K112982 1/2

APR - 2 2012

510(k) Premarket Notification
Summary of Safety and Effectiveness

Submission Information

Manufacturer: Small Bone Innovations, Inc.
1380 South Pennsylvania Avenue
Morrisville, PA 19067
Ph: 215-428-1791 Fax: 215-428-1795

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

Date: October 4, 2011

Proprietary Name: SBi Anatomic Ankle Arthrodesis Interlocking Nail System

Classification name/Identification: Class II, An intramedullary fixation rod is a device intended to be implanted that consists of a rod made of alloys such as cobalt-chromium-molybdenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures

Product Code: HSB

Common/Usual Name and Reference Number: Intramedullary fixation rod - 21 CFR 888.3020

Substantial Equivalence: Documentation is provided which demonstrated the SBi Anatomic Ankle Arthrodesis Interlocking Nail System to be substantially equivalent to other legally marketed devices.

Device Description: The SBi Anatomic Ankle Arthrodesis Interlocking Nail System consists of implants, associated instruments, and trays. The implants are made of implantable grade titanium while the instrument components and trays are made of several materials: Aluminum, stainless steel, PEEK, POM, and composite materials.

Intended Use: The SBi Anatomic Ankle Arthrodesis Interlocking Nail System intended for tibiotalocalcaneal arthrodesis of the ankle following: Post traumatic and degenerative arthritis involving both ankle and subtalar joints, osteoarthritis, Rheumatoid arthritis, Pseudoarthrosis, Severe foot/ankle deformity, or Instability and skeletal defects after tumor resection. These include neuro-osteoarthroplasty (Charcot's foot), avascular necrosis of the talus, failed joint replacement, failed ankle fusion, and for distal tibia fracture non-unions when used concomitantly with tibiotalocalcaneal pathology.

The implants are intended for single use only and will be offered sterile and non-sterile.

Materials: The implants are made from implantable grade TiAl6V4 titanium (ASTM F136) while the instrument components and trays are made of several materials: Aluminum, stainless steel, PEEK, POM, and composite materials.

Predicate Devices: The subject devices are equivalent to Stryker T2 Ankle Arthrodesis Nail (K051590) and Synthes Titanium Cannulated Hindfoot Arthrodesis Nail Expert System (K051678).

Non-clinical data: Fatigue testing, cadaver implantation evaluations, literature search and evaluation, finite element analysis, and an engineering/dimensional analysis were performed in order to support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

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

APR - 2 2012

Re: K112982
Trade/Device Name: SBi Anatomic Ankle Arthrodesis Interlocking Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: February 2, 2012
Received: February 7, 2012

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 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

4 Statement of Indications for Use

510(k) Number: K112982

Device Name: SBi Anatomic Ankle Athrodesis Interlocking Nail System

Indications For Use:

The SBi Anatomic Ankle Athrodesis Interlocking Nail System is indicated for tibiotalocalcaneal arthrodesis of the ankle following:
- Post traumatic and degenerative arthritis involving both ankle and subtalar joints,
- Rheumatoid arthritis,
- Osteoarthritis,
- Pseudoarthrosis,
- Severe foot/ankle deformity, or
- Instability and skeletal defects after tumor resection.

These include neuro-osteoarthroplasty (Charcot's foot), avascular necrosis of the talus, failed joint replacement, failed ankle fusion, and for distal tibia fracture non-unions when used concomitantly with tibiotalocalcaneal pathology.

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)

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

510(k) Number K112982