K071549 (pg 1/1)

510(k) Summary

Manufacturer:	Small Bone Innovations International, SA Z.A. Les Bruyeres Peronnas France 01960
	AUG - 7 2007
Submitted By:	Small Bone Innovations 1380 South Pennsylvania Avenue Morrisville, PA 19067
Proprietary Name:	SBi rHead Plating System
Classification name:	Class II, 888.3030 – Single / multiple component bone fixation appliances and accessories
Common/Usual Name:	Bone fixation plate
Product Code:	HRS
Substantial Equivalence:	Documentation is provided which demonstrates the SBi rHead Plating System to be substantially equivalent to other legally marketed devices.
Device Description:	The SBi rHead Plating System consists of various plates and screws to treat fractures of the proximal radius. SBi plans to offer two plate designs: the rHead Neck Plate and the rHead Rim Plate. Both have a curved, T-shaped design to match the geometry of the proximal radius. Both will be available in a variety of neck widths, plate lengths, and hole geometries (threaded and non-threaded). Locking and non-locking screws will be included as part of the SBi rHead Plating System.
Intended Use:	The SBi rHead Plating System is indicated for fractures of the proximal radius.
Material:	The implants are made from stainless steel (ASTM F138).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Small Bone Innovations Inc.
% Mr. Robert Hoehn
Senior Regulatory Associate
505 Park Ave. 14th Floor
New York, New York 10022

AUG - 7 2007

Re: K071549
Trade/Device Name: SBi rHead Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: June 4, 2007
Received: June 6, 2007

Dear Mr. Hoehn:

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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

Barbara Boehm for

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

Enclosure

K071549 (pg 1/1)

Indications for Use

510(k) Number:

Device Name: SBi rHead Plating System

Indications For Use:

The SBi rHead Plating System is indicated for fractures of the proximal radius.

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)

Barbara Ruehl

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

510(k) Number K071549