



Food and Drug Administration
10903 New Hampshire Avenue
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SI-BONE, Incorporated
Ms. Roxanne Dubois
Vice President, Regulatory Affairs and Quality Assurance
3055 Olin Avenue, Suite 2200
San Jose, California 95128

October 29, 2015

Re: K151718
Trade/Device Name: iFuse Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: OUR
Dated: October 1, 2015
Received: October 2, 2015

Dear Ms. Dubois:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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 -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K151718

Device Name: SI-BONE iFuse Implant System

Indications for Use:

The iFuse Implant System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life at 12 months post-implantation.

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)

510(k) SUMMARY - iFuse Implant System®

510(k) Owner's Name, Address, and Telephone Number

SI-BONE, Inc., 3055 Olin Avenue, Suite 2200, San Jose, CA 95128; (408) 207-0700

Contact Person

Roxanne Dubois, VP, Regulatory and Quality, SI-BONE, Inc.

Email: rdubois@si-bone.com

Mobile: 408-828-5019; Office: 408-207-0700; Facsimile: 408-557-8312

Date Prepared: October 28, 2015

Trade Name of Device: iFuse Implant System®

Common or Usual Name: Orthopedic Rod

Classification Name: 21 C.F.R. 888.3040 – Smooth or threaded metallic bone fastener;
Product Code OUR

Predicate Devices: iFuse Implant System by SI-BONE, Inc. (K080398, K092375, K110838, K122074, K123850, K131405, K141049, K150714, K150875)

Intended Use

The iFuse Implant System is intended for sacroiliac fusion for conditions including sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months. Clinical studies have demonstrated that treatment with the iFuse Implant System improved pain, patient function, and quality of life at 12 months post-implantation.

Device Description

The iFuse Implant System consists of porous plasma spray coated titanium implants and associated surgical instruments. The iFuse Implant lengths range from 30-90mm with a diameter of 4-7mm. The fusion rods are implanted using instrumentation previously described in K080398, K092375, K110838, K122074, K123850, K131405, K141049, K150714 and K150875.

Technological Characteristics

The iFuse Implant System® consists of a series of metallic (titanium), porous plasma spray coated rods, intended for surgical implant within the bone to create biological fixation, immediate stabilization and fusion. This 510(k) does not involve any changes to the technological characteristics of the device.

Performance Data

No performance testing was required to support the modified labeling that is the subject of this 510(k).

Clinical Tests

Data to support claims of improvement in pain, disability and quality of life at 12 months post-implantation come from prospective and retrospective studies. Prospective studies included INSITE (Investigation of Sacroiliac Fusion Treatment) and SIFI (Sacroiliac Joint Fusion with iFuse Implant System). INSITE is a prospective randomized controlled trial of 148 patients with sacroiliac joint dysfunction assigned to either sacroiliac (SI) joint fusion with iFuse Implant System (n=102) or non-surgical management (NSM, n=46, control group). At both 6 and 12 months, INSITE study data showed improvement in SI joint pain, disability due to lower back pain, and quality of life (by two measures) in the iFuse implant group. SIFI is a prospective multicenter single-arm clinical trial of 172 patients. SIFI data showed improvements in SI joint pain, disability due to SI joint pain, and quality of life (by two measures) compared to baseline findings. The improvements in SIFI and INSITE were very similar. Follow-up to 24 months is planned but is not completed for all of the enrolled patients.

Substantial Equivalence and Conclusion

The iFuse Implant System is substantially equivalent to the predicate device (iFuse Implant System).