October 31, 2017

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

Re: K172268
Trade/Device Name: iFuse Implant System- iFuse Navigation
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: July 26, 2017
Received: July 27, 2017

Dear Roxanne 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 (DICE) 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 (DICE) 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,

Katherine D. Kavlock -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)*
K172268

Device Name

iFuse Implant System - iFuse-Navigation

Indications for Use *(Describe)*

iFuse-Navigation instruments are intended to be used with the iFuse Implant System to assist the surgeon in precisely locating anatomical structures in iFuse procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse-Navigation instruments are intended to be used with the Medtronic StealthStation System.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY - iFuse Implant System®

I. SUBMITTER

SI-BONE, Inc.
Address: 3055 Olin Avenue, Suite 2200, San Jose, CA 95128
Phone: 408-207-0700; Fax: 408-557-8312
Mobile: 408-828-5019; Office: 408-207-0700 x2236
Contact Person: Roxanne Dubois, VP, Regulatory and Quality, SI-BONE, Inc.
Email: rdubois@si-bone.com
Date Prepared: July 26, 2017

II. DEVICE

Name of Device:	iFuse Implant System - iFuse-Navigation
Common or Usual Name:	Orthopedic Stereotaxic Instrument
Regulation Numbers:	21 CFR 882.4560– Stereotaxic instrument
Product Codes:	OLO; Stereotaxic Instrument

III. PREDICATE DEVICES

Primary Predicate:	iFuse Implant System by SI-BONE: K131405, K162733
Reference Predicates:	-K161210, Medtronic Reusable Instruments Compatible with the STEALTHSTATION® System, -K150216, Medtronic Navigated StealthStation System with Synergy Cranial Software - K162921, Orthofix Navigated Instrument System

IV. DEVICE DESCRIPTION

The iFuse-Navigation instrument set is comprised of reusable manual surgical instruments specifically designed for use with the iFuse Implant System.® These instruments are designed to interface with the already-cleared Medtronic StealthStation® Navigation System to assist surgeons in precisely locating anatomical structures for placement of iFuse implants. This surgical imaging technology provides visualization for complex and MIS procedures and confirms the accuracy of advanced surgical procedures.
Use of these navigation systems provides the surgeon access to dynamic, graphical representation of multi-plane 3D images (and 2D images) providing indication of instrument and implant placement.

V. INDICATIONS FOR USE

iFuse-Navigation instruments are intended to be used with the iFuse Implant System to assist the surgeon in precisely locating anatomical structures in iFuse procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse-Navigation instruments are intended to be used with the Medtronic StealthStation System.

VI. TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE

The iFuse Navigation instruments are intended to be used with the iFuse Implant System® (implants and instruments). The iFuse-Navigation instruments are designed to interface with the already-cleared Medtronic StealthStation® Navigation System to assist surgeons in precisely locating anatomical structures for placement of iFuse implants. These instruments have similar designs as the predicate instruments and incorporate the additional design features based on the reference devices to enable navigation and use with the StealthStation TeraTrackers. Like the predicate devices, the subject iFuse-Navigation instruments are made of stainless steel, PEEK and titanium alloy.

The iFuse-Navigation set is intended to be used with the Medtronic StealthStation using an O-arm imaging system instead of a C-arm imaging system. Based on that, the subject device includes a mounting bracket to enable the connection of a TeraTracker™.

The instrument modifications detailed in this submission have no impact on the technological characteristics of either the existing iFuse Implant System implants, instruments, or the StealthStation®.

VII. PERFORMANCE DATA

Testing was completed to ensure the functionality and compatibility with the identified Medtronic products. The following table summarizes the performance testing completed:

Test	**Description**
Registration	Registration testing was performed to ensure that the instruments can be registered to the StealthStation.®
Accuracy	Accuracy testing was completed for comparison to the reference instruments.
Rigidity	Rigidity testing evaluated the connection between the TeraTracker and the instruments.
Compatibility with the iFuse Implant System	Compatibility with the iFuse Implant System has been evaluated to ensure that the iFuse-Navigation instruments are compatible with the iFuse Implant System.

VIII. CONCLUSIONS

The intended use of the subject iFuse-Navigation instruments, as part of the iFuse Implant System, is substantially equivalent to the intended use of the predicate instruments. The verification and validation results support substantial equivalence of the iFuse- Navigation instruments compared to the predicate and reference devices.