MAY 17 2004

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Noah J. Bartsch, MS Specialist, Regulatory Affairs Telephone: (574) 371-8552 Fax: (574) 372-4605
Date:	February 13, 2004
Trade Name:	Coonrad/Morrey Elbow Cement Restrictor
Common Name:	Cement Obturator
Classification Name and Reference:	Orthopaedic Surgical Mesh 21 CFR § 878.3300
Predicate Devices:	Zimmer Allen Medullary Plugs, K001733, cleared June 20, 2000. *Zimmer Poly-Plug*™ Intramedullary System, K950312, cleared May 17, 1995
Device Description:	The Coonrad/Morrey Elbow Cement Restrictor is designed to impede the flow of bone cement distal to the prosthesis in the intramedullary canal during total elbow arthroplasty. The plugs are molded from polyethylene, and they are inserted into the intramedullary canal prior to the introduction of bone cement and insertion of the appropriate prosthesis.
Intended Use:	Intramedullary cement plugs are indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement. The larger intramedullary cement plugs are useful in revision surgery where a wide, smooth intramedullary canal must be plugged.

Comparison to Predicate Device:	The Coonrad/Morrey Elbow Cement Restrictor is equivalent to other commercially available intramedullary cement plugs currently on the market, by virtue of design and functionality. The device has the same intended use as the predicate devices, and has demonstrated the ability to functionally perform the intended use.
Performance Data (Non-clinical):	Non-Clinical Performance and Conclusions: Non-clinical testing demonstrated that the Coonrad/Morrey Elbow Cement Restrictor meets performance requirements and is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2004

Noah J. Bartsch, MS
Specialist, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K040389
Trade/Device Name: Coonrad/Morrey Elbow Cement Restrictor
Regulation Number: 21 CFR 878.3150, 888.3160
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: JDC, JDB
Dated: February 13, 2004
Received: February 17, 2004

Dear Mr. Bartsch:

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 (301) 594-4659. 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,

for Mark N Melkerson

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

 K040389 1/1

Indications for Use

510(k) Number (if known):

Device Name:

Coonrad/Morrey Elbow Cement Restrictor

Indications for Use:

Intramedullary cement plugs are indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement.

The larger intramedullary cement plugs are useful in revision surgery where a wide, smooth intramedullary canal must be plugged.

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

510(k) Number K040389

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2004

Noah J. Bartsch, MS
Specialist, Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K040389
Trade/Device Name: Coonrad/Morrey Elbow Cement Restrictor
Regulation Number: 21 CFR 878.3150, 888.3160
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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.

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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 (301) 594-4659. 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,

for Mark N Melkerson

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

 K040389 1 1

Indications for Use

510(k) Number (if known):

Device Name:

Coonrad/Morrey Elbow Cement Restrictor

Indications for Use:

Intramedullary cement plugs are indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement.

The larger intramedullary cement plugs are useful in revision surgery where a wide, smooth intramedullary canal must be plugged.

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

510(k) Number K040389

 3

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

February 17, 2004

ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581
ATTN: NOAH J. BARTSCH

510(k) Number: K040389
Received: 17-FEB-2004
Product: COONRAD/MORREY ELBOW
CEMENT RESTRICTOR

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification 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.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA)(Public Law 107-250), authorizes FDA to collect user fees for premarket notification submissions. (For more information on MDUFMA, you may refer to our website at http://www.fda.gov/oc/mdufma).

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) 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 www.fda.gov/cdrh/ode/a02-01.html.

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission, please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health

K040389

Form Approved:OMB No. 0910-0511 Expiration Date: August 31, 2006. See instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification Number on your check.

A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:

1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent.
2. Include a printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check.
3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (*Note: in no case should payment be submitted with the application.*)
4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.)
5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a. You are responsible for paying all fees associated with wire transfers.
6. Include a copy of the completed Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.

1. COMPANY NAME AND ADDRESS (Include name, street address, city, state, country, and post office code)

ZIMMER, INC.
P.O. BOX 708
WARSAW, IN 46581-0708

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)
810550219

2. CONTACT NAME
NOAH BARTSCH

2.1 E-MAIL ADDRESS
noah.bartsch@zimmer.com

2.2 TELEPHONE NUMBER (Include Area Code)
574-371-8552

2.3 FACSIMILE (FAX) NUMBER (Include Area Code)
574-372-4605

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:

- ☑ Premarket notification (510(k)); except for third party reviews
- ☐ Biologics License Application (BLA)
- ☐ Premarket Approval Application (PMA)
- ☐ Modular PMA
- ☐ Product Development Protocol (PDP)
- ☐ Premarket Report (PMR)

3.1 Select one of the types below:

- ☑ Original Application

Supplement Types:

- ☐ Efficacy (BLA)
- ☐ Panel Track (PMA, PMR, PDP)
- ☐ Real-Time (PMA, PMR, PDP)
- ☐ 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status.)

- ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
- ☑ NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. 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, parents, and partner firms
- ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
- ☐ The sole purpose of the application is to support conditions of use for a pediatric population
- ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

6. 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 ☑ NO

7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2004)

B(4)

Form FDA 3601 (08/2003)

OC
H

CDRH Submission Cover Sheet

Date of Submission: February 13, 2004

FDA Document Number: K 040389

Section A — Type of Submission

PMA	PMA Supplement	PDP	510(k)	Meeting
☐ Original submission ☐ Modular submission ☐ Amendment ☐ Report ☐ Report Amendment	☐ Regular ☐ Special ☐ Panel Track ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA Supplement	☐ Presubmission summary ☐ Original PDP ☐ Notice of intent to start clinical trials ☐ Intention to submit Notice of Completion ☐ Notice of Completion ☐ Amendment to PDP ☐ Report	☒ Original submission: ☒ Traditional ☐ Special ☐ Abbreviated ☐ Additional Information: ☐ Traditional ☐ Special ☐ Abbreviated	☐ Pre-IDE meeting ☐ Pre-PMA meeting ☐ Pre-PDP meeting ☐ 180-day meeting ☐ Other (specify):

IDE	Humanitarian Device Exemption	Class II Exemption	Evaluation of Automatic Class III Designation	Other Submission
☐ Original submission ☐ Amendment ☐ Supplement	☐ Original submission ☐ Amendment ☐ Supplement ☐ Report	☐ Original submission ☐ Additional information	☐ Original submission ☐ Additional information	Describe submission:

Section B — Applicant or Sponsor

Company/Institution name: Zimmer, Inc.			Establishment registration number: 1822565
Division name (if applicable): N/A			Phone number (include area code): 574-372-4113
Street address: P.O. Box 708			FAX number (include area code): 574-372-4605
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Ted Wendt, Ph.D.			
Contact Title: Vice President, Regulatory Affairs and Compliance		Contact e-mail address: ted.wendt@zimmer.com	

Section C — Submission Correspondent (If Different from Above)

