DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 23, 2015

Zimmer, Incorporated
Ms. Caroline Bloemker
Regulatory Affairs Associate
P.O. Box 708
Warsaw, Indiana 46580

Re: K150501
Trade/Device Name: Zimmer® Nexel® Total Elbow Ulnar Cement Diverter
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDC
Dated: February 24, 2015
Received: February 26, 2015

Dear Ms. Caroline Bloemker:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Lori A. Wiggins -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150501

Device Name
Zimmer® Nexel® Total Elbow Ulnar Cement Diverter

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

510(k) Summary

Sponsor:	Zimmer, Inc. P.O. Box 708 Warsaw, IN 46581-0708
Contact Person:	Caroline Bloemker Associate, Regulatory Affairs Telephone: (574) 371-1980 Fax: (574) 372-4605
Date:	February 24, 2015
Trade Name:	*Zimmer® Nexel®* Total Elbow Ulnar Cement Diverter
Common Name:	Cement Diverter
Classification and Product Code:	Class II Accessory 21 CFR § 888.3150 Elbow joint metal/polymer constrained cemented prosthesis (JDC)
Classification Panel:	Orthopedics/87
Predicate Device(s):	*Zimmer® Nexel®* Total Elbow, manufactured by Zimmer, Inc., K123862, cleared March 12, 2013.
Purpose and Device Description:	The *Zimmer Nexel* Total Elbow system includes a cemented total elbow prosthesis and instrumentation. No changes are being made to the implants, but two changes to the instrumentation are being proposed in this submission. • The *Zimmer Nexel* Total Elbow surgical technique is being modified to include a back table utilization of the Ulnar Bearing Assembly Tool (UBAT). • As a result of the surgical technique change, the subject *Zimmer Nexel* Total Elbow Ulnar Cement Diverter is being added as an accessory instrument to the existing *Zimmer Nexel* Total Elbow system. The proposed cement diverter is a sterile, single-use manual orthopedic instrument manufactured from Ultra High Molecular Weight Polyethylene in conformance with ASTM F648-14. The subject component diverts excess bone cement from the

articular surfaces of the existing ulnar implant component during implantation.

Intended Use:

Since the subject component is a Class II accessory to the Nexel Total Elbow, it will assume the below Nexel Total Elbow indications.

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.

Comparison to Predicate Device:

The proposed surgical technique change does not have an effect on the intended use or technological characteristics of the predicate device.
The cement diverter is being introduced due to the change in the surgical technique. Since the cement diverter is unique to the *Nexel* Total Elbow system, it is being added as a Class II accessory to the *Nexel* Total Elbow system and assumes the same classification.
The proposed device is identical in intended use to the predicate device. The materials, sterility, performance characteristics, and technological characteristics are comparable to the existing *Nexel* Total Elbow system and do not introduce new questions of safety and effectiveness.

Performance Data (Nonclinical and/or Clinical):

Non-Clinical Performance and Conclusions:

The results of non-clinical testing demonstrate that the proposed surgical technique and cement diverter are safe and effective when utilized with the predicate, *Nexel* Total Elbow system, for their intended use. Testing/analysis performed included:

- Cadaveric Evaluation confirmed the safety and effectiveness of the final cement diverter design and surgical technique update when used with the *Nexel* Total Elbow ulnar component.
- Functional Relationship Analysis (FRA) confirmed compatibility requirements to ensure the cement diverter fits appropriately to all existing *Nexel* Total Elbow ulnar components.

Clinical Performance and Conclusions:

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

Substantial Equivalence Conclusions

Zimmer considers the proposed cement diverter to be a unique instrument to the *Nexel* Total Elbow system; therefore, it will assume the intended use of the predicate device. It does not introduce new materials, biocompatibility concerns, indications or risks, and therefore Zimmer considers the new surgical technique and cement diverter substantially equivalent to the predicate submission.