February 11, 2026

SI-BONE, Inc.
Jayasri Prabakaran
Associate Director of Regulatory Affairs
471 El Camino Real
Suite 101
Santa Clara, California 95050

Re: K253488
Trade/Device Name: iFuse INTRA Ti™ 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 23, 2025
Received: October 24, 2025

Dear Jayasri Prabakaran:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MAZIAR SHAH-MOHAMMADI -S

For: Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253488

Please provide the device trade name(s).

iFuse INTRA Ti Implant System

Please provide your Indications for Use below.

The iFuse INTRA Ti Implant System is intended for fusion of the sacroiliac joint for 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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

iFuse INTRA Ti™ Implant System

I. 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: Jayasri Prabakaran, Director, Regulatory Affairs

FDA Establishment Registration No.: 3007700286

Date Prepared: February 5, 2026

II. DEVICE

Trade Name of Device	iFuse INTRA Ti™ Implant System
Classification Name	Sacroiliac Joint Fixation
Classification	II
Regulation Number	21 CFR 888.3040 (Smooth or threaded metallic bone fixation fastener)
Product Code	OUR

III. PREDICATE DEVICES

Primary Predicate:

Predicate Device	Manufacturer	510(k)#	Clearance Date
Catamaran Sacroiliac Joint Fixation System	Tenon Medical	K180818	13 June 2018

Additional Predicates:

Predicate Device	Manufacturer	510(k)#	Clearance Date
iFuse TORQ Implant System	SI-BONE, Inc.	K203247 K241574	4 March 2021 2 July 2024
DePuy Synthes 6.5 mm Cannulated Screws	Synthes USA Products	K161616	16 February 2017
iFuse 3D Implant System	SI-BONE, Inc.	K162733	10 March 2017

Reference devices:

Device name	Manufacturer	510(k)#	Clearance Date
Sofamor Danek Rialto SI Fusion System	Medtronic	K161210	12 August 2016
iFuse Bedrock Granite System	SI-BONE, Inc.	K233508 K220195	26 May 2022
iFuse TORQ TNT Implant System	SI-BONE, Inc.	K241504	19 August 2024
iGPS Navigation Instruments	SI-BONE, Inc.	K251780	15 September 2025

IV. DEVICE DESCRIPTION

The iFuse INTRA Ti Implant System consists of a sterile, single-use implant with porous features designed to promote joint fusion. The implant is additively manufactured using Ti-6Al-4V ELI per ASTM F3001. The iFuse INTRA Ti instruments are single-use devices used for placement of the implant.

V. INDICATIONS FOR USE

The iFuse INTRA Ti Implant System is intended for fusion of the sacroiliac joint for 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. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The subject device is substantially equivalent to its predicates in terms of intended use, indications for use, technological characteristics, materials, manufacturing methods, and principles of operation. Therefore, based on the intended use, indications for use, technological characteristics, and principles of operation, iFuse INTRA Ti Implant System is substantially equivalent to its predicate devices.

VII. PERFORMANCE DATA

SI-BONE performed the following performance tests:

- Cadaveric Testing
- Simulated Use Testing
- Bench Testing (Axial pullout, Implant removal, Fenestration fill, survivability, impaction)
- Elemental (chemical) Analysis
- MR Safety testing
- Mechanical testing per ASTM F3574:
  - Static Shear Testing
  - Dynamic Shear (Fatigue) Testing
- Static Torsion (characterization only)

Evaluation of design changes do not affect the testing previously conducted on the additional predicate, SI-BONE's iFuse TORQ Implant System (K203247). The performance tests leveraged from iFuse TORQ implants include:

- Static Shear Testing
- Shear Fatigue Testing
- Static Tensile Testing
- Abrasion Properties

The test results demonstrate that the device is substantially equivalent to the predicate device.

VIII. CONCLUSION

The iFuse INTRA Ti implant is substantially equivalent to its predicate devices in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation. Testing has shown substantially equivalent benchtop performance. Test results demonstrate that the subject device is substantially equivalent to the legally marketed devices and do not raise different questions of safety and effectiveness than the predicate devices.