September 22, 2022

Abanza Tecnomed S.L.
Aitor Olaso
Quality And Regulatory Affairs Manager
Calle Nueva 8-11
Mutilva, Navarra 31192
Spain

Re: K212197
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: August 15, 2022
Received: August 16, 2022

Dear Aitor Olaso:

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)*

K212197

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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5. 510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary:

5.1 Submitter Information

Company:	ABANZA TECNOMED, S.L. Calle Nueva 8 - 11 Mutilva, Navarra 31192 Spain Telephone: +34 948 04 46 43 Fax: N/A regulatory@abanzamed.com
Contact:	Aitor Olaso Quality And Regulatory Affairs Manager ABANZA TECNOMED, S.L. Calle Nueva 8 - 11 Mutilva, Navarra 31192 Spain Telephone: +34 948 04 46 43 Fax: N/A regulatory@abanzamed.com
Date Summary Prepared:	July 13, 2021

5.2 Name of the Device

Trade Name:	WasherCap™ Fixation System
Common Name:	Fastener, Fixation, Nondegradable, Soft Tissue. Classification name: Smooth or threaded metallic bone fixation fastener
Classification Name:	Orthopedic Regulation number: 888.3040 Class II
Review Panel:	Orthopedic (OR)
Regulation:	888.3040
Class:	Class II
Product Code:	MBI

5.3 Equivalence Claimed to Predicate Device

The WasherCap™ Fixation System is equivalent to the OrthoPediatrics ACL Reconstruction System (K130217), manufactured by OrthoPediatrics, Corp..

5.4 Device Description

WasherCap™ Fixation System is an implantable device indicated for soft tissue graft fastening during Anterior Cruciate Ligament repair surgery.

WasherCap™ Fixation System consists of three components: a Cap, a Screw and a Washer. The Cap and the Washer are manufactured from polyetheretherketone (PEEK) as per ASTM F-2026. The Screw is made of titanium alloy as per ASTM F136.

The WasherCap™ Fixation System is provided sterile and individually packaged and, it is available in a variety of sizes and should be implanted following the surgical procedure.

5.5 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.

5.6 Substantial Equivalence

The WasherCap™ Fixation System is intended for fixation of soft tissue grafts during ACL repair surgeries. Compared to the predicate device, the subject device is a single three-piece device achieving the same intended effect by fastening the soft tissue grafts inside the device which is implanted to the bone. The indication of the subject device is within the indication of the predicate device.

In addition, the WasherCap™ Fixation System and the predicate device share the same technological characteristics, including performance, basic design, materials, device usage, sterility and sizes.

Therefore, the WasherCap™ Fixation System is substantially equivalent to the predicate device.

5.7 Performance Data

Based on the Risk analysis, design validation and performance testing, the substantial equivalence determination is supported with:

Non-Clinical Studies

- *DESIGN VALIDATION*
  - Design Validation Protocol and Report of WasherCap™ Fixation System.
- *PERFORMANCE TESTING*
  - Cyclic and load-to-failure properties of WasherCap™ Fixation System.
- *PYROGENICITY*
  - Bacterial endotoxin test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>)
  - Pyrogen test according to USP chapter <151> for pyrogenicity determination
  - The subject device is not labeled as non-pyrogenic or pyrogen free.

Clinical Studies:

- No clinical studies were conducted.

5.8 Conclusion

Based on the information provided by ABANZA TECNOMED, S.L. within this submission, the WasherCap™ Fixation System possesses the same intended use, basic design, materials and technological characteristics as the legally marketed predicate device. Therefore, the WasherCap™ Fixation System is substantially equivalent and it will perform as safety and effectively within the same intended use.