January 30, 2025

Abanza Tecnomed S.l.
℅ Jessica Czamanski
Regulatory Consultant
Presicion Life Science Partners
300 Creek View Road
Newark, Delaware 19711

Re: K243712
Trade/Device Name: WasherCap™ Mini Fixation System (Model 45)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 2, 2024
Received: December 2, 2024

Dear Jessica Czamanski:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferriera, MS, RAC
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243712

Device Name

WasherCap™ Mini Fixation System (Model 45)

Indications for Use *(Describe)*

WasherCap™ Mini Fixation System is intended for fixation of suture/tape (soft tissue) to bone in the shoulder, knee and hand/wrist, in skeletally mature pediatric and adult patients for the following procedures:

• Knee:
- Meniscal root repair: using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes.

- Meniscal transplant: using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes.

- ACL/PCL Repair: using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes.

- ACL Reconstruction: only with WasherCap™ Mini Fixation System 4.5mm size and using 2 non-absorbable UHMWPE 1.4mm tapes or 1 non-absorbable UHMWPE 2.2mm tape.

• Shoulder:
- Rotator Cuff Repair: using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes.

• Hand/Wrist:
- Triangular fibrocartilage complex (TFCC): only with WasherCap™ Mini Fixation System 3.5mm size and using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes.

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.

K243712 – 510(k) Summary

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92.

I. Submitter

Submitter Name:	Abanza Tecnomed, S.L.
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	Spain
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Date of Preparation:	January 30, 2025

II. Application Correspondent

Contact's Name:	Precision Life Sciences Partners LLC
Contact Person:	Jessica Czamanski
Address:	300 Creek View Road
	Newark, DE, 19711
	USA
Telephone:	(754) 422-9101
Email:	jczamanski@plsp.pro

III. Device

Trade Name:	WasherCap™ Mini Fixation System (Model 45)
Common Name:	Non-Degradable Soft Tissue Fixation Device
Classification Name:	Fastener, Fixation, Nondegradable, Soft Tissue
Product Classification:	Class II
Regulation Number:	21 CFR 888.3040
Product Code:	MBI

IV. Predicate Devices

Primary Predicate

Manufacturer:	Arthrex
Device Name:	Arthrex SwiveLock Suture Anchor
510(k) Number:	K203495

Product Classification:	Class II
Regulation Number:	21 CFR 888.3030
Product Code:	MAI, MBI

Additional Predicates:

Manufacturer:	Parcus Medical, LLC
Device Name:	X-Twist PEEK Suture Anchor
510(k) Number:	K221135
Product Classification:	Class II
Regulation Number:	21 CFR 888.3040
Product Code:	MBI

Manufacturer:	Abanza Tecnomed, S.L.
Device Name:	WasherCap™ Fixation System
510(k) Number:	K212197
Product Classification:	Class II
Regulation Number:	21 CFR 888.3040
Product Code:	MBI

V. Device Description

The WasherCap™ Mini Fixation System consists of an implantable device, a handled inserter, a handled screwdriver, a drill guide, a drill bit and a suture threader. The WasherCap™ Mini implantable device is pre-loaded on the handled inserter with the suture threader.

The drill guide and the drill bit should be used to perform a drilling guided specifically to the angulation necessary to create the bone socket where the screw of the implant should be located. The suture/tape is passed through the cap with the suture threader and the screw is threaded with the handled screwdriver, setting the tension of the suture/tape.

The WasherCap™ Mini Fixation System is provided sterile and individually packaged. All components are for single use only.

The WasherCap™ Mini Fixation System is available in different sizes and should be implanted following the corresponding surgical procedure.

VI. Intended Use

The WasherCap™ Mini Fixation System is intended for fixation of suture/tape (soft tissue) to bone.

VII. Indications for Use

WasherCap™ Mini Fixation System is intended for fixation of suture/tape (soft tissue) to bone in the shoulder, knee and hand/wrist, in skeletally mature pediatric and adult patients for the following procedures:

- Knee:
  - Meniscal root repair: using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes.
  - Meniscal transplant: using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes.
  - ACL/PCL Repair: using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes.
  - ACL Reconstruction: only with WasherCap™ Mini Fixation System 4.5mm size and using 2 non-absorbable UHMWPE 1.4mm tapes or 1 non-absorbable UHMWPE 2.2mm tape.
- Shoulder:
  - Rotator Cuff Repair: using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes.
- Hand/Wrist:
  - Triangular Fibrocartilage complex (TFCC): only with WasherCap™ Mini Fixation System 3.5mm size and using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes.

VIII. Comparison of Technological Characteristics

The proposed WasherCap™ Mini Fixation System is similar to its primary predicate (K203495) in that both fixate sutures/tapes to bone via a threaded component which holds the suture/tape in place. The main difference in technological characteristics is that the proposed WasherCap™ Mini Fixation System is composed of PEEK and titanium alloy, while the primary predicate (K203495) is only composed of PEEK, which leads to a different type of surface interfacing with the bone. Additionally, the threaded titanium component of the subject device is mainly screwed onto the PEEK component which is implanted into the bone and partially screwed into the bone, while the SwiveLock predicate device's threaded PEEK component is entirely screwed into the bone. While both subject and predicate devices are preloaded onto their respective insertion tools, the predicate device is also pre-loaded with sutures that may or may not be used for fixation, while the subject device is not preloaded with sutures.

