Deltacor GmbH
% Lucas Tatem
Senior Associate, Regulatory Affairs
Mcra LLC
803 7th Street NW
Washington, District of Columbia 20001

January 19, 2024

Re: K230817
Trade/Device Name: TORPEDO 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: December 26, 2023
Received: December 26, 2023

Dear Lucas Tatem:

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: 2024.01.19 14:07:52 -05'00'

for

Colin O'Neill, M.S.
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K230817

Device Name
TORPEDO Implant System®

Indications for Use *(Describe)*
The TORPEDO Implant System® is intended for sacroiliac fusion for the following indications:
• 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 skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
• Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name:	TORPEDO Implant System®
Manufacturer:	Deltacor GmbH Rudolf-Diesel- Str. 10 D-97440 Werneck, Germany Phone: +49 9722 9220
Contact:	Maximilian Reuss Project Manager Deltacor GmbH Rudolf-Diesel- Str. 10 D-97440 Werneck, Germany Phone: +49 151 1477 9824 Email: Mreuss@deltacor.de
Prepared by:	MCRA, LLC 803 7th Street NW Washington, DC 20001
Date Prepared:	January 19, 2024
Classification:	21 CFR §888.3040, Smooth or threaded metallic bone fixation fastener
Class:	II
Product Codes:	OUR
Primary Predicate:	SI-BONE, Inc. iFuse Implant System (K193524)
Additional Predicate:	Zyga Technology, Inc. SImmetry Sacroiliac Joint Fusion System (K141549)

Indications For Use:
The TORPEDO Implant System® is intended for sacroiliac fusion for the following indications:

- 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 skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

Device Description:
The Deltacor TORPEDO Implant System® consists of canulated spiral-shaped titanium implants (CP Ti Grade 4, ASTM F67) and a placement instrument. The structured surface and special shape of the implant is intended to prevent rotation or displacement of the sacroiliac joint (SI). The cannulated implant can be augmented into the bone in a controlled manner using the laterally inserted holes between the helix. The placement instrument uses a guide wire to achieve precise placement. The TORPEDO Implant System® offers a minimally invasive option for treating SI joint dysfunction.

Primary Predicate Device:
The Deltacor TORPEDO Implant System® is substantially equivalent to the iFuse Implant System (SI-BONE Inc., K193524) primary predicate device with regards to intended use, indications, design, surgical approach, principles of operation, and performance characteristics.

Additional Predicate Device:
The Deltacor TORPEDO Implant System® is substantially equivalent to the SImmetry Sacroiliac Joint Fusion System (K141549) additional predicate device with regards to intended use, indications for use, general principles of operation, and fundamental scientific technology.

Reference Devices:
The Deltacor TORPEDO Implant System® is substantially equivalent to the reference devices with respect to biological safety and mechanical performance testing methodology. The BoneTrust® (K182313) and BoneTrust® Mini Implant System (K200573) are referenced in support of biocompatibility of the subject device.

Performance Testing Summary:
The subject device underwent static torsion testing per ASTM F543-17, static axial pull-out testing per ASTM F543-17, static four-point bending fatigue testing per ASTM F1264-16, and dynamic bending fatigue testing per ASTM F3574-22. Additionally, clinical data including sales and complaints data, clinical literature, and patient-level clinical data were provided to support the safety of the TORPEDO Implant System®.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the predicate devices cited above with respect to intended use, indications, materials, general principles of operation, fundamental technological characteristics, and performance. The subject and primary predicate devices are packaged in similar materials and are both provided sterile (via gamma sterilization). The totality of the non-clinical and clinical data provided in the 510(k) submission demonstrate that the TORPEDO Implant System® is as safe, as effective, and is substantially equivalent to the cited predicate devices.

Conclusion:

The Deltacor TORPEDO Implant System® devices are substantially equivalent to the predicate devices cited above with respect to intended use, indications for use, fundamental technological characteristics, materials, and performance.