



September 23, 2026

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

Re: K262067

Trade/Device Name: iFuse Granite Onyx™ Implant System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB, OLO
Dated: August 26, 2026
Received: August 26, 2026

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.

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485

clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

COLIN
O'NEILL -S 

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.

K262067

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Please provide the device trade name(s).

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iFuse Granite Onyx™ Implant System

Please provide your Indications for Use below.

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When connected to compatible pedicle screw systems with 5.0-, 5.5-, or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Granite Onyx Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of 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, and/or
- failed previous fusion.

When connected to compatible pedicle screw systems with 5.0-, 5.5-, or 6.0- mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Granite Onyx Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally immature patients as an adjunct to 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 Granite Onyx Navigation instruments are intended to be used with the iFuse Granite Onyx Implant System and the Medtronic StealthStation System to assist the surgeon in precisely locating anatomical structures in iFuse Granite Onyx 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 Onyx iGPS instruments are compatible with Globus ExcelsiusGPS® Instrument Trackers and intended to be used with the iFuse Granite Onyx 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 procedures provided that the required fiducial markers and rigid patient anatomy can be identified on CT scans or fluoroscopy.

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](#))

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Please select the age group(s) for which the device(s) is to be used.

- ☐ Neonates/Newborns (Birth to < 29 days old)
☐ Infants (29 days old to < 2 years old)
☒ Children (2 years old to < 12 years old)
☒ Adolescents (12 years old to < 22 years old)
☒ Adults (22 years old and greater)

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SI-BONE, Inc.
Traditional 510(k) Submission

iFuse Granite Onyx™ Implant System

510(k) SUMMARY

iFuse Granite Onyx™ 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: September 16, 2026

II. DEVICES

DEVICE 1:

Trade Name of Device	iFuse Granite Onyx™ Implant System
Regulation Name	Thoracolumbosacral Pedicle Screw System
Regulation Number	21 CFR 888.3070
Regulatory Class	II
Product Code	NKB

DEVICE 2:

Trade Name of Device	iFuse Granite Onyx Navigation Instruments intended to be used with the iFuse Granite Onyx Implant System and the Medtronic StealthStation System
Regulation Name	Stereotaxic instruments
Regulation Number	21 CFR 882.4560
Regulatory Class	II
Product Code	OLO

DEVICE 3:

Trade Name of Device	Onyx iGPS instruments compatible with Globus ExcelsiusGPS® Instrument Trackers and intended to be used with the iFuse Granite Onyx Implant System and the Globus ExcelsiusGPS® Robotic Navigation System (including the Globus Excelsius3D® Imaging System)
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SI-BONE, Inc.**Traditional 510(k) Submission****iFuse Granite Onyx™ Implant System**

Regulation Name	Stereotaxic instruments
Regulation Number	21 CFR 882.4560
Regulatory Class	II
Product Code	OLO

III. PREDICATE DEVICES

Primary Predicate:

Predicate Device	Manufacturer	510(k)#	Clearance Date
Device 1: Invictus Spinal Fixation System	Alphatec Spine, Inc.	K214006	4 April 2022

Additional Predicates:

Predicate Device	Manufacturer	510(k)#	Clearance Date
Device 1: iFuse Bedrock Granite Implant System	SI-BONE, Inc.	K233508 K222774 K220195	26 January 2024 22 December 2022 26 May 2022
Device 1: A8 INTEGR8 Porous Pedicle Screws	Allumin8	K242827	20 October 2025
Device 2: Navigated CD HORIZON® SOLERA® Taps	Medtronic Sofamor Danek, USA Inc.	K140454	22 May 2014
Device 3: Excelsius GPS™ Instruments	Globus Medical, Inc.	K171651	16 August 2017

Reference devices:

Device name	Manufacturer	510(k)#	Clearance Date
iFuse TORQ TNT Implant System	SI-BONE, Inc.	K241504	19 August 2024
iGPS Navigation Instruments	SI-BONE, Inc.	K251780	15 September 2025

IV. PURPOSE

This 510(k) includes:

- A description of the Onyx implant, associated instrumentation, substantial equivalence comparison between the subject device and its predicates, and testing.

V. DEVICE DESCRIPTION

The iFuse Granite Onyx Implant System consists of an implant and the associated instruments to provide fixation and fusion of spinal segments in the thoracolumbar and sacral spine. The implant is manufactured using Ti-6Al-4V ELI per ASTM F3001. The implant system also includes two different set screws to be used with commercially available pedicle screw systems via Ø 5.0mm, Ø 5.5mm and Ø 6.0mm titanium alloy or cobalt chrome spinal fixation rods.

SI-BONE, Inc.

Traditional 510(k) Submission

iFuse Granite Onyx™ Implant System

VI. INDICATIONS FOR USE

When connected to compatible pedicle screw systems with 5.0-, 5.5-, or 6.0-mm posterior rods made from either titanium alloy or cobalt chrome alloys, the iFuse Granite Onyx Implant System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

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VII. 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. The differences in the indication for use statement from the previously cleared legally marketed predicate are not critical to the intended use of the subject device. Therefore, based on

SI-BONE, Inc.

Traditional 510(k) Submission

iFuse Granite Onyx™ Implant System

the intended use, technological characteristics, and principles of operation, iFuse Granite Onyx Implant System is substantially equivalent to its predicate devices.

VIII. PERFORMANCE DATA

SI-BONE performed the following performance tests:

- Simulated Use Testing
- Bench Testing
 - i. Implant Static and Dynamic Flexion-Extension Testing per ASTM F1798.
 - ii. Implant Static Axial Grip Testing per ASTM F1798.
 - iii. Implant Static Torsional Grip Testing per ASTM F1798.
 - iv. Implant Static Anterior-Posterior Testing per ASTM F1798.
 - v. Implant Static and Dynamic Cantilever Testing per modified ASTM F2193.
 - vi. Torsion, Insertion, and Removal Torque Testing per ASTM F543.
 - vii. Axial Pullout Testing per ASTM F543.
 - viii. Construct Static and Dynamic Compression Bending Testing per ASTM F1717.
 - ix. Functional Performance Testing for implants and instruments.
 - x. Durability and accuracy testing for navigated instruments

Testing was performed on a range of rod diameters and manufacturing methods to demonstrate compatibility with the iFuse Granite Onyx™ Implant System.

The test results demonstrate that the subject device, iFuse Granite Onyx Implant System (including associated instrumentation) is substantially equivalent to the predicate devices.

IX. CONCLUSION

The iFuse Granite Onyx Implant System (including associated instrumentation) 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. The differences in the indication for use statement from the previously cleared, legally marketed predicates are not critical to the intended use of the subject device. 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.