Company/Institution name: Zimmer, Inc.			Establishment registration number: 1822565
Division name (if applicable): N/A			Phone number (include area code): 574-371-8552
Street address: P.O. Box 708			FAX number (include area code): 574-372-4605
City: Warsaw	State/Province: Indiana	Country: USA	ZIP/Postal Code: 46581-0708
Contact Name: Noah J. Bartsch MS			
Contact Title: Regulatory Affairs Specialist		Contact e-mail address: noah.bartsch@zimmer.com	

OR
II

Section D1 — Reason for Submission -- PMA, PDP, or HDE

- ☐ New device
- ☐ Withdrawal
- ☐ Additional or expanded indications
- ☐ Licensing agreement
- ☐ Change in design, component or specification:
  - ☐ Software
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other (specify below)
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
  - ☐ Distributor
- ☐ Process change:
  - ☐ Manufacturing
  - ☐ Sterilization
  - ☐ Packaging
  - ☐ 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
- ☐ Reponse to FDA correspondence:
  - ☐ Request for applicant hold
  - ☐ Request for removal of applicant hold
  - ☐ Request for extension
  - ☐ Request to remove or add manufacturing site
- ☐ Change in ownership
- ☐ Change in correspondent
- ☐ Other reason (specify):

Section D2 — Reason for Submission -- IDE

- ☐ New device
- ☐ Addition of institution
- ☐ Expansion / extension of study
- ☐ IRB certification
- ☐ Request hearing
- ☐ Request waiver
- ☐ Termination of study
- ☐ Withdrawal of application
- ☐ Unanticipated adverse effect
- ☐ Notification of emergency use
- ☐ Compassionate use request
- ☐ Treatment IDE
- ☐ Continuing availability request
- ☐ Change in:
  - ☐ Correspondent
  - ☐ Design
  - ☐ Informed consent
  - ☐ Manufacturer
  - ☐ Manufacturing process
  - ☐ Protocol - feasibility
  - ☐ Protocol – other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current investigator
  - ☐ Annual progress
  - ☐ Site waiver limit reached
  - ☐ 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
- ☐ Other reason (specify):

Section D3 — Reason for Submission – 510(k)

- ☐ New device
- ☒ Additional or expanded indications
- ☐ Other reason (specify):
- ☐ Change in technology
- ☐ Change in design
- ☐ Change in materials
- ☐ Change in manufacturing process

Section E Additional Information on 510(k) Submissions

Product codes of devices to which substantial equivalence is claimed:				Summary of, or statement concerning, safety and effectiveness data:
1 LZN	2 JDI	3	4	☒ 510(k) summary attached
5	6	7	8	☐ 510(k) statement

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K001733	1 Allen Medullary Plugs	1 Zimmer, Inc.
2 K950312	2 *Zimmer Poly-Plug*™ Intramedullary System, included in ZCH Alpha Hip Prosthesis w/PMMA Precoat	2 Zimmer, Inc.
3	3	3
4	4	4
5	5	5
6	6	6

Section F Product Information – Applicable to All Applications

Common or usual name or classification name:
Cement Obturator

Trade or proprietary or model name	Model number
1 Coonrad/Morrey Elbow Cement Restrictor	1 8105 series
2	2
3	3
4	4
5	5
6	6

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

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

Data included in submission: ☒ Laboratory testing ☐ Animal trials ☐ Human trials

Section G — Product Classification – Applicable to All Applications

Product code:	C.F.R. Section	Device class:
LZN	21 CFR 878.3300	☐ Class I ☒ Class II ☐ Class III ☐ Unclassified
Classification panel: Orthopedics/87		

Indications (from labeling):

Intramedullary cement plugs are indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement.

The larger intramedullary cement plugs are useful in revision surgery where a wide, smooth intramedullary canal must be plugged.

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

Section H — Manufacturing/Packaging/Sterilization Sites Relating to a Submission

☒ Original ☐ Add ☐ Delete	FDA Establishment registration number: 1822565	☒ Manufacturer ☐ Contract manufacturer	☐ Contract Sterilizer ☐ Repackager/Relabeler

Company/Institution name: Zimmer, Inc.	
Division name (if applicable): N/A	Phone number (include area code): 574-372-4113
Street address: P.O. Box 708	FAX number (include area code): 574-372-4605

City:	State/Province:	Country:	ZIP/Postal Code:
Warsaw	Indiana	USA	46581-0708

Contact name: Ted Wendt, Ph.D.	
Contact Title: Vice President, Regulatory Affairs and Compliance	Contact e-mail address: ted.wendt@zimmer.com

(b)(4)

☐ Manufacturer ☒ Contract Sterilizer
☐ Contract manufacturer ☐ Repackager/relabeler

(b)(4)

[redacted]

Traditional 510(k) Premarket Notification

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Traditional 510(k) Premarket Notification

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P.O. Box 708
Warsaw, IN 46581-0708
574 267-6131

February 13, 2004

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

Dear Sir or Madam:

Subject: Traditional 510(k) Premarket Notification – Coonrad/Morrey Elbow Cement Restrictor

As required by Section 510(k) of the Federal Food, Drug and Cosmetic Act, as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, FDA Modernization Act of 1997 (FDAMA) and in accordance with Title 21 of the Code of Federal Regulations (CFR) Part 807, subpart E, the above noted premarket notification is hereby submitted to the Food and Drug Administration (FDA). As required by 21 CFR 807.90(c), this document is submitted in duplicate. A CD-ROM with identical content to the paper submission is also included for your convenience.

These devices have not been previously submitted to FDA for identical or different indications, are not currently being reviewed for different indications by the same or different branch within ODE, and have not been previously cleared by FDA for different indications. All data and information submitted herein are truthful and accurate to the best of our knowledge and no material fact has been omitted.

If you require any additional information or have any questions, please contact me by telephone at (574) 371-8552, by e-mail at noah.bartsch@zimmer.com or fax at (574) 372-4605.

Sincerely,

Noah J. Bartsch MS
Specialist, Regulatory Affairs

njb/njb
Enclosure

SK 53

0008

Coonrad/Morrey Elbow Cement Restrictor

Traditional 510(k) Premarket Notification

Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708

Device Name

Coonrad/Morrey Elbow Cement Restrictor

Section 514 Compliance

Section 514 of the Act does not apply to this type of device at this time.

Summary of Safety and Effectiveness

A summary of information regarding safety and effectiveness for the proposed device is presented in Exhibit A.

Device Description

Overview

Intramedullary cement plugs are used clinically to prevent uncontrolled cement flow in the intramedullary canal during total joint arthroplasty. They are inserted into the surgically prepared canal prior to the introduction of bone cement and insertion of the appropriate prosthesis.

The Coonrad/Morrey Elbow Cement Restrictor is an intramedullary cement plug designed to impede the flow of cement distal to the prosthesis in the intramedullary canal during total elbow arthroplasty. The implant is a flat, thin polyethylene disc featuring radial slits originating near the center and ending at the outward edge, (see Figure 1).

