August 19, 2024

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

Re: K241504
Trade/Device Name: iFuse TORQ TNT™ 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 24, 2024
Received: May 28, 2024

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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP) titled “Predetermined Change Control Plan for Additional Trajectories and

Implant Modifications" Version 2. Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device, or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

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,

STEPHANIE SMITH -S

For Ronald P. Jean, Ph.D.
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)*
K241504

Device Name
iFuse TORQ TNT™ Implant System

Indications for Use *(Describe)*
The iFuse TORQ TNT Implant System is indicated for fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures.

The iFuse TORQ TNT 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 TNT Navigation instruments are intended to be used with the iFuse TORQ TNT Implant System to assist the surgeon in precisely locating anatomical structures in iFuse TORQ TNT 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 TNT 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 TNT™ 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, Associate Director, Regulatory Affairs

FDA Establishment
Registration No.: 3007700286

Date Prepared: May 24, 2024

II. DEVICE

| | |
|---|---|
| Trade Name of Device | iFuse TORQ TNT™ Implant System |
| Classification Name | Sacroiliac Joint Fixation |
| Classification | II |
| Regulation Number | 21 CFR 888.3040; Smooth or threaded metallic bone fixation fastener |
| Product Code | OUR, HWC, OLO |

III. PREDICATE DEVICES

Primary Predicate:

| Predicate Device | Manufacturer | 510(k)# | Clearance Date |
|---|---|---|---|
| iFuse TORQ Implant System | SI-BONE, Inc. | K203247 | 25 February 2021 |

Additional Predicate:

| Predicate Device | Manufacturer | 510(k)# | Clearance Date |
|---|---|---|---|
| 7.3 mm Cannulated Screw | Depuy Synthes | K161616 | 16 February 2017 |

## IV. PURPOSE

This 510(k) includes:

- A description of testing sufficient to establish substantial equivalence between the subject device and its predicates.
- A description of a pre-determined change control plan (PCCP) for adding use of the subject device in 4 new trajectories and a modified version with changes to implant thread length and pitch.

## V. DEVICE DESCRIPTION

iFuse TORQ TNT System consists of a fully threaded, 3D-printed porous implant with optional washers along with instruments used to place the implant under either fluoroscopic guidance or with certain navigation systems. The implant is made from titanium alloy (Ti-6Al-4V ELI) and manufactured using 3D printing. The implant has features specific to pelvic anatomy. The subject device is very similar to its primary predicate, iFuse TORQ implant system, except that it is longer in length (up to 170 mm) and smaller in diameter. The longer length enables placement in the transiliac transsacral trajectory.

## VI. INDICATIONS FOR USE

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

The iFuse TORQ TNT 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 TNT Navigation instruments are intended to be used with the iFuse TORQ TNT Implant System to assist the surgeon in precisely locating anatomical structures in iFuse TORQ TNT 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 TNT Navigation instruments are intended to be used with the Medtronic StealthStation System.

## VII. SUMMARY OF SUBSTANTIAL EQUIVALENCE

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 indication for use statement from the previously cleared legally marketed predicate are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device. Therefore, based on the intended use, indications for use, technological characteristics, and principles of operation, iFuse TORQ TNT Implant System is substantially equivalent to its predicate device.

## VIII. PERFORMANCE DATA

SI-BONE performed the following performance tests:

- Static and dynamic cantilever testing per ASTM F2193
- Torsion, driving torque, and axial pullout per ASTM F543
- Elemental Analysis per ASTM F3001
- Stereological evaluation of the porous layer ASTM 1854 and 21 CFR 888.3358
- Navigation Instruments Positional Error Verification per ASTM F2554
- Simulated Use Testing of the navigation instruments

Evaluation of design changes do not affect the testing previously conducted on the primary predicate (K203247); this testing leveraged from the iFuse TORQ Implant System (K203247):

- Static Shear Testing per ASTM F1044
- Shear Fatigue Testing per ASTM F1160 and ISO 13179-1
- Static Tensile Testing per ASTM F1147
- Abrasion Properties per ASTM F1978

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

## IX. PRE-DETERMINED CHANGE CONTROL PLAN

This 510(k) submission included a Predetermined Change Control Plan, described below. Following completion of activities listed below, the changes described herein will be implemented.

**PCCP1 - Trajectories.** Placement of the subject device in one or more of the following trajectories will be subject to: 1) review of prior surgical techniques, 2) review of post-market surveillance data for similar implants, 3) risk analysis (hazard analysis, failure modes and effects analysis), 4) confirmation of placements in anatomic models [if required]), and 5) review with experienced surgeons:

- Various trajectories for fracture fixation (e.g., anterior inferior iliac spine to posterior ilium)
- Sacroalar iliac (SAI)

When analysis for the SAI trajectory is complete, the indication statement will read:

> The iFuse TORQ TNT Implant System is indicated for fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures.
>
> The iFuse TORQ TNT 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 TNT Navigation instruments are intended to be used with the iFuse TORQ TNT Implant System to assist the surgeon in precisely locating anatomical structures in iFuse

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

**PCCP 2 – modified version**. A version of the subject device will be developed, with changes to thread length and pitch. The device will undergo assessment and/or testing similar to that performed for the fully threaded versions cleared herein. Testing will include the following: Fatigue testing per ASTM F2193-20, pullout testing per ASTM F543-23.

## X. CONCLUSION

The iFuse TORQ TNT implant is substantially equivalent to its predicate 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 difference in the indication for use statement from the previously cleared, legally marketed predicates are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device. Test results demonstrate that the device is substantially equivalent to the legally marketed device and does not raise different questions of safety and effectiveness than the predicate device.