March 4, 2021

SI-BONE, Inc.
Susan Noriega
Sr. Director Regulatory Affairs
471 El Camino Real, Suite 101
Santa Clara, California 95050

Re: K203247
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

Dear Susan Noriega:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 25, 2021. Specifically, FDA is updating this SE as an administrative correction due to a typographical error in the Indications for Use form.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Colin O'Neill, M.B.E., OHT6: Office of Orthopedic Devices, (301) 796-6428, colin.oneill@fda.hhs.gov.

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

February 25, 2021

SI-BONE, Inc.
Susan Noriega
Sr. Director Regulatory Affairs
471 El Camino Real, Suite 101
Santa Clara, California 95050

Re: K203247
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
Dated: January 22, 2021
Received: January 25, 2021

Dear Susan Noriega:

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K203247

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 small and large bones of the pelvis

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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PRAStaff@fda.hhs.gov

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SI-BONE® | iFuse Implant System®
Minimally Invasive Sacroiliac Joint Surgery

510(k) SUMMARY
iFuse-TORQ™ Implant System

I. DATE PREPARED

February 22, 2021

II. 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: Susan Noriega, Sr. Director Regulatory Affairs

FDA Establishment
Registration No.: 3007700286

III. 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 fastener Product Code: OUR

IV. PREDICATE DEVICES

Primary Predicate Device	**Manufacturer**	**510(k)#**	**Clearance Date**
M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System	Medacta International SA	K193083	December 3, 2019
Additional Predicate Devices	**Manufacturer**	**510(k)#**	**Clearance Date**
iFuse-3D Implant System	SI-BONE, Inc.	K193524	March 31, 2020
Genesys Spine Sacroiliac Joint Fusion System	Genesys Spine	K191748	September 26, 2019

V. DEVICE DESCRIPTION

The iFuse-TORQ Implant System consists of the iFuse-TORQ Implants and associated Instruments which are included in two Instrument Sets: iFuse-TORQ Instrument Set and iFuse-TORQ Revision Instrument Set. The iFuse-TORQ Implant System is designed to provide a non-impacted, threaded solution for sacroiliac joint fusion, as well as compression across the SI joint, and for fracture fixation of small and large bones of the pelvis.

The iFuse-TORQ Implants are sterile, single use 3D-printed implants that are provided in various lengths and diameters, and feature flutes and multiple fenestrations along the shaft length (**Table 1**). The iFuse-TORQ Implants are provided in two primary configurations – fully threaded and lag implant designs with optional washers. The cannulated implants include a tapered distal tip and dual-single-dual lead threads that are compatible with off-the-shelf 3.2 mm guidewires. The iFuse-TORQ Implant designs allow for packing of autograft and allograft materials.

Table 1. iFuse-TORQ Implant Key Dimensions

Implants	Description
Fully Threaded Implant	
Models:	100XXT, 115XXT, 135XXT*
Diameters:	Ø10.0 mm, Ø11.5 mm, Ø13.5 mm
Lengths:	30 mm – 90 mm in 5 mm increments
Lag Implant	
Models:	100XXLG, 115XXLG, 135XXLG
Diameters:	Ø10.0 mm (with optional 16mm washer), Ø11.5 mm (with optional 18mm washer), Ø13.5 mm (with optional 18mm washer)
Lengths:	40 mm – 90 mm in 5 mm increments

*Note that XX represents length

The iFuse-TORQ Instruments are provided in two sets: iFuse-TORQ Instrument Set (with Primary and Navigation Instruments) and the iFuse TORQ Revision Instrument Set. The iFuse-TORQ Instruments Sets consist of single use, disposable and reusable instruments. The instruments are provided non-sterile and are intended for cleaning and steam sterilization by the user prior to each use. The iFuse-TORQ Instruments consist of both Class II and Class I medical devices which facilitate the introduction, adjustment / positioning, final placement, and removal (if required) of the implants in the target anatomy.

