July 29, 2022

Auxein Medical Private Limited
Rahul Luthra
Director
Plot No. 168, 169, 170 Phase-IV, Sector 57,
Kundli Industrial Area
Sonipat, Haryana 131028
India

Re: K213104
Trade/Device Name: Auxilock Titanium Screw-In Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 22, 2022
Received: June 27, 2022

Dear Rahul Luthra:

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,

For,

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)*
K213104

Device Name
Auxilock Titanium Screw-In Suture Anchor

Indications for Use *(Describe)*
Auxilock Titanium Screw-In Suture Anchor:
The Auxilock Titanium Screw-In Suture Anchor is intended to be used with #2 Biobraid suture with white, blue, black colors for use for the reattachment of soft tissue to bone for the following indications:

Shoulder:
Bankart lesion repairs, SLAP lesion repairs, Acromiolavicular separation repairs, Rotator cuff tear repairs, Capsular shift or Capsutolabral reconstructions, Biceps tenodesis, and Deltoid Repairs, Anterior Shoulder Instability Repair.

Foot and Ankle:
Hallux valgus reconstruction, Medial or Lateral instability repairs/reconstructions, Achilles tendon repair/reconstructions, Mid-foot reconstruction, Metatarsal ligament/tendon repairs/reconstructions, Bunionectomy.

Elbow, Wrist and Hand:
Scapholunate ligament reconstruction, Ulnar or radial collateral ligament reconstructions, Lateral epicondylitis repair, Biceps tendon reattachment, Tennis elbow repair.

Knee:
Extra-capsular repairs: Medial collateral ligament repair, Lateral collateral ligament repair, Posterior oblique ligament, Iliotibial band tenodesis, Patellar tendon repair - Vastus medialis obliquous advancement.

Hip:
Capsular repair, Acetabular labral repair.

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.

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510(k) Summary

General Company Information as required by 807.92 (a)

Submitter's Name:	Auxein Medical Private Limited
Address:	**Auxein Medical Private Limited** Plot No. 168-169-170, Phase-4, Kundli Industrial Area, HSIIDC, Sector-57, Sonepat-131028, Haryana, India
Contact Person Name:	Mr. Rahul Luthra
Title:	Director
Phone Number:	+91 9560557733
Dated:	29.07.2022

Person Responsible for Regulatory Compliance

Name:	Mr. Mohit Kumar
Title:	Sr. Research Engineer
Email Id:	m.kumar@auxein.com
Dated:	29.07.2022

Proprietary Name:
Auxilock Titanium Screw-In Suture Anchor

Common or Usual Name:
Soft Tissue Fixation Device

Classification Name:
Fastener, fixation, non-degradable, soft tissue

Product Code:
MBI

Device Class: II

Review Panel: Orthopedic

Regulation Number:
21 CFR 888.3040

Primary Product Code	Classification Name	Common Name	Regulation Number
MBI	Fastener, fixation, non-degradable, soft tissue	Soft Tissue Fixation Device	21 CFR 888.3040

Following are the predicate device 510(k) with which we are declaring substantial equivalence:
The following is the range of variants covered with their corresponding predicate devices.

Primary Predicate:

510(k) Number	K152566
Applicant	Smith & Nephew
Common Name	Suture Anchor
Device Name	PEBA Anchor/Suture Combination

Secondary Predicate:

510(k) Number	K053344
Applicant	Smith & Nephew
Common Name	Suture Anchor
Device Name	TwinFix 2.8mm, 3.5mm and BioRaptor 2.9mm Suture Anchors

Device Description:

