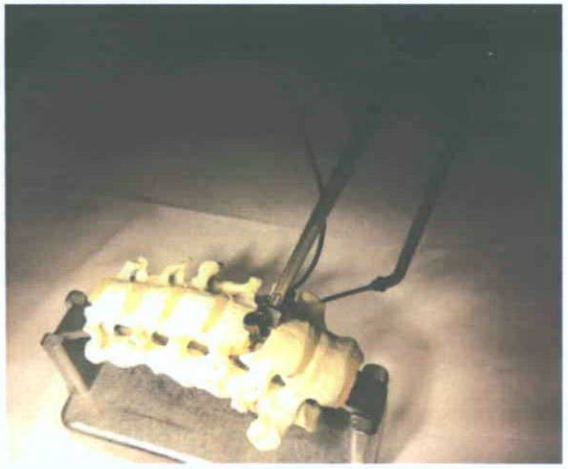
	Straight Awl	Straight Drill	Angled Awl	Angled Drill Bit which attaches to the Fixed Angle Driver
Drill/Awl Sleeve	X	X		
Drill/Awl Spring Sleeve	X	X		
Tip with Malleable Shaft for Angled Drill/Awl	X	X	X	X
Short Centering Tip for Angled Drill/Awl	X	X	X	X

Note: All guide tubes or tips must be removed before screw insertion.

Straight Awl & Drill/Awl Sleeve

Straight Awl & Drill/Awl Spring Sleeve

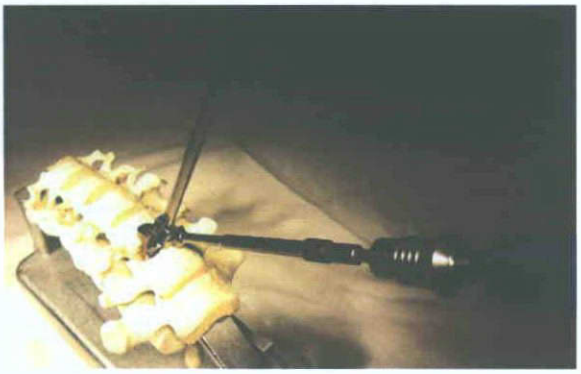
Angled Awl



Angled Awl with Malleable Shaft Handle

Angled Drill (with bit), with Malleable Shaft Handle

Drill/Awl Sleeve:
This sleeve is placed directly into the inserter guide after implant insertion. Straight Awls and Drills can be used with this instrument. Both have a positive hard stop just below the color-coded sleeve that contacts the top of this sleeve.



Drill/Awl Spring Sleeve:
This sleeve is intended to be pre-attached to straight drills and awls prior to insertion into the inserter guide. Both straight drills and awls have a bump mid-way along the shaft. To properly attach the spring sleeve, slide the sleeve onto the straight drill or awl until the cantilever springs on the spring sleeve pop over the bump. Now the spring sleeve is retained on the straight drill or awl. To remove the sleeve, slide it over the bump in the opposite direction.

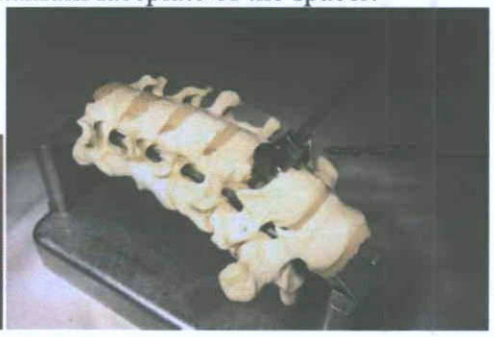
Standard drills and awls have a positive hard stop just below the color coded sleeve that interacts with this guide tube.

Tip with Malleable Shaft for Angled Drill/Awl:
The tip with malleable shaft can be used with any awl or drill option but is primarily used with the angled awls and angled drill bits. It is intended to be placed directly into the inserter guide prior to inserting a drill or awl. It has a malleable nitinol handle that can be positioned to help avoid anatomical challenges. Angled drills and awls have a visible hard stop against the face of this guide. Straight drills and awls have an internal stop.

