



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

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

November 20, 2015

Re: K152711

Trade/Device Name: Parcus GFS Naked  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class III  
Product Code: MBI  
Dated: October 21, 2015  
Received: October 22, 2015

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 Parts 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" (21CFR 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 yours,

**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): K152711

Device Name: Parcus GFS Naked

### Indications for Use:

The Parcus GFS Naked 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



## 510(k) Summary

<b>Submitter:</b>	Parcus Medical, LLC 6423 Parkland Dr Sarasota, FL 34243
<b>Company Contact:</b>	Paul Vagts Phone: (941)755-7965 Fax: (941)755-6543
<b>Date Prepared:</b>	September 17, 2015
<b>Device Trade Name:</b>	Parcus GFS Naked
<b>Common Name:</b>	Ligament Retention Device
<b>Device Class:</b>	Class II
<b>Classification Name:</b>	Fastener, Fixation, Non-Degradable, Soft Tissue 21 CFR 888.3040 - Product Code MBI
<b>Predicate Device:</b>	The predicate devices are the GFS II Standard, GFS II Large and GFS Mini, K133757, February 4, 2014.

### Device Description:

The Parcus GFS Naked 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 are provided sterile.

### Intended Use:

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

### Substantial Equivalence Summary:

The GFS Naked are very similar to the predicate Parcus Medical GFS, GFS II and GFS Mini devices in that they are comprised of the same materials, are intended for the same indications and utilize similar designs. While the GFS Naked are offered in both smaller and larger sizes, testing has shown that this does not raise any concerns regarding the safety or efficacy of the device.

### Summary Performance Data:

The GFS Naked were evaluated and testing was conducted on the worst case configurations. Devices were assembled with suture 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.