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 small and large bones of the pelvis

VII. SUMMARY OF SUBSTANTIAL EQUIVALENCE

The SI-BONE iFuse-TORQ Implant System has the same intended use, similar indications for use and technological characteristics as the FDA cleared Medacta International M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System (most recently cleared in K193083 and K171595). The iFuse-TORQ Implant is fabricated from similar materials, manufactured using similar processes, and utilizes similar cleaning and identical sterilization processes as the SI-BONE iFuse-3D Implant (most recently cleared in K193524 and in K162733). Additionally, the iFuse-TORQ Implant 3D-printed porous surface is based on similar 3D-printed technology used for the SI-BONE iFuse-3D Implant.

Design verification and validation testing provided in the subject premarket notification, including Sterilization and Cleaning Validations, Packaging / Transit Validations, Shelf Life Assessment; Biocompatibility Assessment; and Bench Performance Testing, including MR Compatibility Assessment, as well as Simulated Use Testing, demonstrate that the iFuse-TORQ Implant System meets requirements of the product specification for its intended clinical use and is substantially equivalent to the predicate devices.

VIII. SUMMARY OF VERIFICATION AND VALIDATION ACTIVITIES

SI-BONE performed comprehensive Design Verification and Validation Testing to demonstrate the performance of SI-BONE's iFuse-TORQ Implant System for its intended clinical use (**Table 2**). Sterilization and Cleaning Validations, Packaging / Transit Validations, Shelf-Life Assessment; Biocompatibility Assessment; and Bench Performance Testing, including MR Compatibility Assessment, as well as Simulated Use Testing have been performed.

Table 2. Design Verification and Validation Testing

Test	Standards
Sterilization Validation	
Sterilization Validation iFuse-TORQ Implants	• SS EN ISO 11137-1:2015 - *Sterilization of Health Care Products: Radiation Sterilization - Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices* • SS EN ISO 11137-2:2015 - *Sterilization of Health Care Products: Radiation Sterilization - Part 2: Establishing the Sterilization Dose – Method VD-Max 25* • SS EN ISO 11137-3:2017 - Sterilization of health care products – Radiation – Part 3: Guidance on Dosimetric aspects of development, validation, and routine control • ANSI / AAMI / ISO 11737-1:2018 - *Sterilization of medical devices — Microbiological methods, Part 1: Determination of population of microorganisms on products* • ANSI / AAMI / ISO 11737-2:2019 - *Sterilization of medical devices — Microbiological methods, Part 2: Tests of sterility performed in the definition, validation, and maintenance of a sterilization process*
Sterilization Validation iFuse-TORQ Instruments	• ANSI/AAMI/ISO 17665-1:2006/(R)2013 - *Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices* • AAMI TIR12-2010 - *Designing, testing, and labeling reusable medical device for reprocessing in health care facilities. A guide for medical device manufacturers* • ANSI/AAMI ST79:2017 - *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* • ANSI/AAMI ST77:2013 - *Containment devices for reusable medical device sterilization*
Cleaning Validation	
Cleaning Validation iFuse TORQ Implants	• EN ISO 19227:2018 - *Implants for Surgery – Cleanliness of Orthopedic Implants – General Requirements* • ISO 10993-5:2009 - *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*
Cleaning Validation Assessment iFuse-TORQ Instruments	• AAMI TIR30:2011(R):2016 - *A compendium of processes materials, test methods, and acceptance criteria for cleaning reusable medical devices*
Repeat Cleaning and Steam Sterilization Assessment – iFuse-TORQ Instruments	• AAMI TIR12:2010 - *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers* • AAMI TIR17:2017 - *Compatibility of materials subject to sterilization*
Packaging Validation	
Packaging Validation iFuse-TORQ Implants	• EN ISO 11607-1:2019 - *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems* • ASTM D4332-14 – *Standard Practice for Conditioning Containers, Packaging, or Packaging Components for Testing* • ASTM D4169-16 (Distribution Cycle 13) – *Standard Practice for Performance Testing of Shipping Containers and Systems* • ASTM F2096-11 (2019) – Standards Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test) • ASTM F88-15 – *Standard Test Method for Seal Strength of Flexible Barrier Materials*
Packaging Validation	• ASTM D4332-14 – *Standard Practice for Conditioning Containers, Packaging, or*