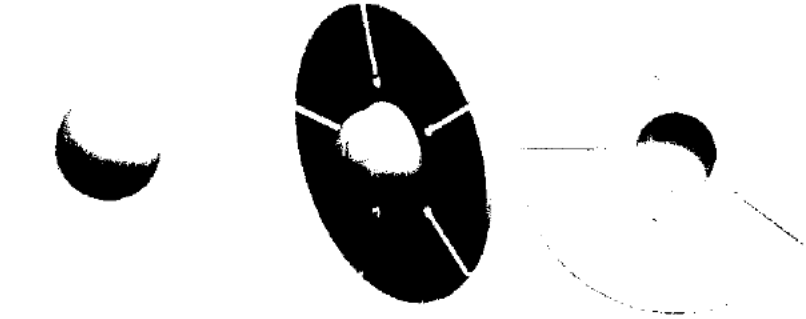


Figure 1. The Coonrad/Morrey Elbow Cement Restrictor.

When folded, this design conforms to the opening in the bone canal. The rigidity (b)(4) (b)(4) which keeps the implant in place. The implant then acts as an obstruction, which impedes the flow of bone cement.

The (b)(4) with the implant inserter instrument. The implant is designed to detach from the inserter instrument nozzle upon introduction of bone cement into the prepared intramedullary canal.

The Coonrad/Morrey Elbow Cement Restrictor is available in two different sizes to accommodate for anatomical differences, and is a single use only, sterile device.

Size Interchangeability

The two sizes of the Coonrad/Morrey Elbow Cement Restrictor (16 mm and 25 mm in diameter) are both designed for use with the same inserter instrument.

Indications for Use

See Exhibit B for the Indications for Use.

Predicate Devices

The following devices are predicates for the Coonrad/Morrey Elbow Cement Restrictor:

1. Zimmer Allen Medullary Plugs (K001733, cleared June 20, 2000).
2. *Zimmer Poly-Plug*™ Intramedullary System (K950312, cleared May 17, 1995).

Copies of the substantial equivalence letters are presented in Exhibit C.

Substantial Equivalence Comparison

See Exhibit D for a comparison table between the predicate devices and the proposed Coonrad/Morrey Elbow Cement Restrictor.

Engineering Drawings/Dimensions

Representative engineering drawings for the proposed Coonrad/Morrey Elbow Cement Restrictor components are included in Exhibit E.

Catalog Numbers

All catalog numbers for the proposed Coonrad/Morrey Elbow Cement Restrictor components are listed in Exhibit F.

Materials

The Coonrad/Morrey Elbow Cement Restrictor implants are made from [redacted] (b)(4) [redacted].

Surgical Instrumentation Unique to the Device

The inserter instrument is also used with other devices; therefore, there is no surgical instrumentation unique to this device.

Methods/Facilities and Controls

Method of Manufacturing

(b)(4) [redacted]

Packaging

The Coonrad/Morrey Elbow Cement Restrictor system consists of two separately packaged components combined into one unit package. The first component contains the two implants – one size 16 mm and one size 25 mm – which are packaged together in one TYVEK pouch. The second component is the implant inserter instrument, which is packaged in a second TYVEK pouch. Both pouches are then packaged inside a single, common TYVEK pouch.

Sterile package protection is afforded by placing the packaged components into a paperboard folding carton which is then shrink-wrapped. The sterile package materials are:

TYVEK Pouches:

A polyethylene and polyester lamination, heat-sealed to DuPont TYVEK spunbonded high density polyethylene, style uncoated 1073B.

Labeling

Representative labeling for the Coonrad/Morrey Elbow Cement Restrictor system is presented in Exhibit G, along with the carton labeling and the package insert.

Sterilization

Sterilization Method

Gamma Irradiation (Cobalt 60) at a contract sterilizer.

Absorbed Radiation Dose

Minimum to maximum dose range is 25 - 37 kGy.

Sterility Assurance Level

SAL greater than or equal to 10^{-6}.

Sterilization Validation Method

The minimum sterilization dose was verified (method 1, dose setting validation) and the gamma radiation processing and dose mapping were conducted using ANSI/AAMI/ISO 11137-1994, "Sterilization of health care products – Requirements for validation and routine control - Radiation Sterilization."

Biocompatibility

Biocompatibility testing for HDPE was conducted per AAMI/ANSI/ ISO 10993-1 and is on file at Zimmer.

Color Additives

This device does not have any color additives. No additional biocompatibility testing is required.

Software

This is an orthopaedic implant and has no associated software.

Pyrogenicity

This device is not labeled as nonpyrogenic. Per USP XXIII (161), requirements

for specified endotoxin levels do not apply to orthopaedic implants.

Latex

There is no natural latex rubber in this product or its packaging.

Performance Testing

(b)(4)

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Noah J. Bartsch, MS Specialist, Regulatory Affairs Telephone: (574) 371-8552 Fax: (574) 372-4605
Date:	February 13, 2004
Trade Name:	Coonrad/Morrey Elbow Cement Restrictor
Common Name:	Cement Obturator
Classification Name and Reference:	Orthopaedic Surgical Mesh 21 CFR § 878.3300
Predicate Devices:	Zimmer Allen Medullary Plugs, K001733, cleared June 20, 2000. *Zimmer Poly-Plug*™ Intramedullary System, K950312, cleared May 17, 1995
Device Description:	The Coonrad/Morrey Elbow Cement Restrictor is designed to impede the flow of bone cement distal to the prosthesis in the intramedullary canal during total elbow arthroplasty. The plugs are molded from polyethylene, and they are inserted into the intramedullary canal prior to the introduction of bone cement and insertion of the appropriate prosthesis.
Intended Use:	Intramedullary cement plugs are indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement. The larger intramedullary cement plugs are useful in revision surgery where a wide, smooth intramedullary canal must be plugged.

Comparison to Predicate Device:	The Coonrad/Morrey Elbow Cement Restrictor is equivalent to other commercially available intramedullary cement plugs currently on the market, by virtue of design and functionality. The device has the same intended use as the predicate devices, and has demonstrated the ability to functionally perform the intended use.
Performance Data (Non-clinical):	Non-Clinical Performance and Conclusions: Non-clinical testing demonstrated that the Coonrad/Morrey Elbow Cement Restrictor meets performance requirements and is as safe and effective as the predicate devices.

K011359

Indications for Use

510(k) Number (if known):

Device Name:

Coonrad/Morrey Elbow Cement Restrictor

Indications for Use:

Intramedullary cement plugs are indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement.

The larger intramedullary cement plugs are useful in revision surgery where a wide, smooth intramedullary canal must be plugged.

