DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 10, 2017

SI-BONE, Inc.
Roxanne Dubois
VP, Regulatory and Quality
3055 Olin Ave, Suite 2200
San Jose, California 95128

Re: K162733
Trade/Device Name: iFuse Implant System® - iFuse-3D implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR
Dated: January 31, 2017
Received: February 2, 2017

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" (21 CFR 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,

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): K162733

Device Name: iFuse Implant System® - iFuse-3D implant

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.

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.

510(k) SUMMARY - iFuse Implant System®

I. SUBMITTER

SI-BONE, Inc.
3055 Olin Avenue, Suite 2200, San Jose, CA 95128
Phone: (408) 207-0700; Fax: 408-557-8312
Contact Person: Roxanne Dubois, VP, Regulatory and Quality, SI-BONE, Inc.
Email: rdubois@si-bone.com
Mobile: 408-828-5019; Office: 408-207-0700 x2236
Date Prepared: March 9, 2017

II. DEVICE

Trade Name of Device:	iFuse Implant System® - iFuse-3D implant
Common or Usual Name:	Sacroiliac Joint Fixation
Regulation Number:	21 CFR 888.3040 – Smooth or threaded metallic bone fastener
Product Code:	OUR; Sacroiliac Joint Fixation

III. PREDICATE DEVICES

Primary Predicate:	iFuse Implant System by SI-BONE, K160652
Reference Predicate:	Synthes Cannulated Screw, K021932
	Spine Frontier, K150017

IV. DEVICE DESCRIPTION

The iFuse Implant System consists of cannulated triangular, titanium (Ti 6Al 4V ELI, ASTM F136/F3001) implants with a porous surface and an instrument system. The principle of operation is that the triangular implant shape and porous surface are designed to prevent and minimize motion/micromotion of the sacroiliac (SI) joint, and thereby stabilize the SI joint. The mechanism of action is that the interference fit allows fixation, stabilization and fusion. The delivery system uses guide pins for accurate permanent surgical placement. The implants are available in varying lengths and diameters, and are provided sterile (gamma sterilization). Fenestrations allow packing of autograft and/or allograft material.

V. 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.

VI. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE

The iFuse Implant System consists of manual instruments and a series of triangular titanium implants intended for surgical implantation across the sacroiliac joint to create immediate stabilization and fusion. The proposed implant is additively manufactured.

VII. PERFORMANCE DATA

Performance testing was conducted to support the design and development of the proposed implant including mechanical testing, simulated use testing, and biocompatibility testing. The mechanical testing included static and fatigue bending testing, as well as pull-out testing of the finished device. Additionally, MR safety testing to establish that the device is MR conditional was conducted as well as Limulus amebocyte lysate (LAL) testing to establish that the device meets the specified 20 EU/device limit. The test results show that the exhibited characteristics are comparable to the predicate and reference devices. The interconnected porous surface was found to have comparable porosity and mechanical characteristics compared to the predicates and acceptable performance in a simulated use test. Characterization of the porous structure was performed. The device was also found to be MR conditional, non-pyrogenic and biocompatible. The performance tests demonstrate that the device is as safe, as effective and performs at least as well as the legally marketed devices identified in Section III. Validation tests included printing validation (e.g. build parameters), powder bed recycling validation and cleaning validation.

VIII. CONCLUSIONS

The intended use is unchanged compared to the predicate devices and the verification and validation results, technological characteristics, and the performance data support that the proposed implants are substantially equivalent to the predicate devices. The performance data also demonstrate that the device is as safe, as effective and performs at least as well as the legally marketed devices identified in Section III.