November 27, 2018

SI-BONE, Inc.
Roxanne J. Dubois
Vice President, Regulatory Affairs
471 El Camino Real, Suite 101
Santa Clara, California 95050

Re: K182983
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 26, 2018
Received: October 29, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182983

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.

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®

I. SUBMITTER

SI-BONE, Inc.
471 El Camino Real, Suite 101, Santa Clara, CA 95050
Phone: 408-207-0700; Fax: 408-557-8312

Contact Person: Roxanne J. Dubois, VP, Regulatory Affairs, SI-BONE, Inc.
Email: rdubois@si-bone.com
Phone: 408-828-5019; Fax: 408-557-8312
Date Prepared: October 26, 2018

II. DEVICE

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

III. PREDICATE AND REFERENCE DEVICES

Predicate:	iFuse Implant System® by SI-BONE, Inc., K162733
Reference Device:	VIPER® Systems (Pedicle Screw Spinal System), K121020

IV. DEVICE DESCRIPTION

The iFuse Implant System® consists of cannulated triangular, titanium (iFuse implants: Ti 6Al 4V ELI, ASTM F136/F1580 and iFuse-3D implants: Ti 6Al 4V ELI, ASTM 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 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).

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 to provide immediate SI joint stabilization and allow long-term fusion. There are no changes to the technological characteristics of the device that is the subject of this 510(k).

VII. PERFORMANCE DATA

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

VIII. CONCLUSIONS

The intended use, indications for use and the technological characteristics are unchanged compared to the predicate device and support that the proposal contained within this 510(k) is substantially equivalent to the predicate device.