Zimmer Inc
Patricia Beres
Regulatory Affairs Principal
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K181307
Trade/Device Name: Zimmer Nexel Total Elbow, Connrad/Morrey Total Elbow
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDC
Dated: December 18, 2018
Received: December 19, 2018

Dear Patricia Beres:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael C. Owens -S
Digitally signed by Michael C. Owens -S
Date: 2019.01.28 15:14:12 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181307

Device Name
Coonrad/Morrey Total Elbow

Indications for Use *(Describe)*
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181307

Device Name
Zimmer Nexel Total Elbow

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.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Comprehensive Shoulder System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708
Establishment Registration Number:

Contact Person: Patricia Sandborn Beres
Regulatory Affairs Principal
Telephone: (574-267-6639)
Fax: fax (574-372-1683)

Date: January 25, 2019

Subject Device: **Trade Name:** Coonrad/Morrey Total Elbow
Zimmer Nexel Total Elbow

Common Name: Total Elbow Prosthesis

Classification Name: Elbow joint metal/polymer constrained cemented prosthesis (21 CFE §888.3150)
Product Code: JDC

Predicate Device(s): All predicate devices are manufactured by Zimmer Inc.

Device	510(k) Number
Zimmer Nexel Total Elbow	K150501
Coonrad/Morrey Total Elbow	K053189
Coonrad/Morrey Total Elbow	K040389
Coonrad/Morrey Total Elbow	K001989
Coonrad/Morrey Total Elbow	K973357

Purpose and Device Description:

The Coonrad/Morrey Total Elbow and Zimmer Nexel Total Elbow are total elbow prosthesis designed for use with bone cement. They are available in multiple sizes and in right and left configurations. The devices are designed to replace the articulating surfaces of and restore motion to the humeroulnar (elbow) joint. The implants are constrained in design and consist of a humeral component and an ulna component joined through bearings in a hinged fashion.

The purpose of this submission is the addition of MR conditional language to the labeling for these products. The addition of MR labeling to the subject devices does not impact indications, materials, design features or dimensions of the components, compatibility, packaging or sterilization. Additionally, this submission includes minor modifications to the subject device systems.

Intended Use and Indications for Use:

Coonrad/Morrey Total Elbow

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.

Zimmer Nexel Total Elbow

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

Summary of Technological Characteristics:

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** Identical to predicate
- **Indications for Use:** Identical to predicate
- **Materials:** Identical to predicate
- **Design Features:** Identical to predicate
- **Sterilization:** Identical to predicate

Summary of Performance Data (Nonclinical and/or Clinical)

- **Non-Clinical Tests:**
  - Biomet has performed non-clinical Magnetic Resonance Imaging (MRI) studies on implants which are determined to be MR Conditional in accordance to ASTM F2503-13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. MR Tests included the following:
    - RF heating- ASTM F2182-11a
    - Image Distortion- ASTM F2119-07
    - Magnetically Induced Displacement Force - ASTM 2052-14
    - CEM43 analysis
  - Engineering rationale and testing have been provided to support the minor design modifications
- **Clinical Tests:**
  - None provided

Substantial Equivalence Conclusion

Non-clinical tests provided in this Traditional 510(k) establish the conditional safety and compatibility of the passive implants in a magnetic resonance (MR) environment. The subject devices are substantially equivalent to the legally marketed predicated devices.