Prescription Use _X_ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ____ (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)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

C-000205

JUN 2 0 2000

Mr. Fred McClure
Regulatory Affairs Associate
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K001733
Trade Name: Zimmer PolyPlug Intramedullary System and Allen Medullay Plugs
Regulatory Class: II
Product Code: JDI, LZN
Dated: May 30, 2000
Received: June 7, 2000

Dear Mr. McClure:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). You may, therefore, market the device, subject to the general control provisions of the Act. The general control 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 (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.

This letter will allow you to begin marketing your device as described in your 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 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, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C-950104

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 1995

Ms. Angie Ide
Senior Regulatory Affairs Associate
Zimmer
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K950312
ZCH Alpha Hip Prosthesis with PMMA Precoat
Regulatory Class: II
Product Code: JDI and LZN
Dated: January 25, 1995
Received: January 26, 1995

Dear Ms. Ide:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed within bone with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.

2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.

3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

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 (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 (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. 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.

This letter immediately will allow you to begin marketing your device as described in your 510(k) premarket notification. 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, but it does not mean that FDA approves your device. Therefore, you may not promote or in any way represent your device or its labeling as being approved by FDA. If you desire specific advice regarding labeling for your device in accordance with 21 CFR Part 801, promotion, or advertising please contact the Office of Compliance, Promotion and Advertising Policy Staff (HFZ-302) at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Paul R. Beninger, M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Substantial Equivalence Comparison

Property or Characteristic	Proposed Coonrad/Morrey Total Elbow Cement Restrictor	Predicate Device #1 Allen Medullary Plugs	Predicate Device #2 *Zimmer Poly-Plug*™ Intramedullary System
Indications for use	• Indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement.	• Indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement.	• Indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement.
Design	(b)(4) [redacted]	• Able to establish adequate contact with the canal wall to perform the indicated purpose. • For use with an inserter instrument to place the implant at a desired depth in the prepared intramedullary canal.	• Able to establish adequate contact with the canal wall to perform the indicated purpose. • For use with an inserter instrument to place the implant at a desired depth in the prepared intramedullary canal.
Materials	[redacted]	• HDPE or UHMWPE	• HDPE
Sterility	• Terminally sterilized by gamma radiation. • Gamma radiation processing and dose mapping are conducted according to ANSI/AAMI/ISO 11137-1994. • Accepted for release as sterile though a validated dosimetric release program designed to provide a sterility assurance level (SAL) of 10^{-6} or better.	• Terminally sterilized by gamma radiation. • Gamma radiation processing and dose mapping are conducted according to ANSI/AAMI/ISO 11137-1994. • Accepted for release as sterile though a validated dosimetric release program designed to provide a sterility assurance level (SAL) of 10^{-6} or better.	• Terminally sterilized by gamma radiation. • Gamma radiation processing and dose mapping are conducted according to ANSI/AAMI/ISO 11137-1994. • Accepted for release as sterile though a validated dosimetric release program designed to provide a sterility assurance level (SAL) of 10^{-6} or better.

Property or Characteristic	Proposed Coonrad/Morrey Total Elbow Cement Restrictor	Predicate Device #1 Allen Medullary Plugs	Predicate Device #2 *Zimmer Poly-Plug*™ Intramedullary System
Biocompatibility	• Biocompatibility testing (short term toxicity) conducted per AAMI/ANSI/ISO 10993-1 and Good Laboratory Practices and on file at Zimmer. • The material meets or exceeds ASTM standards, is common to orthopaedic products today, and has an extensive safe clinical history.	• Biocompatibility testing (short term toxicity) conducted per AAMI/ANSI/ISO 10993-1 and Good Laboratory Practices and on file at Zimmer. • The materials used meet or exceed ASTM standards, are common to orthopaedic products today, and have an extensive safe clinical history.	• Biocompatibility testing (short term toxicity) conducted per AAMI/ANSI/ISO 10993-1 and Good Laboratory Practices and on file at Zimmer. • The material used meets or exceeds ASTM standards, is common to orthopaedic products today, and has an extensive safe clinical history.
Pyrogenicity	• Per USP XXIII (161), requirements for specified endotoxin levels do not apply to orthopaedic implants.	• Per USP XXIII (161), requirements for specified endotoxin levels do not apply to orthopaedic implants.	• Per USP XXIII (161), requirements for specified endotoxin levels do not apply to orthopaedic implants.
Mechanical safety	• No mechanical safety concerns.	• No mechanical safety concerns.	• No mechanical safety concerns.
Human factors	• Device use depends upon surgical technique. • Recommended procedures are made available to aid surgeons.	• Device use depends upon surgical technique. • Recommended procedures are made available to aid surgeons.	• Device use depends upon surgical technique. • Recommended procedures are made available to aid surgeons.
Compatibility with the environment and/or other devices	• Excluded under 21 CFR § 25.34 (g), "Devices and Electronic Products."	• Excluded under 21 CFR § 25.34 (g), "Devices and Electronic Products."	• Excluded under 21 CFR § 25.34 (g), "Devices and Electronic Products."
Where used	• Hospital operating suites where total joint arthroplasty is performed.	• Hospital operating suites where total joint arthroplasty is performed.	• Hospital operating suites where total joint arthroplasty is performed.

B(4) Product Drawing Design

B(4) Product Drawing Design

B(4) Product Drawing Design

Coonrad/Morrey Elbow Cement Restrictor

Implant Catalog Number

Description	Catalog Numbers
Coonrad/Morrey Elbow Cement Restrictors with Nozzle	32-8105-038-00

CE
0123

Rev. L January 2004
Printed in U.S.A.
 87-6202-576-00

INTRAMEDULLARY CEMENT PLUGS

Manufactured by:

Zimmer, Inc.
1800 West Center Street
Warsaw, Indiana 46580
USA

Authorized Representative:

Zimmer, Ltd.
9 Lancaster Place
South Marston Park
Swindon, SN3 4FP, UK

Carefully read all instructions and be familiar with the surgical techniques prior to use.

DESCRIPTION

- Intramedullary cement plugs are used to control, restrict, or impede the flow of bone cement in total joint arthroplasty. The use of a cement plug is essential for the introduction of low viscosity cement into the intramedullary canal by means of a cement applicator.
- Intramedullary cement plugs are made from ultra-high molecular-weight polyethylene (UHMWPE) or high-density polyethylene and may contain barium sulfate.

INDICATIONS

- Intramedullary cement plugs are indicated for use in total joint arthroplasty to control, restrict, or impede the flow of cement.
- The larger intramedullary cement plugs are useful in revision surgery where a wide, smooth intramedullary canal must be plugged.

INDIVIDUALIZATION OF TREATMENT

Preparing the Intramedullary Canal:
After initial preparation with a rasp, brush and debride the canal to remove loose trabecular bone, fat, and other soft tissue. Care should be taken not to enlarge the diameter of the canal and to preserve the irregularities of the endosteal surface. This will allow for improved cement/bone interlock. For revisions, a sufficiently large cement plug should be selected preoperatively.

