March 31, 2020

Si-Bone, Inc
Susan Noriega
Sr. Director Regulatory Affairs
47 El Camino Real, Suite 101
Santa Clara, California 95050

Re: K193524
Trade/Device Name: SI-BONE 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, 2020
Received: March 5, 2020

Dear Susan Noriega:

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,

for

Colin O’Neill, MBE
Assistant Director (Acting)
DHT6B: Division of Spinal 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193524

Device Name
SI-BONE iFuse Implant System®

Indications for Use *(Describe)*

The iFuse Implant System is intended for sacroiliac fusion for the following conditions:
• 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.
• To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

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.

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

510(k) SUMMARY
SI-BONE iFuse Implant System®

I. DATE PREPARED

March 4, 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:	SI-BONE iFuse Implant System®
Common or Usual Name:	Sacroiliac Joint Fixation
Classification:	II
Regulation Number:	21 CFR 888.3040, Smooth or threaded metallic bone fastener
Product Code:	OUR

IV. PREDICATE DEVICE

SI-BONE iFuse Implant System®	K190230 (Primary Predicate)
SI-BONE iFuse Implant System®	K110838, K092375, K080298 (Reference Predicates)

V. DEVICE DESCRIPTION

The iFuse Implant System consists of cannulated triangular, titanium implants [iFuse implants: Ti-6Al-4V ELI, ASTM F136/F1580 and iFuse-3D implants: Ti-6Al-4V ELI, ASTM F3001] with a porous surface and an instrument system. The principle of operation is based on the triangular implant shape and porous surface which are designed to prevent and minimize motion / micromotion of the sacroiliac (SI) joint, and thereby stabilize the joint or fracture. The mechanism of action is that the interference fit allows for fixation, stabilization and fusion. The implants are available in varying lengths and diameters and are provided sterile (gamma sterilization).

VI. INDICATIONS FOR USE

The iFuse Implant System is intended for sacroiliac fusion for the following conditions:

- 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.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

VII. SUMMARY OF SUBSTANTIAL EQUIVALENCE

There are no changes to the technological characteristics of the device that are the subject of this 510(k). SI-BONE's iFuse Implant System is technologically identical to and has the same intended use and substantially similar indications for use as the previously cleared predicate devices (K190230; as well as the reference predicates cleared in K110838, K080398 and K092375). The proposed indications for use statement does not introduce any new indications, does not alter the therapeutic effect or use of the implants and does not expand use of the implants beyond uses contemplated under the cleared predicate 510(k)s. In conclusion, the iFuse Implant System with clarified indication for use statement is substantially equivalent to the predicate devices.

VIII. SUMMARY OF VERIFICATION AND VALIDATION ACTIVITIES

There were no changes in the design, technological features, intended use and overall risks associated with the iFuse Implant System. Therefore, no new design verification or validation testing was required; the design verification and validation testing previously conducted and submitted in previously cleared SI-BONE 510(k)s is applicable.

SI-BONE follows established quality system and design control requirements in accordance with the Quality System Regulation (21 CFR 820) and declares conformance to design controls and risk-based assessment procedures, including Hazards Analysis and Use FMEA assessments.

IX. CONCLUSION

The intended use and the technological characteristics are unchanged compared to the predicate device, therefore the subject device is substantially equivalent to the predicate device.