K051605

510(k) Summary

AUG 10 2005

Manufacturer:	Small Bone Innovations 1711 S. Pennsylvania Avenue Morrisville, PA 19067
Submitted By:	Donald W. 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 K-Wires
Classification name:	Class II, 888.3040 – Smooth or threaded metallic bone fixation fastener
Common/Usual Name:	Bone fixation fasteners
Substantial Equivalence:	Documentation is provided which demonstrated the SBI K-Wires to be substantially equivalent to other legally marketed devices.
Device Description:	SBI K-Wires are provided non-sterile. They range in diameter from 0.9mm – 2.0mm and are 150mm long. They are available in single point, double point, and threaded single point.
Intended Use:	SBI K-Wires are indicated for use in fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants
Material:	316L (per ASTM F 138), Titanium 6AL4V-ELI (per ASTM F 136-92), and Cobalt Chrome Alloys

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2005

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

Re: K051605
Trade/Device Name: SBI K-Wires
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY
Dated: June 7, 2005
Received: June 16, 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/industry/support/index.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 K-Wires

Indications For Use:

The SBI K-Wires are indicated for use in fixation of bone fractures, for bone reconstruction, and as guide pins for insertion of other implants.

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

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

...) Number K051605