

K110838

APR 21 2011

510(k) SUMMARY

SI-Bone's iFuse SI Fusion System

Submitter's Name, Address, Telephone Number, Contact Person, and Date Prepared

Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Phone: (267) 675-4611
Facsimile: (267) 675-4601

Contact Person: Janice M. Hogan

Date Prepared: March 25, 2011

Name of Device and Name/Address of Sponsor

iFuse SI Joint Fusion System

SI-Bone, Inc.
550 South Winchester Blvd., Suite 620,
San Jose, CA 95128

Common or Usual Name (Product Code/Definition): Sacroiliac Joint Fixation (OUR/
sacroiliac joint fusion)

Classification Name: 21 C.F.R. 888.3040 – Smooth or threaded metallic bone fixation fastener

Predicate Devices

SI-Bone, Inc's SI Joint Fusion System (K080398; K092375)

Intended Use

The iFuse System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

Technological Characteristics

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. The system includes 4.0 mm and 7.0 mm diameter fusion rods, which range in length from 30 mm to 70 mm.

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Performance Data

Axial pull-out testing, Finite Element Analysis (FEA), and cadaver testing demonstrate that the iFuse is substantially equivalent with respect to fixation of the SI joint.

Substantial Equivalence

The iFuse has the same intended use, principles of operation, and technological characteristics and similar indications for use as the predicate SI Joint Fusion System. There are no differences in the SI Joint Fusion System's technological characteristics or principles of operation, thus the device does not raise any new questions of safety or effectiveness. Performance data demonstrate that the SI Joint Fusion System is as safe and effective as previously cleared SI Joint Fusion System. Thus, the SI Joint Fusion System is substantially equivalent to its predicate device.



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

APR 21 2011

SI-Bone, Inc.
% Ms. Janice M. Hogan
Hogan & Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K110838

Trade/Device Name: SI Joint Fusion System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fastener
Regulatory Class: Class II
Product Code: OUR
Dated: March 25, 2011
Received: March 25, 2011

Dear Ms. Hogan:

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.

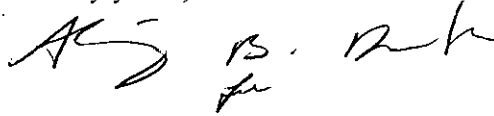
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a stylized flourish at the end.

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 Statement

510(k) Number (if known): K110838

Device Name: iFuse SI Joint Fusion System

Indications for Use:

The iFuse System is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis.

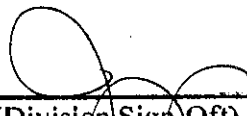
Prescription Use X
(Per 21 C.F.R. 801.109)

AND/OR

Over-The-Counter Use
(Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


for M. Melker

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

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