Intramedullary Cement Plug Size Selection:
To select the correct intramedullary cement plug size, any of these methods are suitable:

1. A fairly accurate measurement of the diameter can be made on preoperative radiographs, allowing for 10 percent magnification. Experience has shown that the true diameter may be somewhat smaller than the radiological measurement indicates because of irregularities in endosteal architecture.
2. The diameter of the last intramedullary reamer or rasp used can provide an accurate assessment of canal diameter dimensions.
3. It is recommended that the diameter of the plug be greater than that of the prepared canal.
4. It is recommended that the Coonrad/Morrey Elbow Cement Restrictor be at least 6 mm larger in diameter than the prepared canal.

Inserting the Allen Medullary Cement Plug or the *Zimmer Poly-Plug*™ Intramedullary Cement Plug:

1. Place the inserter without a cement plug into the canal for a trial fit to assure that it will move freely without becoming entrapped.
2. Attach the cement plug to the inserter and introduce it into the canal to a depth commensurate with the length of the stem.
3. Seat the cement plug with a gentle to firm tap with a hammer.
4. Disengage the cement plug inserter by twisting it in a counterclockwise direction.
5. After final rinsing of the canal using a pulsating water lavage and then drying, apply low viscosity cement in a retrograde fashion to avoid inclusions of air, blood, or saline. Follow the manufacturer's instructions for the cement and applicator used.
6. Insert the prosthesis following the instructions in the surgical technique provided by the manufacturer.

Inserting the Coonrad/Morrey Elbow Cement Restrictor:

1. Attach the cement nozzle provided with the restrictor to the cement cartridge, or the cement cartridge adaptor, after low viscosity bone cement has been inserted into the cartridge.
2. Insert the cement restrictor into the open end of the cement nozzle after bone cement has been extruded to the distal tip of the nozzle.
3. Insert the cement nozzle, with the cement restrictor attached, into the canal to the desired depth.
4. Apply cement in a retrograde fashion, following the manufacturer's instructions for the cement and applicator used. The cement restrictor will deploy during cement extrusion into the canal.
5. Insert the prosthesis following the instructions in the surgical technique provided by the manufacturer.

NOTE: The Coonrad/Morrey Elbow Cement Restrictor is not intended to pressurize the cement.

Revisions:
For revisions, the canal is cleaned thoroughly to remove as much old bone cement as possible before the cement plug size is determined.

Removal of an Incorrectly Placed Intramedullary Cement Plug:
The cement plug can be removed with a reamer; however, removal will necessitate the use of a new cement plug.

WARNINGS
- This device is for single patient use only. Do not reuse.
- Do not reinsert a previously inserted cement plug. Removal may have damaged the plug so that it will no longer function properly.
- Do not use:
  - This product for other than labeled indications (off-label use).
  - Any component if damage is found or caused during setup or insertion.

PRECAUTIONS
- Select a cement plug of the proper diameter to fit the patient's canal beyond the tip of the prosthesis.
- The intramedullary canal should be clean and free from debris before the cement plug is inserted.
- For optimal results, use of low viscosity cement and a cement applicator are recommended.

ADVERSE EFFECTS
In addition to adverse effects associated with total joint arthroplasty, the following adverse effects have been reported or may be anticipated with the use of intramedullary cement plugs:
- Intraoperative plug or inserter breakage
- Plug migration
- Infection

STERILITY
The metal inserters are not provided sterile and must be sterilized prior to use. Steam autoclaving following AORN guidelines is recommended. Before resterilization of any surgical instrument, blood and debris must be removed by thorough cleaning.

These plugs and plastic inserters are provided sterile (sterilized by gamma irradiation—indicated by the "Sterile R" symbol on the labeling) and remain sterile as long as the package integrity has not been violated. Inspect each package prior to use and do not use the component if any seal or cavity is damaged or breached or if the expiration date has been exceeded. Once opened, the component must be used, discarded or resterilized.

RESTERILIZATION INFORMATION
- If required, the devices can be resterilized using Association for the Advancement of Medical Instrumentation (AAMI) guidelines and/or Association of Operating Room Nurses (AORN) recommended practices for sterilization. Do not resterilize implant components that have been previously implanted or contaminated with body fluids or debris.
- Do not use the original plastic cavities or lids for resterilization.
- UHMWPE or high density polyethylene components **must not** be exposed to steam sterilization. The temperatures required for these processes may soften, warp or crack the polyethylene.
- Additional resterilization information is available upon request. In the USA, call 1-800-348-2759. For calls outside the USA, call the local international access code +1-574-267-6131.

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

zimmer

ITEM NO: 32-8105-038-00	OPERATION: 9000
DESCRIPTION: C/M 16 & 25MM PLUG WITH NOZZLE STERILE	PROD CLASS: 400
QTY/PKG: 1	ENGINEER: Cheryl Trease
REV:	REV DATE:
	DATE OF ISSUE: 12-22-03

LABEL SPECIFICATIONS

32-8105-038-00

5-208

LOT 99999999

CAT. NO. 32-8105-38

COONRAD/MORREY TOTAL ELBOW
CEMENT RESTRICTOR PLUGS WITH NOZZLE
1-16 MM
1-25 MM
SINGLE USE ONLY STERILE QTY - 1

CONTENTS STERILE IF PACKAGE NOT OPENED OR DAMAGED

yyyy-mm

5-208

AFFIX TO PATIENT RECORD

LOT 99999999 CAT NO 32-8105-38
COONRAD/MORREY TOTAL ELBOW
CEMENT RESTRICTOR PLUGS WITH NOZZLE
1-16 MM
1-25 MM
SINGLE USE ONLY STERILE QTY 1
CONTENTS STERILE IF PACKAGE NOT OPENED OR DAMAGED

Zimmer

2-580

LOT 99999999 CAT NO 32-8105-38
COONRAD/MORREY TOTAL ELBOW
CEMENT RESTRICTOR PLUGS WITH NOZZLE
1-16 MM
1-25 MM
SINGLE USE ONLY STERILE QTY 1
CONTENTS STERILE IF PACKAGE NOT OPENED OR DAMAGED

