May 26, 2022

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

Re: K220195
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: April 27, 2022
Received: April 28, 2022

Dear Meirav Harsat:

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,

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

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)*
K220195

Device Name
iFuse Bedrock Granite™ Implant System

Indications for Use *(Describe)*
The iFuse Bedrock Granite Implant System is intended for sacroiliac joint 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 6months.
•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

When connected to the SeaSpine Mariner Pedicle Screw System, 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 withdegeneration 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

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant 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. iFuse Bedrock Granite 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.

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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: Meirav Harsat, Director Regulatory Affairs

FDA Establishment
Registration No.: 3007700286

II. DEVICE

Trade Name of Device	iFuse Bedrock Granite™ Implant System
Classification Name	Sacroiliac Joint Fixation
Classification	II
Regulation Number	21 CFR 888.3040; metallic bone fastener Smooth or threaded 21 CFR 888.3070, Thoracolumbosacral pedicle screw system 21 CFR 882.4560, Stereotaxic instrument
Product Code	OUR, NKB, OLO

III. PREDICATE DEVICE

Primary Predicate Device	**Manufacturer**	**510(k)#**	**Clearance Date**
iFuse-3D Implant System	SI-BONE, Inc.	K193524	March 31, 2020
Additional Predicate Device	**Manufacturer**	**510(k)#**	**Clearance Date**
Mariner Pedicle Screw System®	SeaSpine Orthopedics Corporation	K212692	September 21, 2021
iFuse Implant System-iFuse Navigation	SI-BONE, Inc.	K172268	October 31, 2017

IV. DEVICE DESCRIPTION

The iFuse Bedrock Granite™ Implant System consists of implants of various lengths and diameters, and associated instruments sets (Open and MIS). 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 the SeaSpine Mariner Pedicle Screw System in both the SAI and the Iliac trajectories. It is designed for connection to the SeaSpine Mariner Pedicle Screw System via Ø5.5mm or Ø6.0mm titanium alloy or cobalt chrome spinal fixation rods.

V. INDICATIONS FOR USE

The iFuse Bedrock Granite Implant System is intended for sacroiliac joint 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

When connected to the SeaSpine Mariner Pedicle Screw System, 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

The iFuse Bedrock Granite Navigation instruments are intended to be used with the iFuse Bedrock Granite Implant 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. iFuse Bedrock Granite Navigation instruments are intended to be used with the Medtronic StealthStation System.

VI. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The iFuse Bedrock Granite Implant System is substantially equivalent to its predicates in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation as the predicate devices: the SI-BONE iFuse-3D Implant System (most recently cleared in K193524) and the SeaSpine Mariner Pedicle Screw System (most recently cleared in K212692). Any differences between the iFuse Bedrock Granite Implant System and the predicate devices do not raise different questions of safety or effectiveness, as demonstrated by the results of the verification and validation testing. Therefore, based on the intended use, indications for use, technological characteristics and principles of operation, iFuse Bedrock Granite Implant System is substantially equivalent to the predicate devices.

VII. PERFORMANCE DATA

SI-BONE performed comprehensive Design Verification and Validation Testing to demonstrate the safety and performance of SI-BONE's iFuse Bedrock Granite Implant System for its intended clinical use.

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the iFuse Bedrock Granite Implant System was conducted in accordance with the FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," September 4, 2020, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. Applicable testing was successfully completed.

Mechanical Testing

- Static and Dynamic Cantilever Bending
- Static Torsion
- Static Axial Pullout
- Stereological Evaluation of the Porous Layer
- Static Shear
- Shear Fatigue
- Static Tension
- Abrasion
- Static and Dynamic Axial Compression
- Static Axial Torsion
- Static Anterior-Posterior Loading
- Static Axial Slip
- Static Flexion/Extension

VIII. CONCLUSION

The iFuse Bedrock Granite Implant System is substantially equivalent to both the primary and secondary predicate. The iFuse Bedrock Granite Implant System is substantially equivalent to its predicates in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation as the predicate devices: the SI-BONE iFuse-3D Implant System (most recently cleared in K193524) and the SeaSpine Mariner Pedicle Screw System (most recently cleared in K212692). Any differences between the iFuse Bedrock Granite Implant System and the predicate devices do not raise any different questions of safety or effectiveness, as demonstrated by the results of the verification and validation testing. Therefore, based on the intended use, indications for use, technological characteristics, and principles of operation, iFuse Bedrock Granite Implant System is substantially equivalent to the predicate devices.