K051747

SEP - 6 2005

510(k) Summary

Manufacturer:	Small Bone Innovations 1711 S. Pennsylvania Avenue Morrisville, PA 19067
Submitted By:	Mr. Donald Guthner, Vice President Musculoskeletal Clinical Regulatory Advisers 505 Park Avenue, 14th Floor New York, NY 10022 dguthner@mcrallc.com 212-586-0250 – Office 212-750-2112 - Fax
Proprietary Name:	SBI Wrist FIT™
Classification name:	Class II, 888.3030 – Plate, Fixation, Bone, Non-Spinal Class II, 888.3040 – Screw, Fixation, Bone, Non-Spinal
Common/Usual Name:	Internal Fixation System
Substantial Equivalence:	Documentation is provided which demonstrated the SBI Wrist FIT™ to be substantially equivalent to other legally marketed devices.
Device Description:	The system features non-sterile stainless steel plates with cortical locking, non-locking, and Cannulated screws in two diameters (2.4mm and 2.7mm), high angle screws with low profile heads when inserted into specially designed screw holes at angles as high as 60° to 70° off perpendicular, or 30° to 70° from the plate or bone axis, and the instruments with which to implant them.
Intended Use:	SBI WristFIT™ (Fracture in Tension) Distal Radius System implants are indicated in the treatment of fractures, non-unions, pseudoarthrosis, and degenerative changes as well as corrective osteotomies geared towards a functionally stable osteosynthesis is small and long bones. This includes: • Distal radius fractures • Distal ulna fractures • Radial osteotomies • Radial fusions • Tarsal fractures
Material:	316L Stainless Steel

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Small Bone Innovations, LLC
c/o Mr. Donald W. Guthner, Vice President
Musculoskeletal Clinical Regulatory Advisers, LLC
505 Park Avenue, 14th Floor
New York, New York 10022

Re: K051747
Trade/Device Name: SBI WristFIT™
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 21, 2005
Received: June 29, 2005

Dear Mr. Guthner:

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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number:

Device Name: SBI WristFIT™

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- distal radius fractures
- distal ulna fractures
- radial osteotomies
- radial fusions
- tarsal fractures

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 General, Restorative, and Neurological Devices

510(k) Number K051747