Zimmer

2-720

LOT 99999999 CAT NO 32-8105-38

COONRAD/MORREY TOTAL ELBOW
CEMENT RESTRICTOR PLUGS WITH NOZZLE
1-16 MM
1-25 MM
SINGLE USE ONLY STERILE QTY 1

yyyy-mm

Zimmer

CE STERILE R

+H12432810503800 1A*

VYDDD99999999A04AT

2-720

2-200

TECHNICAL MEMORANDUM

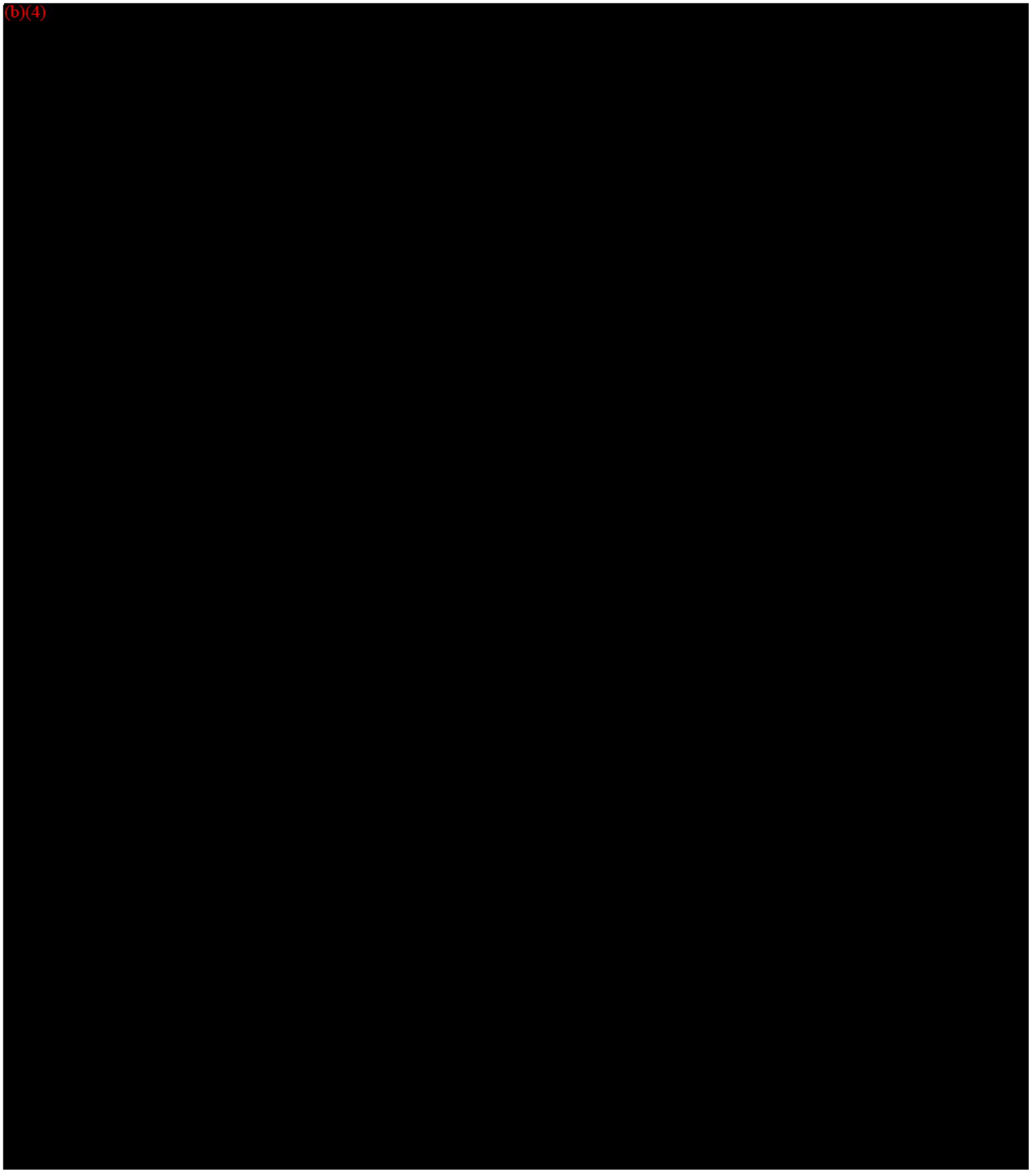
zimmer

Research Laboratories

(b)(4)

[redacted]

(b)(4)



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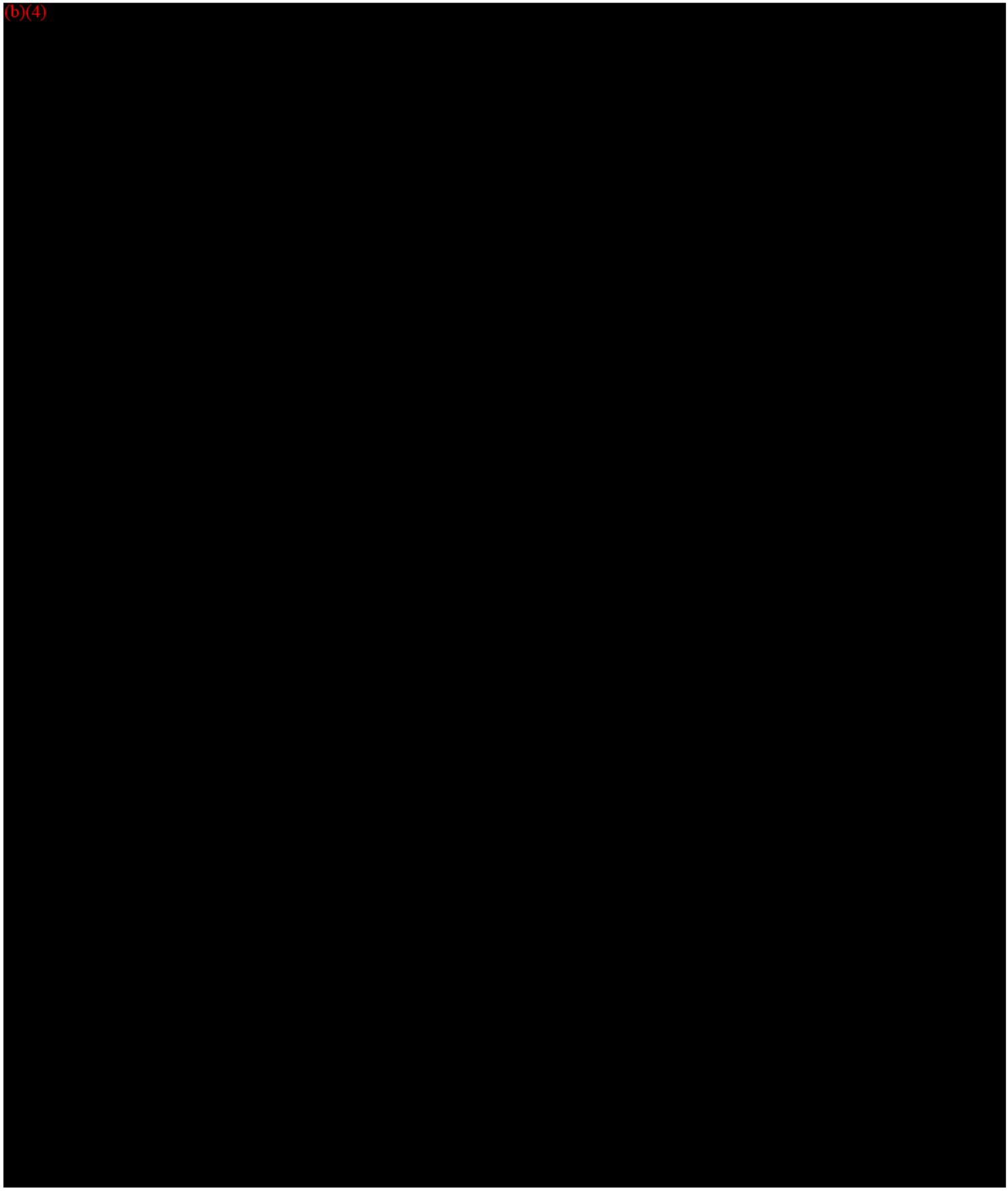

