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6. 510(k) Premarket Notification
Summary of Safety and Effectiveness

Submission Information

Manufacturer: Small Bone Innovations, Inc.
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Morrisville, PA 19067
Ph: 215-428-1791 Fax: 215-428-1795

DEC 2 0 2010

Submitted By: Small Bone Innovations, Inc.
John Minier
1380 South Pennsylvania Avenue
Morrisville, PA 19067

Proprietary Name: SBi rHead™ Radial Head Extended Stems
Classification name: Class II, 888.3170 – Elbow joint radial (hemi-elbow) polymer prosthesis
888.3160 - Prosthesis, Elbow joint metal/polymer semi-constrained cemented prosthesis
Product Code: KWI & JDB
Common/Usual Name and Reference Number:
Prosthesis, Elbow, Hemi-, Radial, polymer 21 CFR 888.3170
Prosthesis, elbow, semi-constrained, cemented 21 CFR 888.3160

Substantial Equivalence: Documentation is provided which demonstrated the SBi rHead™ Radial Head Extended Stems to be substantially equivalent to other legally marketed SBi devices. The legally marketed predicate devices to which this device is substantially equivalent are the Ascension (K032686) and Tornier (K060438) Radial Head Systems.

Device Description: The SBi rHead, rHead Lateral, and rHead Recon prostheses are implants that are intended to replace the proximal end of the radius. The implants consist of two (2) parts, the head and a stem, which fit together. The rHead™ Standard is designed with a Morse taper coupling mechanism to firmly attach the head onto the stem. The rHead™ RECON is designed with a "ball/socket" (bipolar) coupling mechanism between the head and stem which adds an element of alignment flexibility. The rHead™ Lateral is designed using a dovetail coupling mechanism.

The stem is made from a Cobalt Chrome alloy (CoCrMo) with or without a powder titanium (Ti) coating. The radial stem geometry is designed to anatomically fit within the intramedullary canal. The intramedullary surfaces of the stem are roughened to assist in optimal fixation. A version of the stem may be plasma sprayed with a powder titanium coating to further assist in optimal fixation. The extended stem provides additional fixation in situations where excess bone loss due to trauma has occurred. Stems are for cemented or uncemented use when used with the rHead heads.

Each component is supplied in various sizes to support the differences in human anatomies. Each implant can be used in either the right or left arm and the heads and stems are modular.

rHead Radial Head Extended Stems are made from a Cobalt Chrome alloy (CoCrMo) with or without a powder titanium (Ti) coating. rHead Radial Head Extended Stems are configured to fit the rHead, rHead Recon, and rHead Lateral heads as well as rHead, rHead Recon, and rHead Lateral heads that fit the Radial Capitellum radial head implants.

The rHead, rHead Lateral, and rHead Recon prostheses are used with trials and surgical instruments including a sterilization tray.

The implants are intended for single use only.

Intended use of the extended stems when used as a hemi-elbow implant:

The SBi rHead Radial Head is indicated for use in replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and or proximal radio-ulnar joint with:

- Joint destruction or subluxation visible on x-ray
- Resistance to conservative treatment

Primary replacement after fracture of the radial head
Symptomatic sequelae after radial head resection
Revision following failed radial head arthroplasty

Intended use of the extended stems when used with a uni-elbow implant:

The SBi Radial-Capitellar Implant is indicated for use in the elbow for reduction or relief of pain and/or improved elbow function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease including osteo-arthritis or traumatic arthritis
- Inflammatory degenerative joint disease including rheumatoid arthritis
- Correction of functional deformity
- Revision procedures where other treatments and devices have failed and
- Treatment of fractures that are unmanageable using other technologies

Materials: rHead Radial Head Extended Stem is made from implant grade Cobalt Chrome alloy (CoCrMo) per ASTM F1537. The intramedullary stem portion of the stem may be coated by plasma spray. The raw material of the plasma spray is a titanium powder per ASTM F1580.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Small Bone Innovations, Inc.
% Mr. John Minier
1380 South Pennsylvania Avenue
Morrisville, PA 19067

DEC 20 2010

Re: K102180
Trade/Device Name: SBi rHead™ Radial Head Extended Stems
Regulation Number: 21 CFR 888.3160
Regulation Name: Elbow joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: II
Product Code: JDB, KWI
Dated: November 18, 2010
Received: November 19, 2010

Dear Mr. Minier:

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

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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

5. Statement of Indications for Use

510(k) Number: K102180 (p3 1/1)

Device Name: SBi rHead Radial Head Extended Stem

Indications for use when used with a hemi-elbow implant:

The SBi rHead Radial Head is indicated for use in replacement of the radial head for degenerative, or post-traumatic disabilities presenting pain, crepitation and decreased motion at the radiohumeral and or proximal radio-ulnar joint with:

- Joint destruction or subluxation visible on x-ray
- Resistance to conservative treatment

Primary replacement after fracture of the radial head

- Symptomatic sequelae after radial head resection
- Revision following failed radial head arthroplasty

Indications for use when used with a uni-elbow implant:

The SBi Radial-Capitellar Implant is indicated for use in the elbow for reduction or relief of pain and/or improved elbow function in skeletally mature patients with the following conditions:

- Non-inflammatory degenerative joint disease including osteo-arthritis or traumatic arthritis
- Inflammatory degenerative joint disease including rheumatoid arthritis
- Correction of functional deformity
- Revision procedures where other treatments and devices have failed and
- Treatment of fractures that are unmanageable using other technologies

Prescription Use √ (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)

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for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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