November 9, 2020

SI-BONE, Inc.
Nancy Kaiser
Sr. Regulatory Affairs Manager
471 El Camino Real, Suite 101
Santa Clara, California 95050

Re: K203110
Trade/Device Name: iFuse Implant System - iFuse Navigation Instrument Set
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 14, 2020
Received: October 15, 2020

Dear Nancy Kaiser:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203110

Device Name
iFuse Implant System - iFuse-Navigation Instrument Set

Indications for Use *(Describe)*
iFuse-Implant System - iFuse-Navigation Instrument Set is 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.

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SI-BONE® | iFuse Implant System®
Minimally Invasive Sacroiliac Joint Surgery

510(k) SUMMARY - iFuse Implant System® - iFuse-Navigation Instrument Set

I. DATE PREPARED

October 14, 2020

II. 510(k) SUBMITTER

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

Contact Person: Susan Noriega, Sr. Director Regulatory Affairs

FDA Establishment
Registration No.: 3007700286

III. DEVICE

Trade Name of Device:	iFuse Implant System - iFuse-Navigation Instrument Set
Common or Usual Name:	Orthopedic Stereotaxic Instrument
Classification:	II
Regulation Number:	21 CFR 882.4560– Stereotaxic instrument
Product Code:	OLO

IV. PREDICATE DEVICE

SI-BONE, Inc., iFuse Implant System - iFuse-Navigation: K172268

V. DEVICE DESCRIPTION

iFuse Implant System - 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.

VI. INDICATIONS FOR USE

iFuse Implant System - iFuse-Navigation Instrument Set 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.

VII. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The iFuse Navigation instruments, specifically the 7.0 mm Navigation Broach, described and cleared in 510(k) number K172268, serves as the predicate device for this premarket notification. The 4.0 mm Navigation Broach, the subject of this Special 510(k), has the same intended use/ indications for use and similar technological characteristics as the 7.0 mm Navigation Broach described and cleared in K177268. Furthermore, there have been no changes in the operating principle, component materials, manufacturing processes or sterilization method since FDA's clearance of K177268. Therefore, the iFuse-Navigation Instrument Set with 4.0 mm Navigation Broach is substantially equivalent to the predicate device currently marketed under K177268.

VIII. SUMMARY OF VERIFICATION AND VALIDATION ACTIVITIES

Performance testing conducted on the proposed device demonstrates that it performs as designed, is suitable for its intended use and is substantially equivalent to the predicate device. The following testing were successfully performed for the 4.0 mm Navigation Broach: registration with Medtronic StealthStation and dimensional analysis.

IX. CONCLUSION

No new issues of safety or effectiveness are raised by the modifications. Based on all information in this Special 510(k), the iFuse Implant System - iFuse-Navigation Instrument Set with 4.0 mm Navigation Broach is substantially equivalent to the identified predicate device currently marketed under K177268.