The Titanium Screw-In Suture Anchor is a threaded, tapered fastener for use in attachment of soft tissue to bone. The self-tapping AUXILOCK® Titanium screw-in suture anchor is mostly used as a medial row anchor in rotator cuff repair surgery, Bankart or SLAP surgeries. It is recommended for use in small and large-joint repairs without the need for tapping or drilling. AUXILOCK® Titanium screw-in anchors are available in diameter of 2.8mm, 3.5mm, 5.0mm and 6.5mm. The anchor design incorporates a cancellous thread with a tiny core diameter to maximize pull-out strength in cancellous or osteoporotic bone. The AUXILOCK® Titanium screw-in anchor is designed for ultimate mechanical properties (pull-out strength, tensile strength, etc.) and ease-of-use. The anchor design incorporates a cortical thread with a small core diameter to maximize pull-out strength in a cortical or hard bone. The drill guide and drill bit are provided in the instrument set for the accurate placement of the anchor. It in turn minimizes the anchor slippage or breakage during the surgery.
All of the Auxein's Non-Absorbable Suture Anchors are provided sterile, for single use only. All Non-Absorbable Suture Anchors are preassembled onto an inserter, sized appropriately to accommodate the indicated procedures. Auxein's Non-Absorbable Suture Anchors come in various configurations, including: with attached non-absorbable suture(s). In certain configurations, the Non-Absorbable Suture Anchors are packaged with a guide and awl. All configurations of the Non-Absorbable Suture Anchors are identical to the identified predicate devices.
The device is made from a Titanium alloy, Ti-6Al-4V (ASTM F136) as per grade 5.

Note: The #2 Biobraid Suture is not to be used as a stand-alone. It should be used only with the assembled implant.

These implants are sold in sterile conditions (Ethylene Oxide Sterilization). The system is indicated for use in adult patients only. All implants are for single use only.

Indications for Use:

Auxilock Titanium Screw-In Suture Anchor:
The Auxilock Titanium Screw-In Suture Anchor is intended to be used with #2 Biobraid suture with white, blue, black colors for use for the reattachment of soft tissue to bone for the following indications:

Shoulder
Bankart lesion repairs, SLAP lesion repairs, Acromiolavicular separation repairs, Rotator cuff tear repairs, Capsular shift or Capsutolabral reconstructions, Biceps tenodesis, and Deltoid Repairs, Anterior Shoulder Instability Repair.

Foot and Ankle
Hallux valgus reconstruction, Medial or Lateral instability repairs/reconstructions, Achilles tendon repair/reconstructions, Mid-foot reconstruction, Metatarsal ligament/tendon repairs/reconstructions, Bunionectomy.

Elbow, Wrist and Hand
Scapholunate ligament reconstruction, Ulnar or radial collateral ligament reconstructions, Lateral epicondylitis repair, Biceps tendon reattachment, Tennis elbow repair.

Knee
Extra-capsular repairs: Medial collateral ligament repair, Lateral collateral ligament repair, Posterior oblique ligament, Iliotibial band tenodesis, Patellar tendon repair - Vastus medialis obliquous advancement.

Hip
Capsular repair, Acetabular labral repair.

Summary of Technological Characteristics as compared to the predicate devices
A comparison between the Auxilock Titanium Screw-In Suture Anchor and predicate devices has been performed which has resulted in demonstration of similarities in dimensional and performance criteria.

Following is the summary of parameters in which the comparison has been verified:

S.No.	Characteristics	Subject Device (Auxein)	Predicate Devices **K152566,** PEBA Anchor/Suture Combination, (Primary Predicate) **K053344,** TwinFix 2.8mm, 3.5mm Suture Anchors (Secondary Predicate)	Remarks
1.	Product Code	MBI	MBI	Identical

				as predicate device.
2.	Regulation Number	21 CFR 888.3040	21 CFR 888.3040	Identical as predicate device.
3.	Regulatory Class	Class II	Class II	Identical as predicate device.
4.	Indications for use	**Auxilock Titanium Screw-In Suture Anchor** The Auxilock Titanium Screw-In Suture Anchor is intended to be used with #2 Biobraid suture with white, blue, black colors for use for the reattachment of soft tissue to bone for the following indications: **Shoulder:** Bankart lesion repairs, SLAP lesion repairs, Acromiolavicular separation repairs, Rotator cuff tear repairs, Capsular shift or Capsutolabral reconstructions, Biceps tenodesis, and Deltoid Repairs, Anterior Shoulder Instability Repair. **Foot and Ankle:** Hallux valgus reconstruction, Medial or Lateral instability repairs/reconstructions, Achilles tendon repair/reconstructions, Mid-foot reconstruction, Metatarsal ligament/tendon repairs/reconstructions,	The PeBA Series Anchor/Suture Combination (Primary Predicate) is intended for the fixation of surgical suture material for the following indications: **Shoulder**: Bankart lesion repairs, SLAP lesion repairs, Acromio-clavicular separation repairs, Rotator cuff tear repairs, Capsular shift or capsulolabral reconstructions, Biceps tenodesis, Deltoid repairs. **Foot and Ankle**: Hallux Valgus repairs, Medial or lateral instability repairs, Achilles tendon repairs/reconstructions, Midfoot reconstructions, Metatarsal ligament/tendon repairs/reconstructions **Elbow, Wrist, and Hand**: Scapholunate ligament reconstructions, Ulnar or radial collateral ligament reconstructions, Tennis elbow repair, Biceps tendon reattachment.	Identical as predicate devices.

