SI-BONE Inc.
Robyn Capobianco
VP Clinical and Regulatory Affairs
471 El Camino Real, Suite 101
Santa Clara, California 95050

July 2, 2024

Re: K241574
Trade/Device Name: iFuse TORQ® Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, HWC, OLO
Dated: May 31, 2024
Received: June 3, 2024

Dear Robyn Capobianco:

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.

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,

Eileen Cadel -S Digitally signed by Eileen Cadel -S Date: 2024.07.02 14:56:32 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K241574

Device Name
iFuse TORQ® Implant System

Indications for Use *(Describe)*
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 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. iFuse TORQ 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(K) SUMMARY– iFuse TORQ® Implant System

Date Prepared: May 31, 2024

## I. SUBMITTER

SI-BONE, Inc.
471 El Camino Real, Suite 101, Santa Clara, CA 95050
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Contact Person:
Robyn Capobianco, VP Clinical & Regulatory Affairs
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Phone: 650-219-8342

## II. DEVICE

| | |
|---|---|
| Trade Name of Device: | iFuse TORQ® Implant System |
| Common or Usual Name: | Sacroiliac Joint Fixation |
| Classification: | II |
| Regulation Number: | 21 CFR 888.3040, Smooth or threaded metallic bone fixation fastener |
| Product Codes: | OUR, HWC, OLO |

## III. PREDICATE DEVICE

| | |
|---|---|
| Primary Predicate: | iFuse TORQ Implant System (K222605) |
| Additional Predicates: | iFuse TORQ Implant System (K231689) |
| | iFuse Bedrock Granite Implant System (K220195) |

## IV. DEVICE DESCRIPTION

The iFuse TORQ Implant System consists of the iFuse TORQ Implants and associated Instruments. Implants are threaded, fenestrated, cannulated, 3D-printed from medical grade titanium alloy (Ti-6Al-4V ELI per ASTM F3001). The implants are fully threaded or a lag design that is provided with optional washers. The washers are intended to add additional support under the head of the screw in situations where the bone quality is poor. The cannulated implants are compatible with off-the-shelf 3.2 mm guidewires. The implants, available in various lengths and diameters, allow for packing of autograft and allograft materials.

This 510(k) covers extension of the porous lattice surface over the entire shank of the Ø10.0 mm screws, an optimized laser path during additive manufacturing process, and use of two implants in the SAI (posteromedial) trajectory for sacroiliac joint fusion.

## V. INDICATIONS FOR USE

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 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. iFuse TORQ Navigation instruments are intended to be used with the Medtronic StealthStation System.

## VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modifications to the subject implant screws do not alter the device's fundamental scientific technology compared to the predicate. Risk analyses and performance data confirm that the proposed changes do not raise different questions of safety and effectiveness.

## VII. PERFORMANCE DATA

All necessary bench testing was conducted on the modified iFuse TORQ implants including:

- Porosity testing per ASTM F1854
- Static Shear per ASTM F1044
- Static Fatigue per ASTM F1160
- Static Tensile per ASTM F1147
- Abrasion per ASTM F1978
- Dynamic Cantilever Testing per ASTM F2193
- Static Torsion Testing per ASTM F543

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

## VIII. CONCLUSIONS

The subject device is substantially equivalent to its predicate in terms of intended use and indications for use, technological characteristics, materials, manufacturing methods, and principles of operation. The differences in the technological characteristics between the subject device and the predicate do not raise different questions of safety and effectiveness. Based on the performance testing and the technological characteristics, it can be concluded that the subject device is substantially equivalent to the predicate devices.