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 Milhous

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