February 25, 2025

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

Re: K250238
Trade/Device Name: WasherCap™ Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: January 24, 2025
Received: January 27, 2025

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,

Thomas Mcnamara -S

For: Christopher Ferreira, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250238

Device Name

WasherCap™ Fixation System

Indications for Use *(Describe)*

WasherCap™ Fixation System is intended for fixation of soft tissue grafts, including tendons and ligaments, during surgical procedures such as in Anterior Cruciate Ligament (ACL) reconstruction of the knee.

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.

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WahserCap™ Fixation System – 510(k) Summary

I. Submitter

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Date of Preparation:	January 24, 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
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III. Device

Trade Name:	WasherCap™ Fixation System
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 Device

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™ Fixation System is an implantable non-active device consisting of three components: the washer, the cap, and the screw. All components building the WasherCap™ Fixation System are made of high-quality biocompatible materials, with a long-existence use in terms of human safety and patient's clinical performance.
The Washer and the Cap are made from non-degradable organic thermoplastic polymer biomaterial, so-called Polietheretherketone (PEEK by Invibio™ Biomaterial Solutions in accordance with ASTM 2026) and the Screw is made from implantable degree Titanium Alloy (Ti-6Al- 4V ELI) in accordance with ISO 5832-3 and ASTM F136 standards.
To achieve correct implantation and use of the device, this device requires specific accessories: WasherCap™ Instrument Set. The required accessories are product- specific reusable surgical instruments that have been designed for the implantation of the WasherCap™ Fixation System. Use of the WasherCap™ Instrument Set will ensure the surgical procedure, and the use of the WasherCap™ Fixation System are carried out in an appropriate manner.

VI. Intended Use

The WasherCap™ Fixation System is intended for fixation of soft tissue grafts to bone.

VII. Indications for Use

WasherCap™ Fixation System is intended for fixation of soft tissue grafts, including tendons and ligaments, during surgical procedures such as in Anterior Cruciate Ligament (ACL) reconstruction of the knee.

VIII. Comparison of Technological Characteristics

The proposed WasherCap™ Fixation System is identical to its predicate, except for a 1mm difference which will allow compatibility with the full range of tendon grafts used in ACL reconstruction surgery, which spans 6mm – 11mm. The subject device includes accessories sized appropriately to effectively use the 11mm implant.

All materials and manufacturing processes are identical to those used for the predicate.

IX. Sterilization

There are no differences in the sterilization process between the subject and predicate device.

X. Performance Data

All performance data for the WasherCap™ Fixation System was obtained using the same validated methodology used in the predicate submission (K212197).

Performance Testing – Bench

Mechanical testing verifications were performed on the proposed WasherCap™ Fixation System 11mm implant to ensure device performance was identical to that of the predicate (K212197). Testing was performed using the same acceptance criteria and protocols used in the predicate submission. The proposed device was found to be substantially equivalent in performance compared to its predicate.

Biocompatibility

There is no change in materials or manufacturing of the WasherCap™ Fixation System. The biocompatibility data in the predicate submission (K212197) support the subject device.

Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical safety and electromagnetic compatibility have not been evaluated.

Software Verification and Validation

The device does not contain software/firmware.

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™ Fixation System has the same intended use, indications for use, operating principle, fundamental technology, materials, and manufacturing as the predicate device. Additional testing was performed to ensure performance of the proposed 11mm implant and

associated instruments is identical to the predicate, and that the addition of the new size does not introduce new questions for safety and effectiveness. The information provided in this submission demonstrated that the subject device, WasherCap™ Fixation System, is substantially equivalent to its predicate, WasherCap™ Fixation System K212197.