DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 18, 2016

Parcus Medical, LLC
Mr. Paul Vagts
RA/QA Manager
6423 Parkland Drive
Sarasota, Florida 34243

Re: K162198
Trade/Device Name: GFS Ultimate
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: October 21, 2016
Received: October 24, 2016

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K162198**

Device Name: GFS Ultimate

Indications for Use:

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

Prescription Use __X__ AND/OR Over the Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Submitter: Parcus Medical, LLC
6423 Parkland Dr
Sarasota, FL 34243

Company Contact: Paul Vagts
Phone: (941)755-7965
Fax: (941)755-6543

Date Prepared: November 17th, 2016

Device Trade Name: GFS Ultimate

Common Name: Ligament Retention Device

Device Class: Class II

Classification Name: Fastener, Fixation, Non-Degradable, Soft Tissue 21 CFR 888.3040 - Product Code MBI

Predicate Device: The predicate devices are the Parcus GFS, K090923, cleared June 30, 2009.

Device Description:

The GFS Ultimate 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. The GFS Ultimate devices are provided sterile.

Intended Use:

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

Substantial Equivalence Summary:

The GFS Ultimate are very similar to the predicate Parcus Medical GFS devices in that they are comprised of the same materials, are manufactured in comparable fashion, are intended for the same indications and utilize similar designs. LAL testing was conducted on the GFS Ultimate and it was concluded that the GFS Ultimate does not raise any additional concerns regarding pyrogenicity. While the GFS Ultimate features an adjustable loop length, testing has shown that this does not raise any concerns regarding the safety or efficacy of the device.

Summary Performance Data:

The GFS Ultimate were evaluated and testing was conducted on the worst case configurations. Devices were assembled per the DFU 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.