K123862

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

510(k) Summary of Safety and Effectiveness

Sponsor:

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

Contact Person:

Joanna L. Surma
Associate Project Manager, Regulatory Affairs
Telephone: (574) 371-1642
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Date:

13 December 2012

Trade Name:

Zimmer Nexel Total Elbow

Common Name:

Total Elbow Prosthesis

Classification

21 CFR § 888.3150
Elbow joint metal/polymer constrained cemented prosthesis

Product Code:

JDC – Prosthesis, Elbow, Constrained, Cemented

Predicate Device:

Coonrad/Morrey Total Elbow, manufactured by Zimmer, K001989, cleared 25 July 2000

Coonrad/Morrey Total Elbow, manufactured by Zimmer, K053189, cleared 9 December 2005

Device Description:

The Zimmer Nexel total Elbow is a total elbow prosthesis designed for use with bone cement. It is available in multiple sizes and in right and left configurations.

How the Device Functions: The Zimmer Nexel Total Elbow is an implant designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implant is a constrained device assembly and consists of the following components: humeral component, ulnar component, humeral bearing-A, ulnar bearings-B, axle pin and humeral screws.

The Following Scientific Concepts, Design Features and Physical Properties form the Basis for the Zimmer Nexel Total Elbow: The humeral component has a humeral stem designed to be implanted with bone cement into the patient's humeral medullary canal, an anterior flange designed to accept a

bone graft and limit torsional and posterior migration, a humeral yoke with rounded corners to avoid the creation of stress risers within the medial and lateral humeral supracondylar columns, and plasma spray region to enhance fixation to bone cement within the medullary canal, and to improve fatigue strength. The ulnar component has an ulnar stem designed to be implanted with bone cement into the patient's ulnar medullary canal, an ulnar eye that is both highly polished and nitrogen-enriched to limit wear of the apposing polymer bearings, and plasma spray region to enhance fixation to bone cement within the medullary canal. Bearings A and B are designed to broadly distribute joint reaction forces.

Materials Used: The humeral and ulnar components are made of a titanium alloy, the bearings A and B are made of Vitamin E highly cross-linked polyethylene, and the humeral screws and axle pin are made of a cobalt-chromium-molybdenum alloy.

Comparison to the Predicate: The proposed device (Zimmer Nexel Total Elbow) and the predicate device (Coonrad/Morrey Total Elbow) have the same intended use and similar indications for use. The proposed device humeral and ulnar components are very similar in terms of materials used and design/dimensions to the predicate device humeral and ulnar components. The primary differences between the proposed and predicate devices are that the proposed device bearing components are made of Vitamin E highly cross-linked polyethylene (the predicate device bearing components are made of ultra-high molecular-weight polyethylene), and the proposed device has bearings that articulate on both the outer and inner diameters of the ulnar eye (the predicate device has bearings that articulate on the inner diameter of the ulnar eye). Additionally, the proposed device uses screws and a 1-part axle pin to fix the bearings in place, while the predicate device uses a 2-part (snap-fit) axle pin.

Intended Use:

Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
- Post-traumatic lesions or bone loss contributing to elbow instability
- Ankylosed joints, especially in cases of bilateral ankylosis from causes other than active sepsis
- Advanced rheumatoid, post-traumatic, or degenerative arthritis with incapacitating pain
- Instability or loss of motion when the degree of joint or soft tissue damage precludes reliable osteosynthesis
- Acute comminuted articular fracture of the elbow joint surfaces that precludes less radical procedures, including 13-C3 fractures of the distal humerus
- Revision arthroplasty

Caution: This device is intended for cemented use only.

510(k) Summary of Safety and Effectiveness – Zimmer Nexel Total Elbow

Comparison to Predicate Device:

The Zimmer Nexel Total Elbow is substantially equivalent to the predicate device in terms of form and function. The Zimmer Nexel Total Elbow and the predicate device share similar intended uses and indications for use.

Performance Data:

Non-Clinical Performance Testing Conducted:

- Stem Fatigue Testing
- Wear Testing
- Durability Testing
- Modular Connection Fatigue Testing

Non-Clinical Performance Testing Conclusions:

Non-clinical testing demonstrated that the New Zimmer Total Elbow meets performance requirements as defined by Design Control activities and is substantially equivalent to the predicate device in terms of safety and efficacy.

In this case, clinical data and conclusions were not needed to demonstrate substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Zimmer, Incorporated
% Ms. Joanna L. Surma
Associate Project Manager, Regulatory Affairs
P.O. Box 708
Warsaw, Indiana 46581-0708

Letter dated: March 12, 2013

Re: K123862
Trade/Device Name: Zimmer Nexel Total Elbow
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: II
Product Code: JDC
Dated: December 13, 2012
Received: December 14, 2012

Dear Ms. Surma:

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 -S

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

Enclosure

Indications for Use

510(k) Number (if known): K123862

Device Name:

Zimmer Nexel Total Elbow

Indications for Use:

Indications for use include:

- Elbow joint destruction which significantly compromises the activities of daily living
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CAUTION: This device is intended for cemented use only.

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)

Casey L. Hanley, Ph.D.

Division of Orthopaedic Devices