



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

Biomet Manufacturing Corporation
Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
56 Bell Drive
Warsaw, Indiana 46580

February 3, 2016

Re: K153398

Trade/Device Name: Comprehensive SRS/Nexel Elbow
Regulation Number: 21 CFR 888.3150
Regulation Name: Elbow joint metal/polymer constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JDC, KWT, KWS, MBF
Dated: December 9, 2015
Received: December 11, 2015

Dear Ms. Sandborn 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. 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 Parts 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,

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)

K153398

Device Name

Comprehensive SRS/Nexel Elbow

Indications for Use (Describe)

The Comprehensive Segmental Revision System is intended for use in cases of:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Correction of functional deformity.
5. Oncology applications including bone loss due to tumor resection.

When used in a proximal or total humeral replacement, the Comprehensive Segmental Revision System is also intended for: Treatment of acute or chronic fractures with humeral head (shoulder) involvement, which are unmanageable using other treatment methods.

When used as a distal or total humeral replacement, the Comprehensive Segmental Revision System is also intended for: Treatment of acute or chronic fractures with humeral epicondyle (elbow) involvement, which are unmanageable using other treatment methods.

The Comprehensive Segmental Revision System is intended for use with or without bone cement in the proximal shoulder.

The Comprehensive Segmental Revision System is intended for use with bone cement in distal humeral and total humeral applications.

Tissue Attachment Augments provide the option for tissue stabilization and attachment.

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 SRS/Nexel Elbow 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:** Biomet Inc.
56 East Bell Drive
PO Box 587
Warsaw, IN 46581
Establishment Registration Number: 1825034
- Contact:** Patricia Sandborn Beres
Senior Regulatory Specialist
574-267-6639
- Date:** November 19, 2015
- Subject Device:** Trade Name: Comprehensive SRS / Nexel Elbow
Common Name: Shoulder, elbow and total humeral replacement prosthesis
- Classification Name:
- KWT - Shoulder joint metal/polymer non-constrained cemented prosthesis (21 CFR 888.3650)
 - KWS - Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660)
 - MBF - Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous coated uncemented prosthesis (21 CFR 888.3670)
 - JDC - Elbow joint metal/polymer constrained cemented prosthesis (21 CFR 888.3150)
- Legally marketed devices to which substantial equivalence is claimed:**
- Comprehensive Segmental Revision System (SRS) - K111746
- Additional reference predicate:**
- Zimmer Nexel Total Elbow – K123862

Device Description

The components of the Comprehensive Segmental Revision System (SRS) components may be combined to create a proximal humeral replacement, distal humeral replacement and total humeral replacement. Previously cleared for use in conjunction with Biomet's Discovery Elbow System, the Comprehensive SRS system is being expanded to be compatible with the Zimmer Nexel Total Elbow. To accomplish this, the only component requiring modification is the Distal Humeral Body. The modified distal humeral bodies will be available in left and right configurations in three sizes 50, 60 and 70mm utilizing the same modular flange as the predicate

device. The yoke geometry will match that of the humeral component in the Nexel Total Elbow System.

Intended Use and Indications for Use

The Comprehensive Segmental Revision System is intended for use in cases of:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Revision where other devices or treatments have failed.
4. Correction of functional deformity.
5. Oncology applications including bone loss due to tumor resection.

When used in a proximal or total humeral replacement, the Comprehensive Segmental Revision System is also intended for:

Treatment of acute or chronic fractures with humeral head (shoulder) involvement, which are unmanageable using other treatment methods.

When used as a distal or total humeral replacement, the Comprehensive Segmental Revision System is also intended for:

Treatment of acute or chronic fractures with humeral epicondyle (elbow) involvement, which are unmanageable using other treatment methods.

The Comprehensive Segmental Revision System is intended for use with or without bone cement in the proximal shoulder.

The Comprehensive Segmental Revision System is intended for use with bone cement in distal humeral and total humeral applications.

Tissue Attachment Augments provide the option for tissue stabilization and attachment.

Summary of Technological Characteristics

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

- **Intended Use:** Identical to the predicate
- **Indications for Use:** Identical to the predicate
- **Materials:** Identical to the predicate
- **Design Features:** Identical to the predicate except that the geometry has been modified to mate with the Nexel Elbow
- **Sterilization:** Identical to the predicate

Summary of Performance Data (Nonclinical and/or Clinical)

- Non-Clinical Tests
 - None Provided – Engineering analysis and MR assessment to determine that the modified components do not present a new worst case condition
- Clinical Tests
 - None Provided

Substantial Equivalence Conclusion

The proposed device has the same intended use as the predicate. The proposed device has similar technological characteristics to the predicate and the information provided herein demonstrates that:

- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate device.