January 16, 2020

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

Re: K192750
Trade/Device Name: AcTiFlip Naked, AcTiFlip Cinch, AcTiFlip WHIP, 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: October 18, 2019
Received: October 21, 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,

Laura C. Rose, Ph.D.
Acting 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)*

K192750

Device Name

AcTiFlip Naked, AcTiFlip Cinch, AcTiFlip WHIP, GFS Ultimate Hip

Indications for Use *(Describe)*

The Parcus AcTiFlip is 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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Surgical Innovation | Customer Driven

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:	January 15, 2020

Device Trade Name:	AcTiFlip Naked, AcTiFlip Cinch, AcTiFlip w/ WHIP, 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:

Parcus GFS II and GFS Mini, K133757, cleared 2/4/14; GFS Naked, K152711, cleared 12/10/15, Parcus GFS Ultimate, K162198, cleared 11/18/16; and Arthrex K190288, cleared 9/13/19.

Device Description:

The Parcus AcTiFlip and GFS Ultimate Hip devices are designed for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair. The devices are made from medical grade titanium and UHMWPE suture and are provided sterile.

Intended Use:

The Parcus AcTiFlip is 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.

PARCUS MEDICAL, LLC.

Surgical Innovation | Customer Driven

Substantial Equivalence Summary:

The Parcus AcTiFlip Naked, AcTiFlip Cinch and AcTiFlip w/ WHIP devices are very similar to the predicate devices in that they are comprised of the same materials, intended for the same indications and utilize similar designs. The titanium button used by the AcTiFlip devices is very similar in design to that of the GFS Naked devices. The suture portion of the AcTiFlip Cinch builds upon the technology utilized by the GFS Ultimate. The suture used by the AcTiFlip w/ WHIP is manufactured by the same supplier as all other suture components and functions in a comparable manner.

The Parcus GFS Ultimate Hip device is very similar to the predicate Parcus Medical GFS Ultimate in that they are comprised of the same materials, intended for the same indications and utilize similar designs. The only difference is the use of an inserter for placement of the titanium button in the hip.

All AcTiFlip Naked, AcTiFlip Cinch, AcTiFlip w/ WHIP and GFS Ultimate Hip are very similar to the Arthrex predicate in that they are all capable of achieving fixation using either extramedular or intramedular fixation.

LAL testing was conducted on a representative device comprised of the same materials manufactured in a comparable fashion and it was concluded that both the Parcus AcTiFlip and the GFS Ultimate Hip devices meet endotoxin limit specifications and do not raise any additional concerns regarding pyrogenicity.

Summary Performance Data:

The Parcus AcTiFlip and GFS Ultimate Hip devices were 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.