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510(k) SUMMARY

SI-Bone, Inc.'s
SI Joint Fusion System

Submitter's Name, Address, Telephone Number

NOV 2 6 2008

SI-Bone, Inc.
15370 Pepper Lane
Saratoga, CA 95070 USA

Contact Person: Jeff Dunn
President/CEO
SI-Bone, Inc.
15370 Pepper Lane
Saratoga, CA 95070

Date Prepared: November 20, 2008

Name of Device: SI Joint Fusion System

Common or Usual Name: Orthopedic Rods

Classification Name: 21 CFR 888.3040 - Smooth or threaded metallic bone fastener

Predicate Devices:

Synthes (USA) 6.5 mm Cannulated Screw (K021932)
Reiley Orthopedics ROI Fusion Rods and Plates (K051309)
SIJF Cannulated Screw System (K051296)

Intended Use:

The SI-Bone SI Joint Fusion system is intended for fracture fixation of large bones and large bone fragments of the pelvis for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Device Description

The SI Fusion System consists of a series of metallic (titanium), porous plasma spray coated rods, intended for surgical implant within the bone, to create fixation. Their intended use is for fracture fixation of large bones and large bone fragments of the pelvis for such conditions as sacroiliac joint disruptions and degenerative sacroiliitis. The system includes 7.0 mm fusion rods, which range in length from 30 mm to 70 mm.

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Performance Data

A Finite Element Analysis (FEA) was performed on the SI Fusion System in comparison to its predicate. In addition, the company has conducted bench-top testing of axial pullout resistance and stability in dynamic cantilever bending. The results demonstrate that the SI Fusion Rod is substantially similar to the predicate devices with respect fixation of the SI joint.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SI-Bone, Inc.
% Mr. Jeffery Dunn
15370 Pepper Lane
Saratoga, California 95070

APR 15 2011

Re: K080398
Trade/Device Name: SI-Bone SI Joint Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: OUR
Dated: October 24, 2008
Received: October 24, 2008

Dear Mr. Dunn:

This letter corrects our substantially equivalent letter of November 26, 2008.

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.

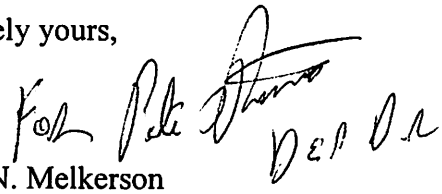
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

Indications for Use

510(k) Number (if known): K080398

Device Name: ST-Bone SI Joint Fusion System

Indications for Use:

The SI-Bone SI Joint Fusion system is intended for fracture fixation of large bones and large bone fragments of the pelvis for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Prescription Use X (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)

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

510(k) Number K080398