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2. 510(k) Summary

Manufacturer:
Small Bone Innovations, Inc.
1380 South Pennsylvania Avenue
Morrisville, PA 19067

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

Contact:
Jeff Zigler
Musculoskeletal Clinical Regulatory Advisers, LLC (MCRA)
1331 H Street NW, 12th Floor
Washington, DC 20005
202.552.5800

Proprietary Name:
SBi SR MTP Toe Implant

Classification name:
Class II, 21 CFR 888.3730 – Toe joint phalangeal (hemi-toe) polymer prosthesis

Common/Usual Name:
Toe joint, phalangeal (hemi-toe) prosthesis

Product Code:
KWD

Substantial Equivalence:
Documentation was provided which demonstrated the SBi SR MTP Toe Implant is substantially equivalent to other legally marketed devices.

Device Description:
The SBi SR MTP Toe Implant is a one-piece, stemmed device intended to replace the articulating surface of the metatarsal at the MTP joint. The implant is available in a range of sizes to match the geometry of the metatarsal head. Design features include an articulating surface which extends posteriorly on the superior side of the implant and a gently barbed stem to improve fixation in the metatarsal.

Intended Use:
The SBi SR MTP Toe Implant is intended for use as a hemi-arthroplasty implant for the metatarsophalangeal joint, for the treatment of degenerative and post-traumatic arthritis, hallux valgus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint.

The SBi SR MTP Toe Implant is intended for implantation with and without bone cement.

Materials:

The implants are made from wrought CoCrMo alloy (ASTM F1587) with a plasma coating comprised of commercially pure titanium (ASTM F1580).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2008

Small Bone Innovations, Inc
% Mr. Jeffrey Zigler
Musculoskeletal Clinical Regulatory Advisors, LLC
1331 H Street, NW, 12th Floor
Washington, DC 20005

Re: K073635
Trade/Device Name: SBi SR MTP Toe Implant
Regulation Number: 21 CFR 888.3730
Regulation Name: Toe joint phalangeal (hemi-toe) polymer prosthesis
Regulatory Class: II
Product Code: KWD
Dated: December 21, 2007
Received: December 26, 2007

Dear Mr. Zigler:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. Indications for Use

510(k) Number (if known): K073635

Device Name: SBi SR MTP Toe Implant

The SBi SR MTP Toe Implant is intended for use as a hemi-arthroplasty implant for the metatarsophalangeal joint, for the treatment of degenerative and post-traumatic arthritis, hallux valgus, hallux rigidus, and an unstable or painful metatarsophalangeal (MTP) joint.

The SBi SR MTP Toe Implant is intended for implantation with and without bone cement.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073635