July 23, 2020

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

Re: K201083
Trade/Device Name: Parcus V-lox Titanium Suture Anchors, Parcus Miti Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: May 26, 2020
Received: May 29, 2020

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,

for

Laura 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)*

K201083

Device Name

Parcus Miti and V-lox Titanium Suture Anchors

Indications for Use *(Describe)*

The Parcus Miti Suture Anchors are indicated for attachment of soft tissue to bone. This product is intended for the following indications:

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.

The Parcus V-lox™ Titanium Suture Anchors are indicated for attachment of soft tissue to bone. This product is intended for the following indications:

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.
Hip:	Acetabular Labral 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.

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."

ANIKA

PARCUS MEDICAL, LLC.
Parcus Medical has joined Anika

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:	July 21st, 2020
Device Trade Name:	• Parcus Miti Suture Anchors, • Parcus V-lox Titanium Suture Anchors
Common Name:	Suture Anchors
Device Class:	Class II
Classification Name:	21 CFR 888.3040 - Product Code MBI
Predicate Device:	• K090075 (cleared March 6, 2009) – Parcus V-lox Titanium Suture Anchors, • K111000 (cleared July 28, 2011) – Parcus Miti Suture Anchors

Device Description:

The Parcus Miti and V-lox Titanium Suture Anchors are a family of threaded, tapered fasteners for use in attachment of soft tissue to bone. The device is made from a Titanium alloy, Ti-6Al-4V ELI (ASTM F136). It comes preloaded with either one, two, or three strands of sutures between 3-0 and #2 in size or suture tape between 1.4mm and 2.0mm wide. The suture and suture tape is available either with or without attached needles, and is provided sterile and attached to a driver. The Miti Suture Anchor is available in diameters of 2.0mm, 2.5mm and 3.5mm and the V-lox Titanium Suture Anchor is available in diameters of 4.5mm, 5.0mm, 5.5mm and 6.5mm.

Intended Use:

The Parcus Miti Suture Anchors are indicated for attachment of soft tissue to bone. This product is intended for the following indications:

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,

ANIKA

PARCUS MEDICAL, LLC.
Parcus Medical has joined Anika

	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.

The Parcus V-lox™ Titanium Suture Anchors are indicated for attachment of soft tissue to bone. This product is intended for the following indications:

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.
Hip:	Acetabular Labral Repair

Substantial Equivalence Summary:

The Parcus Miti and V-lox Titanium Suture Anchors are equivalent to the predicate Parcus Miti and V-lox Titanium Suture Anchors because they are the same devices. No changes from the existing device are proposed with the exception of the inclusion of the MR Conditional parameters into the applicable Instructions for Use. LAL testing has been tested on representative samples and it was concluded that neither the Miti nor the V-lox Titanium Suture Anchors raise any additional concerns regarding pyrogenicity.

ANIKA

PARCUS MEDICAL, LLC.
Parcus Medical has joined Anika

Summary Performance Data:

The Parcus Miti and V-lox Titanium Suture Anchors were evaluated for use in the MR Environment and were determined to fit the definition of MR Conditional. These titanium implants were evaluated based on the FDA Guidance Document – *Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment* and applicable ASTM standards, and worst-case devices were selected for testing. Devices were tested for magnetically induced force, magnetically induced torque, heating by RF fields, and image artifact. The results of this testing have been used to establish the MR system conditions suitable for safe use when these implants are present.

PARCUS MEDICAL, LLC.
6423 Parkland Drive
Sarasota, FL 34243
www.parcusmedical.com

1-941-755-7965
customerservice@parcusmedical.com