Screw Driver Options:

Multiple screw driver options are available to aid in screw placement and help meet surgeons needs and preferences. All drivers have a hexalobe interface at the distal tip and an AO quick connect geometry at the proximal end which engages with an AO quick connect handle or torque limiting handle. The following driver options are available:

Auto-Centering Driver:
This driver is a stab and grab driver. It has an increased shaft diameter at the distal end of the driver. This increased shaft diameter works with the inserter guide to help ensure that the screw head is properly centered as it enters into the titanium faceplate of the spacer.



Driver for Sleeves:
This driver is a stab and grab driver that has two sleeves that can be used to help ensure that the screw is entering the titanium faceplate of the spacer centered and at the proper trajectory. Both the driver and the two sleeves have dark gray color coding to help differentiate them from the drill/awl sleeves and denote that they should be used together. Like the drill and awl sleeves, this driver can be used with the driver sleeve or the driver spring sleeve. The driver sleeve is placed directly into the inserter guide. The driver for sleeves can then be passed down this sleeve to insert the screw. Alternatively, the driver spring sleeve is intended to be pre-attached to the driver for sleeves prior to insertion into the inserter guide. The driver for sleeves has a bump mid-way along the shaft. To properly attach the driver spring sleeve, slide the sleeve onto the driver until the cantilever springs on the spring sleeve pop over the bump. Now the spring sleeve is retained on the straight drill or awl. To remove the sleeve, slide it over the bump in the opposite direction.

Driver used with separate sleeve

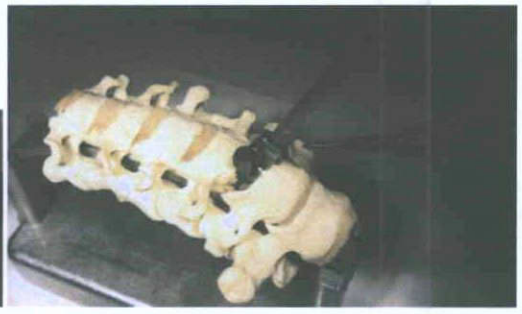
Driver used with pre-loaded sleeve.

Non-Retaining Driver:
This driver does not frictionally lock to the screws and has a gold tip to help denote that it is not intended to be stab and grab. Because it is not a stab and grab, this driver sits deeper into the hexalob drive giving the driver to screw interface more strength. It also has a decreased shaft diameter at the distal end of the driver. This allows for additional versatility which may be necessary during screw removal or revision cases.

OR Tip: All gold-tip drivers are not intended to be stab and grab, but are intended for final tightening.

OR Tip: Using a non-retaining driver during final tightening and screw removal can reduce the chance of stripping the screw or the driver.

Angled Driver Bits and the 45° Fixed Angle Driver:
This angled driver option has a stab and grab screw interface as well as a rigid 45° fixed angle to aid in screw placement and help address anatomical challenges which can be found in the upper and lower regions of the cervical spine. Driver bits are intended to attach to the 45° fixed angled driver. To do so, line up the male square of the driver with the female square within the bit. When the squares are aligned the male square on the driver will sit deeper in the bit. Once the squares are aligned apply force to seat the cantilever springs on the bit over of the retention bump on the driver. The bit will be retained on the driver until it is removed using the bit remover described later in this technique.



Flexible Driver:
This alternate angled driver option has a stab and grab screw interface as well as robust flexible links. This instrument contours to the anatomy and help address anatomical challenges which can be found in the upper and lower regions of the cervical spine.

Non-Retaining Flexible Driver:
This driver combines the benefits of the flexible driver with the versatility of the non-retaining driver. It is not intended to be a stab and grab driver (gold tip), as it does not frictionally engage with the screw.

Screw Insertion

Attach the quick connect handle to the desired driver. Affix the desired size screw to the driver by seating the distal tip of the driver into the hexalobe on the screw head. Place the screw into the appropriate screw hole through the inserter guide assembly. Insert each screw until solid engagement of the cancellous thread occurs. Repeat for the contralateral hole.