(b)(4)

[redacted]

(b)(4)

[redacted]

(b)(4)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Christopher Hack

Subject: 510(k) Number K040389

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Section 522 Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☐ YES	☒ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

Truthful and Accurate Statement ☐ Requested ☒ Enclosed

☒ A 510(k) summary OR ☐ A 510(k) statement

NA ☐ The required certification and summary for class III devices

☒ The indication for use form

Combination Product Category (Please see algorithm on H drive 510k/Boilers) UCP

Animal Tissue Source ☐ YES ☒ NO Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☒ Continued Confidentiality exceeding 90 d

Predicate Product Code with class: Additional Product Code(s) with panel (optional):

JDG JDB

Review: [signature] (Branch Chief) QRB (Branch Code) 5/17/04 (Date)

Final Review: Mark N. Milhern for (Division Director) 5/17/04 (Date)

SCREENING CHECKLIST
FOR ALL PREMARKET NOTIFICATION [510(k)] SUBMISSIONS

510(k) Number: K040339

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

☐ Special 510(k) - Do Sections 1 and 2

☐ Abbreviated 510(k) - Do Sections 1, 3 and 4

☑ Traditional 510(k) or no identification provided - Do Sections 1 and 4

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

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

* - May not be applicable for Special 510(k)s.

** - Required for Class III devices, only.

*** - See pages 3-12 and 3-13 in the Premarket Notification [510)] Manual and the Convenience Kits Interim Regulatory Guidance.

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

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

Section 3: Required Elements for an ABBREVIATED 510(k)* submission:

	Present	Inadequate or Missing
For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type. (If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.)		
For a submission, which relies on a recognized standard, a declaration of conformity [For a listing of the required elements of a declaration of conformity, SEE Required Elements for a Declaration of Conformity to a Recognized Standard, which		

is posted with the 510(k) boilers on the H drive.]		
For a submission, which relies on a recognized standard without a declaration of conformity, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device.		
For a submission, which relies on a non-recognized standard that has not been historically accepted by FDA, a statement that the manufacturer intends to conform to a recognized standard and that supporting data will be available before marketing the device and any additional information requested by the reviewer in order to determine substantial equivalence.		
Any additional information, which is not covered by the guidance document, special control, recognized standard and/or non-recognized standard, in order to determine substantial equivalence.		

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

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

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

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

Passed Screening ✓ Yes ___ No

Reviewer: CS

Concurrence by Review Branch: _____

Date: _____

The deficiencies identified above represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act 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/cdrh/modact/leastburdensome.html

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K_____

Reviewer:_____

Division/Branch:_____

Device Name:_____

Product To Which Compared (510(K) Number If Known):_____

	YES	NO	
1. Is Product A Device			If NO = Stop
2. Is Device Subject To 510(k)?			If NO = Stop
3. Same Indication Statement?			If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?			If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?			If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

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

5. Describe the new technological characteristics:

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

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why th questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

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

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

510(k) MEMORANDUM

Date: 5/11/2004

Reviewer: Christopher Hack BSE, Biomedical Engineer
FDA/CDRH/ODE/DGRD/ORDB, HFZ-410

Document #: K040389

Date on Submission: 2/13/04
Received in ODE: 2/17/04
Document Received: 2/17/04

Review Initiated: 5/1/04
Due Date (60 Days): 5/2/04
Decision Date (90 Days): 5/17/04

RECOMMENDATION: SE

Sponsor and Official Contact:

Zimmer, Inc
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Warsaw, In 46581 0708
Ph: 574.371.8552
Fax: 574.372.4605

Establishment Registration Number 1526534

INTERNAL ADMINISTRATIVE FORM

		YES	NO
1.	Did the firm request expedited review?		x
2.	Did we grant expedited review?		x
3.	Have you verified that the Document is labeled Class III for GMP purposes?	x	
4.	If, not, has POS been notified?		
5.	Is the product a device?	x	
6.	Is the device exempt from 510(k) by regulation or policy?		x
7.	Is the device subject to review by CDRH?	x	
8.	Are you aware that this device has been the subject of a previous NSE decision?		x
9.	If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10.	Are you aware of the submitter being the subject of an integrity investigation?		x
11.	If, yes, consult the ODE Integrity Officer.		
12.	Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

DECISION MAKING FLOWCHART FOR "SUBSTANTIAL EQUIVALENCE"

		YES	NO	
1.	Is the product a device?	x		NO then Stop
2.	Is the device subject to 510(k)?	x		NO then Stop
3.	Is the indication statement the same?	x		YES then Go To 5
4.	Do differences in the indication statement raise new issues of safety and effectiveness?			YES then NSE
5.	Does the device have the same technological characteristics?		x	YES then Go To 7
6.	Could the new characteristics affect safety and effectiveness?			YES then Go To 8

7.	Are the descriptive characteristics precise enough?	x		NO then Go To 10 YES then SE
8.	Are there new types of safety and effectiveness questions?			YES then NSE
9.	Do accepted scientific methods exist to test the impact of the new characteristics?			NO then NSE
10.	Is performance data available?			NO then Request Data
11.	Does the performance data demonstrate substantial equivalence?			FINAL DECISION: SE

SUMMARY OF REVIEW

The Coonrad/Morrey Elbow Cement Restrictor is a cement restrictor intended to impeded cement flow in the humeral canal. It is made from HDPE. It comes in two sizes 16mm and 25mm. This is a fairly straight forward submission and the sponsor has demonstrated Se with predicate devices

REQUIRED FORMS

Truthful & Accuracy Statement: √
Indications for Use Page (IFU): √
510k Summary: √

DEVICE IDENTIFICATION

Trade Name:	Coorad/Morrey Elbow Cement Restrictor
Regulation Number:	878.3300- Orthopaedic surgical Mesh
Regulatory Class:	Class II
Product Code:	JDC, JDB

INTENDED USE AND INDICATIONS

As described in: page 17

Intramedullary cement plugs are indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement

The larger intramedullary cement plugs are useful in revision surgery where a wide, smooth intramedullary canal must be plugged.

COMMENTS:none

DEVICE DESCRIPTION

Intramedullary cement plugs are used clinically to prevent uncontrolled cement flow in the intramedullary canal during total joint arthroplasty. They are inserted into the surgically prepared canal prior to the introduction of bone cement and insertion of the appropriate prosthesis.

The Coonrad/ Morrey Elbow Cement Restrictor is an intramedullary cement plug designed to impede the flow of cement distal to the prosthesis in the intramedullary canal during total elbow arthroplasty. (b)(4) [redacted] (b)(4) [redacted].

