October 28, 2020

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

Re: K202259
Trade/Device Name: Parcus GFS II and GFS Mini, GFS Naked, GFS Ultimate, GFS BTB, ATLAS, Synd-EZ Ti, Actiflip Naked, Actiflip Cinch, Actiflip Whip, and GFS Ultimate Hip
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: July 31, 2020
Received: August 10, 2020

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,

Laura C. Rose, 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)*

K202259

Device Name

Parcus GFS II and GFS Mini, GFS Naked, GFS Ultimate, GFS BTB, ATLAS, Actiflip Naked, Actiflip Cinch, Actiflip Whip, GFS Ultimate Hip and Synd-EZ Ti.

Indications for Use *(Describe)*

The Parcus GFS II and GFS Mini are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

The Parcus GFS Naked devices are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

The GFS Ultimate devices are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

The GFS BTB devices are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair

The Parcus ATLAS is indicated for adjunct fixation of the 1st and 2nd metacarpals in CMC arthroplasty.

The Parcus Actiflip Naked, Actiflip Cinch, and Actiflip Whip are used for fixation of bone to bone or soft tissue to bone, and is intended as fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in the knee, shoulder, and elbow and may include the following indications: anterior cruciate ligament, posterior cruciate ligament, pectoralis repair (minor/major), biceps tendon repair and reattachment (distal/proximal), acromioclavicular repair, and ulnar collateral ligament reconstruction.

The Parcus GFS Ultimate Hip is used for fixation of soft tissue to bone in the hip and is indicated for ligamentum teres reconstruction.

The Parcus Synd-EZ Ti are 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 are 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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ANIKA

PARCUS MEDICAL, LLC.
Parcus Medical has joined Anika

K202259

510(k) Summary

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:	October 26th, 2020
Device Trade Name:	Parcus GFS II and GFS Mini Parcus GFS Naked Parcus GFS Ultimate Parcus GFS BTB Parcus ATLAS Parcus Synd-EZ Ti Parcus Actiflip Naked, Actiflip Cinch, Actiflip Whip, and GFS Ultimate Hip
Common Name:	Fastener, Fixation, Non-Degradable, Soft Tissue
Device Class:	Class II
Classification Name:	21 CFR 888.3040 - Product Code MBI

Predicate Device:

K133757 (cleared February 4, 2014) – Parcus GFS II and GFS Mini
K152711 (cleared November 20, 2015) – Parcus GFS Naked
K162198 (cleared November 18, 2016) – Parcus GFS Ultimate
K183331 (cleared February 7, 2019) – Parcus GFS BTB
K190375 (cleared April 24, 2019) – Parcus ATLAS
K191783 (cleared October 9, 2019) – Parcus Synd-EZ Ti
K192750 (cleared January 16th, 2020) – Parcus Actiflip Naked, Actiflip Cinch, Actiflip Whip, and GFS Ultimate Hip

Device Description:

The Parcus GFS II, GFS Mini, GFS Naked, GFS Ultimate, GFS BTB, ATLAS, Synd-EZ Ti, Actiflip Naked, Actiflip Cinch, Actiflip Whip, and GFS Ultimate Hip are a range of devices design for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair. Each device is made from a medical grade titanium alloy, Ti-6Al4V ELI, and may also include an UHMWPE polyblend suture component. Each device is provided sterile.

Intended Use:

The Parcus GFS II and GFS Mini are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.
The Parcus GFS Naked devices are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.
The GFS Ultimate devices are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.
The GFS BTB devices are indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.
The Parcus ATLAS is indicated for adjunct fixation of the 1st and 2nd metacarpals in CMC arthroplasty.
The Parcus Actiflip Naked, Actiflip Cinch, and Actiflip Whip are used for fixation of bone to bone or soft tissue to bone, and is intended as fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in the knee, shoulder, and elbow and may include the following indications: anterior cruciate ligament, posterior cruciate ligament, pectoralis repair (minor/major), biceps tendon repair and reattachment (distal/proximal), acromioclavicular repair, and ulnar collateral ligament reconstruction.
The Parcus GFS Ultimate Hip is used for fixation of soft tissue to bone in the hip and is indicated for ligamentum teres reconstruction.
The Parcus Synd-EZ Ti are 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 are 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 Parcus GFS II, GFS Mini, GFS Naked, GFS Ultimate, GFS BTB, ATLAS, Synd-EZ Ti, Actiflip Naked, Actiflip Cinch, Actiflip Whip, and GFS Ultimate Hip are equivalent to the predicate Parcus devices because they are the same devices. No changes from the

existing Parcus Medical devices are proposed except for the inclusion of the MR Conditional parameters into the applicable Instructions for Use. Since the biocompatibility, packaging, shelf-life and sterilization process remain unchanged, no further testing or assessments were needed. LAL testing has been tested on representative samples and it was concluded that the Parcus GFS II, GFS Mini, GFS Naked, GFS Ultimate, GFS BTB, ATLAS, Synd-EZ Ti, Actiflip Naked, Actiflip Cinch, Actiflip Whip, and GFS Ultimate Hip do not raise any additional concern.

Summary Performance Data:

The Parcus GFS II, GFS Mini, GFS Naked, GFS Ultimate, GFS BTB, ATLAS, Synd-EZ Ti, Actiflip Naked, Actiflip Cinch, Actiflip Whip, and GFS Ultimate Hip were evaluated for use in the MR Environment and were determined to fit the definition of MR Conditional. These titanium implants were evaluated based on the FDA Guidance Document – *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* and applicable ASTM standards, and worst-case devices were selected for testing. Devices were tested for magnetically induced force, magnetically induced torque, heating by RF fields, and image artifact. The results of this testing have been used to establish the MR system conditions suitable for safe use when these implants are present.

The Parcus GFS II, GFS Mini, GFS Naked, GFS Ultimate, GFS BTB, ATLAS, Synd-EZ Ti, Actiflip Naked, Actiflip Cinch, Actiflip Whip, and GFS Ultimate Hip have been determined to be substantially equivalent to the predicate devices stated above.