The following table (**Table 1**) provides an overview of the comparison of the indications and technological characteristics of the subject and primary predicate device:

Table 1 Comparison of Subject and Primary Predicate Device

Product Features	Proposed Abanza Tecnomed's WasherCap Mini Fixation System (K243712)	Primary Predicate Arthrex's Arthrex SwiveLok Anchor (K203495)	Substantial Equivalence Determination
Design/ Technological Characteristics	- Components: cap and threaded body - Preloaded onto insertion tool - Not preloaded with sutures 	- Components: tip and threaded body - Preloaded onto insertion tool - Preloaded with sutures that may be implanted 	The subject device is composed of a cap and screw that act together to fixate the suture/tape to the bone with the threaded metallic component mainly screwed onto the peek component and partially screwed into the bone. The threaded component of the predicate device is entirely screwed into the bone. The differences in design/technological characteristics did not lead to different questions for safety and effectiveness. Therefore, the devices are substantially equivalent.
Classification	Class II	Same	Substantially equivalent
Product Code	MBI	MAI, MBI	Substantially equivalent
Indications for Use	WasherCap™ Mini Fixation System is intended for fixation of suture/tape (soft tissue) to bone in the shoulder, knee and hand/wrist, in skeletally mature pediatric and adult patients for the following procedures: • Knee: - Meniscal root repair: using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes. - Meniscal transplant: using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes. - ACL/PCL Repair: using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes. - ACL Reconstruction: only with WasherCap™ Mini Fixation System 4.5mm size and using 2 non-absorbable UHMWPE 1.4mm tapes or 1 non-absorbable UHMWPE 2.2mm tape. • Shoulder:	The Arthrex SwiveLock Anchor is intended for fixation of suture (soft tissue) to bone in the shoulder, foot/ankle, knee, hand/wrist, elbow, and hip in skeletally mature pediatric and adult patients for the following procedures: - **Shoulder: Rotator Cuff Repair,** Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Capsulolabral Reconstruction, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulo labral Reconstruction. - **Knee**: **Anterior Cruciate Ligament Repair** (4.75- 5.5 SwiveLock Only), Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis, Quadriceps Tendon Repair (4.75 SwiveLock C Only), **Meniscal Root Repair** (4.75 SwiveLock C Only), Secondary or adjunct fixation for **ACL/PCL reconstruction or repair** (4.75-5.5 SwiveLock only), MPFL Repair/Reconstruction (3.9 SwiveLock Only)	The indications for use of the primary predicate device include additional anatomical sites which have not been validated for the subject device, such as hip, foot and ankle, and elbow applications. Both subject and predicate device indications include applications for the knee, shoulder, and hand/wrist, where the predicate exceeds the indications of the subject device for these anatomical sites. Therefore, the indications for the subject device do not raise new questions for safety or effectiveness and the devices are substantially equivalent.

Product Features	Proposed Abanza Tecnomed's WasherCap Mini Fixation System (K243712)	Primary Predicate Arthrex's Arthrex SwiveLok Anchor (K203495)	Substantial Equivalence Determination
	- Rotator Cuff Repair: using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes. • Hand/Wrist: - TFCC: only with WasherCap™ Mini Fixation System 3.5mm size and using non-absorbable UHMWPE USP 2-0 sutures or non-absorbable UHMWPE 1.4-2.2mm tapes.	- Hand/Wrist: Scapholunate Ligament Reconstruction and Ulnar/Radial Collateral Ligament Reconstruction - Elbow: Biceps Tendon Reattachment, Ulnar/Radial Collateral Ligament Reconstruction, and Lateral Epicondylitis repair - Hip: Capsular Repair, Acetabular labral repair, Gluteus Medius Repair (4.75 - 5.5 mm PEEK SwiveLock suture anchors only), and Proximal Hamstring Repair (4.75 - 5.5 mm PEEK SwiveLock suture anchors only). - Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Mid-foot Reconstruction, Metatarsal Ligament/Tendon Repair, and Bunionectomy	

IX. Sterilization

There are no differences in the sterilization process between the subject and primary predicate device as both are sterilized via Ethylene Oxide.

X. Performance Data

Bench testing was performed on the subject device to evaluate cyclic loading and elongation, insertion, interconnection, and bone anchor pullout force. Bench testing was performed on the subject device and compared to the predicate device: cyclic loading and elongation, and bone anchor pullout force. The results of the testing met the defined acceptance criteria and were assessed against the results obtained with the predicate devices to determine substantial equivalence for design and performance.

Final devices were subjected to Bacterial endotoxin testing per EP 2.6.14/USP <85> to demonstrate that the device meets pyrogen limit specifications.

Performance Testing – Animal

This submission does not include any animal performance testing. It was determined that no such testing is required to demonstrate substantial equivalence.

Performance Testing – Clinical

This submission does not include any clinical performance testing. It was determined that no such testing is required to demonstrate substantial equivalence.

XI. Conclusion

The proposed WasherCap™ Mini Fixation System has the same intended use and operating principle, the primary predicate device. Although the indications for use are different, the indications for the primary predicate exceed those for the proposed WasherCap™ Mini Fixation System. Performance testing was completed on both the subject and primary predicate device and results demonstrated equivalence. The differences in technological characteristics and materials did not raise new questions of safety or effectiveness. Therefore, the information provided in this submission demonstrated that the subject device, WasherCap™ Mini Fixation System, is substantially equivalent to its predicate, Arthrex SwiveLock Anchor K203495.