DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 2, 2017

Parcus Medical, LLC
Mr. Paul Vagts
Director of Regulatory Affairs/Quality Assurance
6423 Parkland Drive
Sarasota, Florida 34243

Re: K170877
Trade/Device Name: Parcus SLiK Fix Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: March 21, 2017
Received: March 24, 2017

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170877

Device Name
Parcus SLiK Fix Screw

Indications for Use *(Describe)*
The Parcus SLiK Fix Screw is intended for use in soft tissue to bone reattachment procedures. Specific indications are the following:

Shoulder: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.

Elbow: Tennis Elbow Repair, Biceps Tendon Reattachment.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.

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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PARCUS MEDICAL, LLC.

510(k) Summary

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

Company Contact:
Joan Rubendall
Phone: (941)755-7965
Fax: (941)755-6543

Date Prepared: May 30, 2017

Device Trade Name: Parcus SLiK Fix Screw

Common Name: Interference Screw/Suture Anchor

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 PEEK CF Interference Screws (K091093, cleared 9/30/09), the Parcus 35/45 Knotless PEEK CF Push-In Suture Anchors (K113730, cleared 1/17/12) and the Parcus Twist PEEK Suture Anchors (K120942, cleared 4/20/12).

Device Description:

The Parcus SLiK Fix Screws are designed for use in the attachment of soft tissue to bone. The screws are made from either Polyetheretherketone (PEEK) or Carbon Fiber Reinforced Polyetheretherketone (PEEK CF) and utilize a PEEK washer for graft/suture positioning. The Parcus SLiK Fix Screws are provided sterile.

Intended Use:

The Parcus SLiK Fix Screws are intended for use in soft tissue to bone reattachment procedures. Specific indications are the following:

Shoulder	Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair.
Knee	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.
Foot/Ankle	Lateral Stabilization, Medial Stabilization, Midfoot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.
Elbow	Tennis Elbow Repair, Biceps Tendon Reattachment.
Hand/Wrist	Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.

Call 1.941.755.7965 PARCUSMEDICAL.COM Fax 1.941.755.6543
6423 Parkland Drive, Sarasota, FL 34243

PARCUS MEDICAL, LLC.

Substantial Equivalence Summary:

The Parcus SLiK Fix Screws are very similar to the predicate Parcus Medical devices in that they are comprised of the same materials, are manufactured in comparable fashions, and are intended for the same indications. While the SLiK Fix Screws are shorter that the existing Parcus Interference Screws and larger in diameter than existing Parcus Suture Anchors, testing has shown that the combination of these features does not raise any concerns regarding the safety or efficacy of the device. LAL testing was conducted on a comparable device and it was concluded that the SLiK Fix Screws do not raise any addition concerns regarding pyrogenicity.

Summary Performance Data:

The SLiK Fix Screws 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. In addition, insertion torque and failure torque values were determined in order to ensure the necessary safety factor exists during insertion of the device. Results were compared with test data for the predicate devices and demonstrated substantial equivalency.

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