February 22, 2021

Parcus Medical, LLC
Alejandra Anderson
QA Specialist
6423 Parkland Drive
Sarasota, Florida 34243

Re: K202662/S001
Trade/Device Name: Parcus Titanium Interference Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: January 5, 2021
Received: January 19, 2021

Dear Alejandra Anderson:

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)*
K202662

Device Name

Parcus Titanium Interference Screw

Indications for Use *(Describe)*
The Parcus Titanium Interference Screw is indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair

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) Number: K202662
Received Date: 09/14/2020

510(k) Summary

510(k) Owner & Submitter: Parcus Medical, LLC
6423 Parkland Dr
Sarasota, FL 34243

Company Contact: Alejandra Anderson
Phone: (941)755-7965
Fax: (941)755-6543

Date Prepared: August 21st, 2020

Device Trade Name:	Parcus Titanium Interference Screws
Common Name:	Interference Screws
Device Class:	Class II
Classification Name:	21 CFR 888.3040 – Product Code MBI

Predicate Device:
Parcus Titanium Interference Screws, K083619, Cleared March 6, 2009.

Device Description:
The Parcus Titanium Interference Screw is a cannulated, threaded, tapered fastener for use in interference fixation of ligaments and tendons in patients requiring ligament or tendon repair. The device is made from a Titanium alloy, Ti-6Al-4V ELI (ASTM F136) and is available in sizes ranging from 7-12mm in diameter and 20-35mm in length.

Intended Use:
The Parcus Titanium Interference Screw is indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

Substantial Equivalence Summary:
The Parcus Titanium Interference Screw is equivalent to the predicate Parcus Titanium Interfere Screws because they are the exact same device. No changes from the existing device are proposed with the exception of the inclusion of the MR Conditional parameters into the Instructions for Use. LAL testing has been tested on the Parcus Titanium Interference Screws and it was concluded that the Parcus Titanium Interference Screws do not raise any additional concerns regarding pyrogenicity.

Summary Performance Data:
The pull-out strength and insertion torque were measured for the smallest (7mm) and largest (12mm) Parcus Titanium Interference Screws as well as an intermediate size. As described above, no changes to the physical device are being made and therefore additional side by side comparisons were not deemed necessary. Based on the performance data included with the submission of K083619, the results of the insertion torque testing and pullout force demonstrated that there were no significant differences between the Parcus Titanium Interference Screw and the competitive devices.