



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

June 3, 2016

SI-BONE, Incorporation  
Ms. Roxanne Dubois  
VP, Regulatory Affairs and Quality Assurance  
3055 Olin Avenue, Suite 2200  
San Jose, California 95128

Re: K160652

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: March 4, 2016  
Received: March 8, 2016

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 Parts 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

510(k) Number (if known)

K160652

Device Name

iFuse Implant System®

Indications for Use (Describe)

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.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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## 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.

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**Date Prepared:** April 26, 2016

**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 and K150714, K150875, K151718, K152681)

### 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.

### 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, K150875, K151718, and K152681.

### 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.

**Non-clinical Performance Data**

Non-clinical performance testing was not required to support the modified labeling that is the subject of this 510(k).

**Clinical Tests**

Data to support claims of improvement in pain, patient function and quality of life come from prospective and retrospective studies, including SIFI (Sacroiliac Joint Fusion with iFuse Implant System). SIFI is a prospective multicenter single-arm clinical trial of 172 patients with 149 patients followed for 24 months. SIFI showed clinically important and statistically significant improvements in SI joint pain, disability due to SI joint pain, and quality of life (by two measures). Patient satisfaction rates were high.

**Substantial Equivalence and Conclusion**

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