DEC 9 2005

Summary of Safety and Effectiveness

Submitter:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Laura D. Williams, RAC Manager, Corporate Regulatory Affairs Telephone: (574) 372-4523 Fax: (574) 372-4605
Date:	November 11, 2005
Trade Name:	Coonrad/Morrey Total Elbow
Common Name:	Total Elbow Prosthesis
Classification Name and Reference	Elbow joint metal/polymer constrained elbow prosthesis - 21 CFR § 888.3150
Predicate Device:	Coonrad/Morrey Total Elbow, manufactured by Zimmer, Inc., K001989, cleared July 25, 2000

Device Description: The Coonrad/Morrey Total Elbow is a total elbow prosthesis designed for use with bone cement. It is available in regular, small and extra small sizes, in right and left configurations.

Intended Use:
Indications include: post-traumatic lesions or bone loss contributing to elbow instability; ankylosed joints, especially in cases of bilateral ankylosis from causes other than sepsis; advanced rheumatoid or degenerative arthritis with incapacitating pain; revision arthroplasty, and instability or loss of motion when the degree of joint damage precludes less radical procedures.

The candidate for total elbow arthroplasty should exhibit joint destruction which significantly compromises the activities of daily living. Patient with single joint involvement (generally those with traumatic or degenerative arthritis) or significant lower extremity disability which require walking aids are less amenable to treatment than patients with advanced and predominantly upper extremity involvement. If possible, elbow replacement should be done after hip or knee surgery to avoid excessive stress to the prosthesis required by crutch walking during total hip or knee rehabilitation.

Comparison to Predicate Device:
Ulnar Assemblies of modified stem length are being added to accommodate varying anatomy. All other dimensions will remain unchanged compared to the predicate devices.

Performance Data (Nonclinical and/or Clinical):
Results of nonclinical analysis indicate that the modified device is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 9 2005

Laura D. Williams, RAC
Manager, Corporate Regulatory Affairs
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K053189
Trade/Device Name: Coonrad/Morrey Total Elbow
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: JDC
Dated: November 11, 2005
Received: November 15, 2005

Dear Ms. Williams:

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/industry/support/index.html.

Sincerely yours,

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

Enclosure

K053189

Indications for Use

510(k) Number (if known):

Device Name:

Coonrad/Morrey Total Elbow

Indications for Use:

Indications include: post-traumatic lesions or bone loss contributing to elbow instability; ankylosed joints, especially in cases of bilateral ankylosis from causes other than sepsis; advanced rheumatoid or degenerative arthritis with incapacitating pain; revision arthroplasty, and instability or loss of motion when the degree of joint damage precludes less radical procedures.

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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

510(k) Number K053189