October 6, 2021

Parcus Medical LLC.
Calen Southern, MS
Senior Specialist, Regulatory Affairs
6423 Parkland Drive
Sarasota, Florida 34243

Re: K212739
Trade/Device Name: ActiFlip
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: August 25, 2021
Received: August 30, 2021

Dear Calen Souther:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212739

Device Name
ActiFlip

Indications for Use *(Describe)*

The Parcus Actiflip is used for fixation of bone to bone or soft tissue to bone, and is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in the knee, shoulder, and elbow and may include the following indications: anterior cruciate ligament, posterior cruciate ligament, pectoralis repair (minor/major), biceps tendon repair and reattachment (distal/proximal), acromioclavicular repair, and ulnar collateral ligament reconstruction.

The Parcus ActiFlip is also intended for fixation of suture (soft tissue) to bone in the foot and ankle for midfoot reconstruction and hindfoot reconstruction with the following procedures: FHL Tendon Transfer, FDL Tendon Transfer, Posterior Tibialis Tendon Transfer, Anterior Tibialis Tendon Transfer.

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."

510(k) Summary

The information contained herein is being provided in accordance with the requirements of 21CFR 807.92(c).

Date Prepared:	October 6, 2021
Applicant:	Parcus Medical, LLC. 6423 Parkland Dr. Sarasota, FL 34243
Official Correspondent:	Calen Souther, MS Senior Specialist, Regulatory Affairs Phone: (770) 616-1389 Email: csouther@anika.com
Trade/Proprietary Name:	ActiFlip
Common Name:	Fastener, Fixation, Non-degradable, Soft Tissue
Regulation Name:	Smooth or threaded metallic bone fixation fastener
Device Class:	Class ll
Regulation Number:	21 CFR 888.3040
Product Code:	MBI
Predicate Device Information:	ActiFlip - K192750 (cleared January 16, 2020), K202259 (cleared October 28, 2020) Miti Suture Anchors – K111000 (cleared July 28, 2011), K201083 (cleared July 23, 2020)
Reason for 510(k) submission:	The purpose of this Traditional 510(k) is to obtain clearance for indications of soft tissue fixation in the foot and ankle for ActiFlip.
Description of Device:	The Parcus ActiFlip device consists of a titanium implantable button that is mounted onto an inserter shaft that allows for placement and deployment of the button. ActiFlip is available in three (3) configurations, with or without UHMWPE suture – Naked (without suture), CINCH, WHIP.
Indications for Use:	The Parcus ActiFlip is used for fixation of bone to bone or soft tissue to bone, and is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in the knee, shoulder, and elbow and may include the following indications: anterior cruciate ligament, posterior cruciate ligament, pectoralis repair (minor/major), biceps tendon repair and reattachment (distal/proximal), acromioclavicular repair, and ulnar collateral ligament reconstruction.

The Parcus ActiFlip is also intended for fixation of suture (soft tissue) to bone in the foot and ankle for midfoot reconstruction and hindfoot reconstruction with the following procedures: FHL Tendon Transfer, FDL Tendon Transfer, Posterior Tibialis Tendon Transfer, Anterior Tibialis Tendon Transfer.

Device Characteristics

	ActiFlip	**ActiFlip**	**Miti Suture Anchor**
510(k) clearance	Subject Device	K192750, K202259	K111000, K201083
Manufacturer	Parcus Medical	Parcus Medical	Parcus Medical
Common Name	Fastener, Fixation, Non-degradable, Soft tissue	Fastener, Fixation, Non-degradable, Soft tissue	Fastener, Fixation, Non-degradable, Soft Tissue
Regulation	21 CFR 888.3040	21 CFR 888.3040	21 CFR 888.3040
Class Name	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener	Smooth or threaded metallic bone fixation fastener
Class	Class ll	Class ll	Class ll
Product Code	MBI	MBI	MBI
Indication for Use	The Parcus ActiFlip is used for fixation of bone to bone or soft tissue to bone, and is intended as a fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in the knee, shoulder, and elbow and may include the following indications: anterior cruciate ligament, posterior cruciate ligament, pectoralis repair(minor/major), biceps tendon repair and reattachment (distal/proximal), acromioclavicular repair, and ulnar collateral ligament reconstruction. The Parcus ActiFlip is also intended for fixation of suture (soft tissue) to bone in the foot and ankle for midfoot reconstruction and hindfoot reconstruction with the following procedures: FHL Tendon Transfer, FDL Tendon Transfer, Posterior Tibialis Tendon Transfer, Anterior Tibialis Tendon Transfer.	The Parcus ActiFlip is used for fixation of bone to bone or soft tissue to bone, and is intended as fixation post, a distribution bridge, or for distributing suture tension over areas of ligament or tendon repair in the knee, shoulder, and elbow and may include the following indications: anterior cruciate ligament, posterior cruciate ligament, pectoralis repair (minor/major), biceps tendon repair and reattachment (distal/proximal), acromioclavicular repair, and ulnar collateral ligament reconstruction.	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.
Material	Medical grade titanium, UHMWPE suture	Medical grade titanium, UHMWPE suture	Medical grade titanium, UHMWPE suture
Single use only	Yes	Yes	Yes
Sterility	Sterile, EO	Sterile, EO	Sterile, EO
Shelf-life	5-years	5-years	5-years

Non-clinical Testing

Performance was established based on acceptance criteria with the rationale that the new specific indications of FHL Tendon Transfer, FDL Tendon Transfer, Posterior Tibialis Tendon Transfer, and Anterior Tibialis Tendon Transfer do not introduce a worst-case for mechanical performance of the subject device.

Clinical Data

Clinical testing was deemed not necessary for demonstrating substantial equivalence to the predicate devices.

Conclusion

The Parcus ActiFlip device is substantially equivalent to the predicate devices in which the basic design features, materials, packaging, sterility, shelf life, and intended uses are the same.

The data and comparison of the technological characteristics within this submission demonstrate that the subject device is substantially equivalent to the predicate devices when used in accordance with the indications for use.