Final Tightening

Attach the torque wrench to the desired driver and insert the tip of the driver into the hexalobe drive of the screw. Turn the handle until an audible "click" is heard at approximately 15±1 in. lbs. of torque. The inserter guide assembly should remain engaged during screw insertion and final tightening to serve as a counter torque.

> OR Tip: The inserter guide should remain engaged during screw insertion and final tightening to serve as a counter torque.

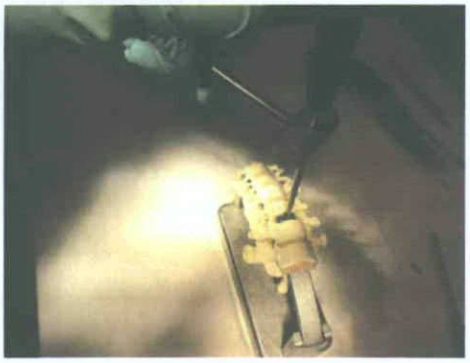
Closure:

The operative site should be closed per hospital protocol and the surgeon's discretion.

Implant Removal

Should it become necessary to remove the Solitaire-C Spacer, the following guidelines should be observed:

- Removal follows the reverse order of implantation
- Soft tissue on the anterior surface of the implant should be removed
- Place the inner shaft into the implant remover
- Attach the implant remover to the implant by turning the knob clockwise to thread the inner shaft into the center fixation hole on the spacer.
- Remove the screws using a screw driver.
- Once screws are removed, remove implant from wound site. The slotted mallet or slide hammer with adapter can be used to aid in implant removal, if necessary. If using the slide hammer, thread the adapter to the distal end of the slide hammer and then slide the adapter over the proximal end of the remover.



Indications for Use

The Solitaire-C Cervical Spacer System is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Cervical degenerative disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The Solitaire-C Cervical Spacer System is to be used with autograft and implanted via an anterior approach. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system. This cervical device is to be used in patients who have had six weeks of non-operative treatment.

Contraindications

Contraindications include, but are not limited to:
1. Infection, systemic, spinal or localized
2. Morbid obesity
3. Signs of local inflammation
4. Fever or leukocytosis
5. Metal sensitivity/allergies to the implant materials

6. any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count
7. Grossly distorted anatomy due to congenital abnormalities
8. Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft)
9. Any case not needing a bone graft and fusion or where fracture healing is not required
10. Any patient having inadequate tissue coverage over the operative site
11. Any patient unwilling to cooperate with the postoperative instructions
12. Prior fusion at the level(s) to be treated.

Warnings

The surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants.

2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.

3. All instruments must be cleaned and sterilized prior to surgery.

4. Do not reuse implants/devices. While an implant/device may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant/device.

5. Do not treat patients with implants/devices that have been even momentarily placed in or used on a different patient.

6. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.

7. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

8. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

9. The Solitaire-C spacer must be implanted with the Solitaire-C titanium screws that are part of the system.

9. The Solitaire-C Cervical Spacer System has not been evaluated for safety and Compatibility in the MR environment. The Solitaire-C Cervical Spacer System has not been tested for heating or migration in the MR environment.

Sterilization

Unless supplied sterile, devices must be sterilized prior to surgical use. Product provided sterile is sterilized by exposure to a minimum dose of 2.5 Megarads (25kGy) gamma radiation. Where specified, do not use implants after expiration date. Re-sterilization is not recommended.

For product supplied non-sterile, all packaging materials must be removed prior to sterilization. The following steam sterilization parameters are recommended:

U.S. Sterilization Parameters:
Cycle: Pre-vacuum Steam
Temperature: 270°F/132°C
Time: 4 minutes
Drying Time: 30 minutes
Note: Allow for cooling

FDA cleared sterilization wraps should be used to maintain sterility after processing.

European Union Sterilization Parameters:
Cycle: Pre-vacuum Steam
Temperature: 275°F/135°C
Time: 3 minutes
Drying Time: 30 minutes
Note: Allow for cooling

Biomet does not recommend stacking of trays during the sterilization process.
Individuals or hospitals not using the recommended method, temperature, and time are advised to validate any alternative methods or cycles using an approved method or standard.

Additional information about instrumentation (including assembly/disassembly) may be found in the system surgical technique, reference guide and/or associated package inserts.

