October 9, 2019

Parcus Medical, LLC
Paul Vagts
Director of Regulatory Affairs
6423 Parkland Drive
Sarasota, Florida 34243

Re: K191783
Trade/Device Name: Parcus Synd-EZ Ti
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HTN
Dated: September 9, 2019
Received: September 10, 2019

Dear Mr. Vagts:

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,

Laurence D. Coyne, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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)*

K191783

Device Name

Parcus Synd-EZ Ti

Indications for Use *(Describe)*

The Parcus Synd-EZ Ti is intended to be used as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as adjuncts in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

The Parcus Synd-EZ Ti is intended to provide fixation during the healing process following syndesmotic trauma, such as fixation of the syndesmosis (syndesmosis disruptions) in connection with Weber B and Weber C ankle 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.

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510(k) Summary – K191783

510(k) Owner & Submitter:	Parcus Medical, LLC 6423 Parkland Dr Sarasota, FL 34243
Company Contact:	Paul Vagts Phone: (941)755-7965 Fax: (941)755-6543
Date Prepared:	September 9th, 2019
Device Trade Name:	Synd_EZ Ti
Common Name:	Fastener, Fixation, Non-Degradable, Soft Tissue
Device Class:	Class II
Classification Name:	21 CFR 888.3040 - Product Code MBI
Predicate Device:	Parcus GFS Ultimate, K162198, cleared 11/18/16, Arthrex Tightrope™ Syndesmosis Device, K043248, 2/16/2005.

Device Description:

The Parcus Synd-EZ Ti consists of two buttons with suture connecting them and are designed to be used for stabilizing the syndesmosis during healing. Building upon the technology of the Parcus GFS Ultimate, the Synd-EZ Ti is easily adjusted for length and resists elongation without requiring knots to secure the fixation. The device is made from medical grade titanium and UHMWPE suture and is provided sterile.

Intended Use:

The Parcus Synd-EZ Ti is intended to be used as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as adjuncts in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

The Parcus Synd-EZ Ti is intended to provide fixation during the healing process following syndesmotic trauma, such as fixation of the syndesmosis (syndesmosis disruptions) in connection with Weber B and Weber C ankle fractures.

Substantial Equivalence Summary:

The Synd-EZ Ti is very similar to the predicate Parcus Medical GFS Ultimate in that it is comprised of the same materials, intended for the same indications and utilizes similar designs. LAL testing was conducted on a representative device and it was concluded that the Synd-EZ Ti does not raise any additional concerns regarding pyrogenicity.

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Summary Performance Data:

The Synd-EZ Ti was evaluated and testing was conducted on the worst case configurations. Devices were assembled to test blocks and placed in a test fixture. Devices were evaluated for strength and elongation under cycle loading and ultimate failure conditions. Results were compared with test data for the predicate device and demonstrated substantial equivalency.