June 10, 2022

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

Re: K213667
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
Dated: May 17, 2022
Received: May 18, 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,

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)*
K213667

Device Name
iFuse-TORQ Implant System

Indications for Use *(Describe)*
The iFuse-TORQ Implant System is indicated for:

• Fusion of the sacroiliac joint for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis
• Fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures

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.

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510(k) SUMMARY – iFuse-TORQ® Implant System

I. 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 of Regulatory Affairs, SI-BONE, Inc.
Email: mharsat@si-bone.com
Phone: 650-862-4942
Date Prepared: June 7, 2022

II. DEVICE

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

III. PREDICATE AND REFERENCE DEVICES

Primary Predicate:	iFuse-TORQ Implant System K203247
Additional Predicate:	Firebird SI Fusion System, K210667

IV. DEVICE DESCRIPTION

The iFuse-TORQ Implant System consists of the iFuse-TORQ Implants and associated Instruments. iFuse-TORQ implants are fully threaded or with a lag design and 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 iFuse-TORQ implants, that are available in various lengths and diameters, allow for packing of autograft and allograft materials.

V. PURPOSE

This 510(k) premarket notification is submitted to request clearance to expand the indications for use the subject device.

VI. INDICATIONS FOR USE

The iFuse-TORQ Implant System is indicated for:

- Fusion of the sacroiliac joint for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis
- Fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device has identical technological characteristics compared to the primary predicate device and similar technological characteristics compared to the additional predicate. The clinical literature review and the design verification test results confirm that the differences do not raise new questions of safety and effectiveness.

VIII. PERFORMANCE DATA

The verification testing conducted per ASTM F543, including axial pullout, torsional strength, and insertion and removal torque, demonstrated that the technological differences between the subject device and the additional predicate do not raise new questions of safety and effectiveness and that the subject device and the additional predicate are substantially equivalent.

IX. CONCLUSIONS

The proposed subject device has the same intended use as the predicates and an indication for use that is substantially equivalent to the predicate devices.

Based on literature search results, it was demonstrated that the differences in the indication for use statement from previous cleared legally marketed predicates are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device.

The proposed device has identical technological characteristics to the primary predicate and similar technological characteristics to the additional predicate. Based on the performance data test results, it was demonstrated that the differences do not raise new questions of safety and effectiveness and do not affect the safety and effectiveness of the device when used as labeled. As such, the subject device has been shown to be substantially equivalent to the primary and additional predicate devices.