Refer to the Biomet Non-sterile Instrument IFU for full processing instructions for instruments.

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(800) 526 2579

www.biometspine.com

(b)(4) Engineering Drawings

(b)(4) Data Information

(b)(4) Data Information

(b)(4) Data Information

(b)(4) Data Information

ATTACHMENT E
Draft Package Insert - Instruments

INTRODUCTION

Biomet Spine provides instruments and instrument trays that are generally manufactured from nitinol, titanium alloy, stainless steel, aluminum and polymeric materials, e.g. Radel and silicone. Biomet Spine instruments and instrument trays are not intended for use with other manufacturer's instruments, implants or instrument trays. Instruments should be placed in the intended location as indicated on the instrument tray.

Reusable surgical instruments and instrument trays must be cleaned and sterilized prior to use. The following steps apply to the cleaning of instruments and instrument trays:

PRECLEANING AT THE POINT OF USE

1. Soil should be wiped from the device with a sponge or towel moistened with water.
2. Cannulated instruments should be flushed to prevent drying of debris inside.
3. To prevent blood and/or debris from drying, devices should be placed in a container and covered with a towel that has been moistened with water.

CLEANING INSTRUCTIONS

1. All Instrument components should be disassembled and rinsed with tap water. The inner shaft of the instruments should be disassembled prior to cleaning.
2. Prepare solution of enzymatic surgical detergent and tap water by adding 2 oz. Of Enzol (Enzymatic Detergent, Johnson& Johnson) to 1 gallon of warm tap water (72ºF/22ºC to 109ºF/43ºC). Instrument components should be immersed in solution for 5 minutes.
3. Scrub components with soft brushes and rinse with a brisk stream of tap water (72ºF/22ºC to 109ºF/43ºC) until all visual soil is removed.
4. Using an ultrasonic cleaner, sonicate all components in the same enzymatic solution (see step # 2) for 10 minutes.
5. Manually clean all components with soft brushes and repeat step # 3 until all visual soil is removed. This step should be repeated until there are no signs of soil or residue remaining. Instruments and trays should be visually clean prior to further processing.
6. Conduct a final rinse with a brisk stream of tap water (72ºF/22ºC to 109ºF/43ºC) for the entire instrument including any inner shafts.
7. Dry components with a soft gauze cloth.
8. Inspect cleaned instrument for wear, loose screws and pins, clamp alignment, cracks and other irregularities. If instruments are discolored, show evidence of corrosion, have loose screws/pins, are out of alignment, are cracked or have other irregularities, **Do Not Use.**

CARE AND HANDLING

• All torque wrenches should be re-calibrated every 6 months.

• Please refer to ASTM standard F1744, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.

• Prior to use, instruments should be visually inspected for wear and function should be tested to assure instruments are functioning properly. If instruments are discolored, show evidence of corrosion, have loose screws/pins, are out of alignment, are cracked or have other irregularities, **Do Not Use.** Instrumentation that appears damaged should be returned to the manufacturer.

STERILIZATION

All packaging materials must be removed prior to sterilization. All instrument components should be sterilized in a loosened state such that components may move freely. The following steam sterilization parameters are recommended:

U.S. Sterilization Parameters:
Cycle: Pre-vacuum Steam
Temperature: 270°F/132°C
Time: 4 minutes
Drying Time: 30 minutes
Note: Allow for cooling

FDA cleared sterilization wraps should be used to maintain sterility after processing.

European Union Sterilization Parameters:
Cycle: Pre-vacuum Steam
Temperature: 275°F/135°C
Time: 3 minutes
Drying Time: 30 minutes
Note: Allow for cooling

Biomet does not recommend stacking of trays during the sterilization process. Individuals or hospitals not using the recommended method, temperature, and time are advised to validate any alternative methods or cycles using an approved method or standard.

Additional information about instrumentation (including assembly/disassembly) may be found in the system surgical technique, and/or reference guide.

INFORMATION

For further information, please contact the Customer Service Department at:
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CE

Key to Label Symbols:

Rx Only
By prescription only


Do not reuse

REF
Reference Number


Caution, consult accompanying documents


Date of Manufacture

Batch Code