When folded, this design conforms to the opening in the bone canal. The (b)(4) [redacted] The implant then acts as an obstruction, which impedes the flow of bone cement.

The center of the [redacted]. The implant is designed to detach from the inserter nozzle upon introduction of bone cement into the prepared intramedullary canal.

The Coonrad/ Morrey Elbow Cement restrictor is available in two different sizes to accommodate for anatomical differences, and is a single use only, sterile device. (sizes are 16mm and 25 mm in diameter)

DEVICE MATERIALS

(b)(4) [redacted]

STERILIZATION

Sterilization method – Gamma Radiation (Cobalt 60)
Absorbed Radiation Dose – 25 -37 kGy
SAL – 10^{-6}
Validation method –
The minimum sterilization dose was verified ANSI/AAMI/ISO 11137-1994

LABELING

Packaging

The elbow cement restrictor system consists of two separately packaged components combined in one unit package. The first component contains two implants – one size 16mm and one size 25mm—which are packaged together in one TYVEK pouch. The second component is the implant inserter instrument, which is packaged in a separate TYVEK pouch. Both are inside a single common TYVEK pouch.

Labels: include company name and address, product name, sizes, sterility information (sterile), and lot number. - adequate

BIOCOMPATIBILITY

Biocompatibility testing was per ISO 10993-1.

TESTING DETAILS

(b)(4) [redacted]

15

(b)(4)

[redacted]

ADDITIONAL INFORMATION RELATING TO PREDICATE DEVICE

Predicate devices: K001733 – Zimmer Allen Medullary Plugs
K950312 -- Zimmer Poly Plug

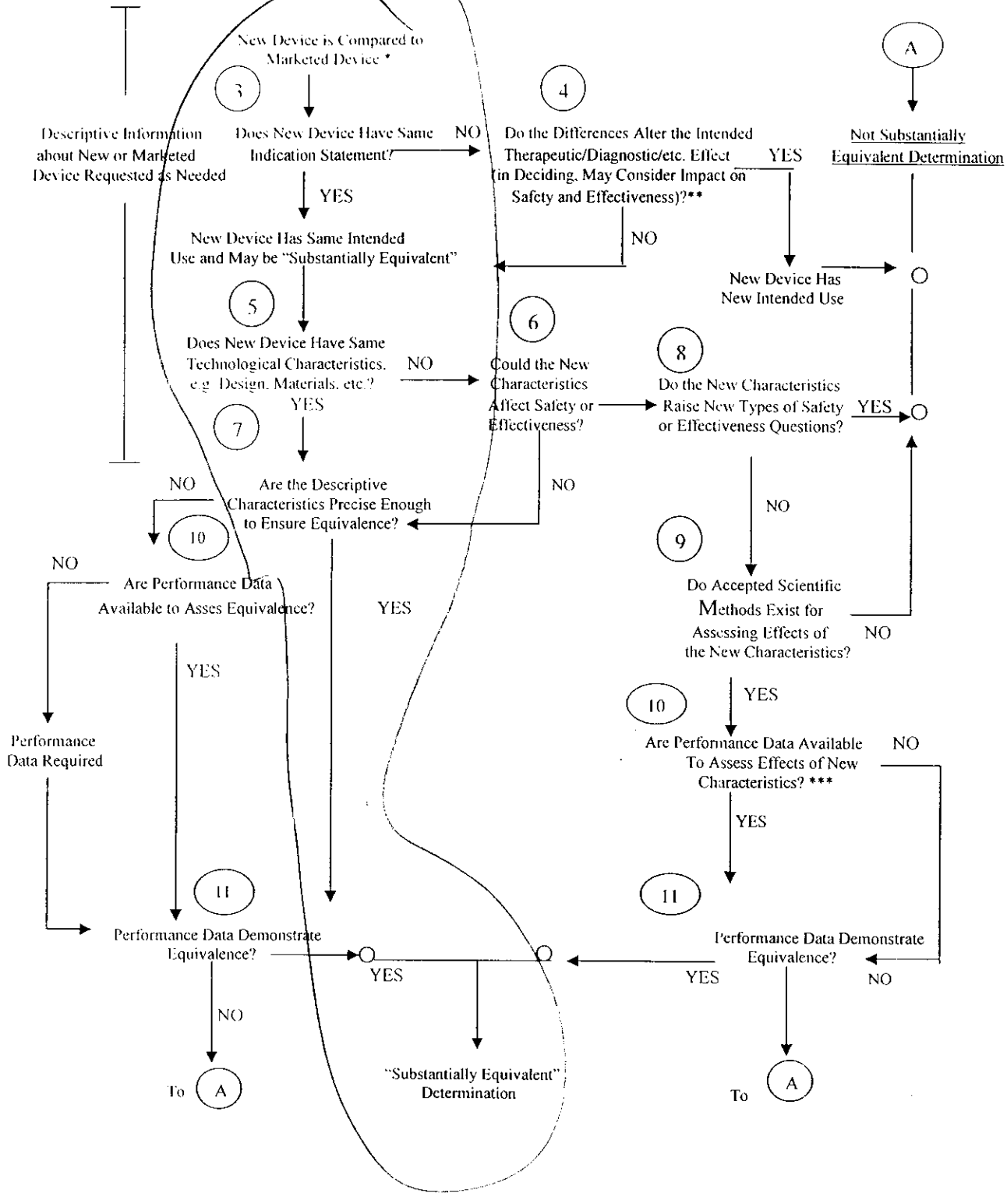
Property or Characteristic	Proposed Coonrad/ Morrey Total Elbow Cement Restrictor	Predicate Device #1 Allen Medullary Plugs	Predicate Device #2 Zimmer Poly-Plug Intramedullary System
Indications for use	Indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement	Indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement	Indicated for use in total joint arthroplasty to control, restrict or impede the flow of cement
(b)(4) [redacted]		-Able to establish adequate contact with the canal wall to perform indicated purpose -for use with an inserter instrument to place the implant at a desired depth in the prepared intramedullary canal.	-able to establish adequate contact with the canal wall to perform the indicated purpose. - for use with an inserter instrument to place the implant at a desired depth in the prepared intramedullary canal
Materials	HDPE	HDPE or UHMWPE	HDPE
Sterility	-terminally sterilized by gamma radiation -as per ISO 11137 -1994 -SAL 10^{-6}	-terminally sterilized by gamma radiation -as per ISO 11137 -1994 -SAL 10^{-6}	-terminally sterilized by gamma radiation -as per ISO 11137 -1994 -SAL 10^{-6}

DEFICIENCIES AND LOG OF CONTACT WITH COMPANY

The following are draft deficiencies:

I originally was going to ask the sponsor to include contraindications in the labeling but found through my research that some of the predicates do not have contraindications listed in their labeling either.
No current deficiencies.

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.