January 6, 2026

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

Re: K253618
Trade/Device Name: QuadLock™ 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: October 30, 2025
Received: November 18, 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253618

Please provide the device trade name(s).

QuadLock™ Fixation System

Please provide your Indications for Use below.

The QuadLock™ Fixation System is intended for fixation of suture/tape (soft tissue) to bone during surgical procedures, in skeletally mature pediatric and adult patients for the following indications for use:

• Knee:

- ACL/PCL Repair: using non-absorbable UHMWPE USP #2 sutures or larger, or non-absorbable UHMWPE 1.4mm tapes or larger.

- ACL Reconstruction: using non-absorbable UHMWPE USP #2 sutures or larger, or non-absorbable UHMWPE 1.4mm tapes or larger.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

QUADLOCK™ FIXATION SYSTEM – 510(k) SUMMARY

I. Submitter

Submitter Name:	Abanza Tecnomed, S.L.
Contact Person:	Andrea Larrañaga Regulatory Affairs Director
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Date of Preparation:	October 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
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III. Device

Trade Name:	QuadLock™ 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

Predicate Device:

Manufacturer:	Abanza Tecnomed, S.L.
Device Name:	WasherCap™ Mini Fixation System
510(k) Number:	K243712
Product Classification:	Class II
Regulation Number:	21 CFR 888.3040
Product Code:	MBI

Reference 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

QuadLock™ Fixation System is a medical device designed for fixation of suture and/or tape (soft tissue) to bone during surgical procedures.

QuadLock™ Fixation System is a medical device comprised of an implantable device supplied with specific single-use surgical accessories to facilitate its implantation. The implant component consists of a PEEK Cap and a Titanium Alloy Screw. The Cap component is inserted into a bone tunnel in a press fit manner through which the sutures and/or tape are threaded. The Screw component screws onto the Cap, securing the sutures/tapes in place in ACL/PCL repairs or ACL reconstruction surgery.

QuadLock™ Fixation System is currently available in 3 different sizes: 9 mm, 10mm and 11mm. QuadLock™ Fixation System is supplied sterile, sterilized via Ethylene Oxide.

VI. Intended Use

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

VII. Indications for Use

QuadLock™ Fixation System is intended for fixation of suture/tape (soft tissue) to bone during surgical procedures, in skeletally mature pediatric and adult patients for the following indications for use:

- **Knee**:
  - **ACL/PCL Repair**: using non-absorbable UHMWPE USP #2 sutures or larger, or non-absorbable UHMWPE 1.4mm tapes or larger.
  - **ACL Reconstruction**: using non-absorbable UHMWPE USP #2 sutures or larger, or non-absorbable UHMWPE 1.4mm tapes or larger.

VIII. Comparison of Technological Characteristics

The proposed QuadLock™ Fixation System shared the same intended use with its predicate (K243712) and reference device (K212197). The main difference in technological characteristics is that the proposed device is larger in size compared to its predicate and smaller in size compared to the reference device. Hence, the proposed device has narrower indications for use. The proposed predicate device shares the same materials, manufacturing process, packaging materials, and sterilization process with the subject device. Although the subject device has reduced indications for use compared to the predicate device, limited to ACL/PCL repair and ACL reconstruction, the predicate device includes identical indications for use.

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

Table 1 Comparison of Subject and Predicate Device

Product Features	Subject Device Abanza Tecnomed's QuadLock™ Fixation System	Predicate Device Abanza Tecnomed's WasherCap™ Mini Fixation System (K243712)	Substantial Equivalence Determination
Design/ Technological Characteristics	- Components: cap and screw - Preloaded onto insertion tool - Not preloaded with sutures 	- Components: cap and screw - Preloaded onto insertion tool - Not preloaded with sutures 	Substantially Equivalent
Classification	Class II	Same	Substantially Equivalent
Product Code	MBI	Same	Substantially Equivalent
Indications for Use	QuadLock™ Fixation System is intended for fixation of suture and/or tape (soft tissue) to bone during surgical procedures, in skeletally mature pediatric and adult patients for the following indications for use: • Knee: - ACL/PCL Repair: using non-absorbable UHMWPE USP #2 sutures or larger, or non-absorbable UHMWPE 1.4mm tapes or larger. - ACL Reconstruction: using non-absorbable UHMWPE USP #2 sutures or larger, or non-absorbable UHMWPE 1.4mm tapes or larger.	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-	Substantially Equivalent for the shared indications for use.

Product Features	Subject Device Abanza Tecnomed's QuadLock™ Fixation System	Predicate Device Abanza Tecnomed's WasherCap™ Mini Fixation System (K243712)	Substantial Equivalence Determination
		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: - 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.	

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

Mechanical testing was performed on final finished devices, as well as comparative testing with the predicate device. The results of the testing confirmed that the device meets its requirements and performs comparatively to the predicate and therefore, does not raise new questions for safety and effectiveness.

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 QuadLock™ Fixation System has the same intended use and operating principle as the predicate device. Although the indications for use are different, the indications for the predicate exceed those for the proposed QuadLock™ Fixation System. Performance testing was completed on both the subject and 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, QuadLock™ Fixation System, is substantially equivalent to its predicate, WasherCap™ Mini Fixation System K243712.