Test	Standards
iFuse-TORQ Instruments	*Packaging Components for Testing* • ASTM D4169-16 (Distribution Cycle 13) – *Standard Practice for Performance Testing of Shipping Containers and Systems*
Shelf Life	
Shelf Life Rationale for iFuse-TORQ Implants	• ASTM F1980-16 – *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*
Biocompatibility Assessments	
Biological Safety Evaluation iFuse-TORQ Implants	• ISO 10993-1:2018 - *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process*
Biological Safety Evaluation iFuse-TORQ Instruments	• ISO 10993-1:2018 - *Biological Evaluation of Medical Devices – Part1: Evaluation and Testing within a Risk Management Process*
Bench Performance Testing – iFuse-TORQ Implant System - Implants	
Bench Testing iFuse-TORQ Implant System	• ASTM F543-17 – *Standard Specification and Test Methods for Metallic Medical Bone Screws* • ASTM F2193-20 - *Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System*
Elemental Analysis iFuse-TORQ Implants	• ASTM F3001-14 – *Standard Specification for Additive Manufacturing Titanium-6-Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion*
Fatigue Testing iFuse-TORQ Implants	• ASTM F2193-20 - *Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System*
Torsion Testing iFuse-TORQ Implants	• ASTM F543-17 – *Standard Specifications and Test Methods for Metallic Medical Bone Screws*
Surface Characteristics and Surface Treatment Performance iFuse-TORQ Implants: Stereological Evaluation of the Porous Layer Static Shear Testing Shear Fatigue Testing Static Tensile Testing Abrasion Properties	 • ASTM F1854-15 - *Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants* • ASTM F1044-05 (2017) - *Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings* • ASTM F1160-14 (2017) - *Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings* • ISO 13179-1:2014 - *Implants for surgery - Plasma-sprayed unalloyed titanium coatings on metallic surgical implants - Part 1: General requirements* • ASTM F1147-05 (2017) - *Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings* • ASTM F1978-18 - *Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser*
MR Compatibility Assessment	• ASTM F2052-15 - *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment* • ASTM F2119-13 - *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants* • ASTM F2182-19e2 - *Standard Test Method for Measurement of Radio Frequency Induced Heating on or Near Passive Implants During Magnetic Resonance Imaging* • ASTM F2213-06 (2011) - *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment* • ASTM F2503 -13 - *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

Test	Standards
Bench Performance Testing -Instruments	
Bench Testing-iFuse-TORQ Implant System - Instruments	• *ASTM F543-17 – Standard Specification and Test Methods for Metallic Medical Bone Screws*
Navigational Instrument Positional Error iFuse-TORQ Instruments	• *ASTM F2554-2018 – Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems*
Navigation Adapter iFuse-TORQ Instruments	N/A
System Validation	
Simulated Use Testing	• ANSI/AAMI HE75:2009/(R) 2018 - *Human factors engineering – Design of medical devices* • EN 62366: 2008, Medical devices – *Application of usability engineering to medical devices (IEC 62366:2007)* • IEC 62366-1: 2015 - *Medical devices – Part 1: Application of usability engineering to medical devices*

IX. CONCLUSION

The SI-BONE iFuse-TORQ Implant System has the same intended use, similar indications for use and technological characteristics as the FDA cleared Medacta International M.U.S.T. Sacral Iliac Screw and Pelvic Trauma System (most recently cleared in K193083 and K171595). The iFuse-TORQ Implant is fabricated from similar materials, manufactured using similar processes, and utilizes similar cleaning and identical sterilization processes as the SI-BONE iFuse-3D Implant (most recently cleared in K193524 and in K162733).

Verification and validation testing provided in the subject premarket notification demonstrates that the iFuse-TORQ Implant System meets the requirements of the product specification for its intended clinical use and is substantially equivalent to the predicate devices.