October 9, 2025

SI-Bone, Inc.
Jayasri Prabakaran
Associate Director, Regulatory Affairs
471 El Camino Real, Suite 101
Santa Clara, California 95070

Re: K253094
Trade/Device Name: iFuse Bedrock Granite® Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, NKB, OLO
Dated: September 23, 2025
Received: September 23, 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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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] Brent Showalter, Ph.D.
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.	K253094 ?

Please provide the device trade name(s). ?

iFuse Bedrock Granite® Implant System

Please provide your Indications for Use below. ?

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

When connected to compatible pedicle screw systems with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to thoracolumbosacral fusion for the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
• Degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies
• Spondylolisthesis
• Trauma (i.e., fracture or dislocation)
• Spinal stenosis
• Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
• Spinal tumor
• Pseudarthrosis
• Failed previous fusion

When connected to compatible pedicle screw systems with 5.5- or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Bedrock Granite Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally immature patients as an adjunct to thoracolumbar fusion for the treatment of progressive spinal deformities (i.e., scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis, as well as the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Please refer to the additional information section in the Instructions for Use on compatible pedicle screw system rods.

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant System and the Medtronic StealthStation System to assist the surgeon in precisely locating anatomical structures in iFuse Bedrock Granite Implant System 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.

The Granite iGPS instruments and iGPS Drill Bits are compatible with Globus ExcelsiusGPS® Instrument Trackers and intended to be used with the iFuse Bedrock Granite Implant System and the Globus ExcelsiusGPS® Robotic Navigation System (including the Globus Excelsius3D® Imaging System), which is intended for use as an aid for precisely locating anatomical structures and for spatial positioning and orientation of an instrument holder or guide tube to be used by surgeons for navigating and/or guiding compatible surgical instruments in open or percutaneous procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy.

Use of the iGPS instruments is limited to use only with the 9.5 mm and 10.5 mm iFuse Bedrock Granite implants.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) SUMMARY

iFuse Bedrock Granite 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, Associate Director, Regulatory Affairs

FDA Establishment
Registration No.: 3007700286

Date Prepared: October 7, 2025

II. DEVICE

Trade Name of Device	iFuse Bedrock Granite® Implant System
Classification Name	Sacroiliac Joint Fixation
Classification	II
Regulation Number	888.3040, 888.3070, 882.4560
Product Code	OUR, NKB, OLO

III. PREDICATE DEVICES

Primary Predicate:

Predicate Device	Manufacturer	510(k)#	Clearance Date
iFuse Bedrock Granite Implant System	SI-BONE, Inc.	K233508	26 January 2024

Additional Predicates:

Predicate Device	Manufacturer	510(k)#	Clearance Date
iFuse Bedrock Granite Implant System	SI-BONE, Inc.	K222774	26 May 2022
Mariner Pedicle Screw System	SeaSpine Orthopedics Corporation	K212692	21 September 2021

Reference Device:

Device	Manufacturer	510(k)#	Clearance Date
iGPS Navigation Instruments	SI-BONE, Inc.	K251780	15 September 2025

IV. DEVICE DESCRIPTION

The iFuse Bedrock Granite® Implant System consists of implants of various lengths and diameters, and associated instruments sets. Instrument sets are provided for both open and minimally invasive approaches. The titanium (Ti-6Al-4V ELI) implant consists of a porous fusion sleeve with threaded length attached to a solid post that has connection and implant placement features of a typical pedicle fixation screw. It is intended to provide sacroiliac joint fusion in the sacral alar iliac (SAI) trajectory (when used with commercially available sacroiliac joint fusion promoting devices), and foundational stabilization when connected to pedicle screw fixation systems in both the SAI and the iliac trajectories. Additionally, iFuse Bedrock Granite can be placed into the S1 pedicle. The device is designed for connection to commercially available pedicle screw systems via Ø5.5 mm or Ø6.0 mm titanium alloy or cobalt chrome alloy spinal fixation rods.

The purpose of this submission is to add an alternative option for the set screw (referred to as the Granite Point Lock Set Screw) used with the iFuse Granite Implant System.

V. INDICATIONS FOR USE

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Use of the iGPS instruments is limited to use only with the 9.5 mm and 10.5 mm iFuse Bedrock Granite implants.

VI. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The subject device is substantially equivalent to the predicate devices in terms of intended use, technological characteristics, principles of operation, materials, manufacturing, labeling, sterility, and non-clinical performance (mechanical testing).

VII. PERFORMANCE DATA

The iFuse Bedrock Granite Implant System demonstrated substantially equivalent mechanical performance based on the testing listed below and a risk analysis compared to the predicate device.

- Axial gripping capacity per ASTM F1798 (Static axial slip)
- Torsional gripping capacity per ASTM F1798 (Static axial torsion)
- Dynamic axial compression per ASTM F1717 (Dynamic compression bending)

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

VIII. CONCLUSION

The iFuse Bedrock Granite System is substantially equivalent to its predicate in terms of intended use, technological characteristics, principles of operation, materials, manufacturing, labeling and sterility.

Mechanical performance test results demonstrate that the subject device is substantially equivalent to the legally marketed predicate device.