



September 15, 2025

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

Re: K251780
Trade/Device Name: iGPS Navigation Instruments
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: August 15, 2025
Received: August 15, 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.

Assistant Director

DHT6C: Division of Restorative,
Repair, and Trauma 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.

K251780

?

Please provide the device trade name(s).

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iFuse TORQ® Implant System

Please provide your Indications for Use below.

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The iFuse TORQ Implant System is indicated for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

The iFuse TORQ Implant System is also indicated for fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures.

The iFuse TORQ Navigation instruments are intended to be used with the iFuse TORQ Implant System and the Medtronic StealthStation System to assist the surgeon in precisely locating anatomical structures in iFuse TORQ 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 TORQ iGPS instruments and iGPS Drill Bits are compatible with Globus ExcelsiusGPS® Instrument Trackers and intended to be used with the iFuse TORQ 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 10.0 mm and 11.5 mm fully threaded iFuse TORQ 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)

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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.

K251780

?

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)	?
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510(k) SUMMARY

iGPS Navigation Instruments

I. 510(k) SUBMITTER

SI-BONE, Inc.
471 El Camino Real, Suite 101,
Santa Clara, CA 95050
Phone: 408-207-0700
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Contact Person: Jayasri Prabakaran, Associate Director, Regulatory Affairs

FDA Establishment
Registration No.: 3007700286

Date Prepared: September 12, 2025

II. DEVICE

Trade Name of Device iGPS Navigation Instruments
Classification Name Orthopedic Stereotaxic Instrument
Classification II
Regulation Number 21 CFR 882.4560; Stereotaxic instruments
Product Code OLO

III. PREDICATE DEVICES

Primary Predicate:

Predicate Device	Manufacturer	510(k)#	Clearance Date
ExcelsiusGPS instruments	Globus Medical Inc.	K171651	16 August 2017

Additional Predicate:

Predicate Device	Manufacturer	510(k)#	Clearance Date
E-GPS Navigated instruments	Precision Spine, Inc.	K220862	14 July 2022

Reference devices:

Predicate Device	Manufacturer	510(k)#	Clearance Date
iFuse TORQ instruments	SI-BONE, Inc.	K203247	25 February 2021
iFuse Bedrock Granite instruments	SI-BONE, Inc.	K220195	26 May 2022

IV. DEVICE DESCRIPTION

SI-BONE's iGPS Navigation Instruments are navigated and reusable instrumentation compatible with the Globus ExcelsiusGPS Robotic Navigation System. The iGPS Navigation Instruments are designed to allow surgeons to place iFuse TORQ and iFuse Bedrock Granite implants using the Globus ExcelsiusGPS® Robotic Navigation System (including the Globus Excelsius3D® Imaging System) along with Globus ExcelsiusGPS® Instrument Trackers.

V. INDICATIONS FOR USE (iFuse TORQ Implant System)

The iFuse TORQ Implant System is indicated for sacroiliac joint fusion for:

- Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.
- Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.

The iFuse TORQ Implant System is also indicated for fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures.

The iFuse TORQ Navigation instruments are intended to be used with the iFuse TORQ Implant System and the Medtronic StealthStation System to assist the surgeon in precisely locating anatomical structures in iFuse TORQ 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 TORQ iGPS instruments and iGPS Drill Bits are compatible with Globus ExcelsiusGPS® Instrument Trackers and intended to be used with the iFuse TORQ 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 10.0 mm and 11.5 mm fully threaded iFuse TORQ implants.

VI. INDICATIONS FOR USE (iFuse Granite Implant System)

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)
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- 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 9.5 mm and 10.5 mm iFuse Bedrock Granite implants.

VII. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The subject devices are substantially equivalent to the primary predicate device in terms of intended use, technological characteristics, materials, and principles of operation. The differences in the indications for use statement from the previously cleared, legally marketed predicate are not critical to the intended use of the devices.

VIII. PERFORMANCE DATA

SI-BONE performed the following performance tests:

- Dimensional comparison with Globus ExcelsiusGPS robotic navigation instruments
- Bench testing
- Simulated use testing

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

IX. CONCLUSION

The iGPS Navigation Instruments are substantially equivalent to its predicate in terms of intended use, technological characteristics, materials, and principles of operation. The difference in the indication for use statement from the previously cleared, legally marketed predicates are not critical to the intended use of the device. Test results demonstrate that the device is substantially equivalent to the legally marketed device and do not raise different questions of safety and effectiveness than the predicate device.