		Bunionectomy. **Elbow, Wrist and Hand:** Scapholunate ligament reconstruction, Ulnar or radial collateral ligament reconstructions, Lateral epicondylitis repair, Biceps tendon reattachment, Tennis elbow repair. **Knee:** Extra-capsular repairs: Medial collateral ligament repair, Lateral collateral ligament repair, Posterior oblique ligament, Iliotibial band tenodesis, Patellar tendon repair - Vastus medialis obliquous advancement. **Hip:** Capsular repair, Acetabular labral repair.	**Knee**: Extra-capsular repairs, medial collateral ligament, lateral collateral ligament, posterior oblique ligament, Iliotibial band tenodesis, Patellar realignment and tendon, repairs, including vastus medialis, obliquous advancement. The K053344, TwinFix 2.8mm, 3.5mm Suture Anchors (Secondary Predicate) is intended for use for the reattachment of soft tissue to bone for the following indications: **Shoulder** Bankart lesion repairs, SLAP lesion repairs, Acromiolavicular separation repairs, Rotator cuff tear repairs, Capsular shift or Capsutolabral reconstructions, Biceps tenodesis, and Deltoid Repairs, Anterior Shoulder Instability Repair. **Foot and Ankle** Hallux valgus reconstruction, Medial or Lateral instability repairs/reconstructions, Achilles tendon repair/reconstructions, Mid-foot reconstruction, Metatarsal ligament/tendon repairs/reconstructions, Bunionectomy. **Elbow, Wrist and Hand** Scapholunate ligament reconstruction, Ulnar or radial collateral ligament	

			reconstructions, Lateral epicondylitis repair, Biceps tendon reattachment, Tennis elbow repair. **Knee** Extra-capsular repairs: Medial collateral ligament repair, Lateral collateral ligament repair, Posterior oblique ligament, Iliotibial band tenodesis, Patellar tendon repair - Vastus medialis obliquous advancement. **Hip** Capsular repair, Acetabular labral repair.	
5.	Material	Titanium Alloy as per ASTM F136 and UHMWPE Suture as per ASTM F2848-17.	Titanium Alloy as per ASTM F136 and and UHMWPE Suture as per ASTM F2848-17.	Conforms to Identical standard as predicate device.
6.	Performance Standards	Mechanical Testing Protocol AMPL-MT-PRT-002, Rev. 01. was used in the scoped Device.	Mechanical Testing Protocol AMPL-MT-PRT-002, Rev. 01. was used in the predicate Device.	Identical as predicate device.
7.	Sterilization	Ethylene Oxide Sterilization Method was used in the subject device.	Ethylene Oxide Sterilization Method was used in the predicate devices.	Identical in predicate device.
8.	Dimensional Verification	Same dimension as of Predicate device.		Identical as predicate device.
9.	Shelf-life	5 Years	5 Years	Identical as predicate device.
10.	Single Use/Reuse	Single Use	Single Use	Identical as predicate device.

11.	Operating Principle	Secure tendon and ligament reconstructions with increased boney ingrowth at the anchor site with minimal invasive technique.	Secure tendon and ligament reconstructions with increased boney ingrowth at the anchor site with minimal invasive technique.	Identical as predicate device.

Discussion on the non-clinical testing performed

Following are the applicable product standards considered for non-clinical standards:

- Material Standards.
- Biocompatibility Standards
- Performance Standards.
- Sterilization, shelf-life and packaging for sterile product.
- Bacterial Endotoxin

Non-Clinical Test Summary:

Bench tests were conducted to verify that the subject device met all design specifications. The test results demonstrated that the subject device complies with the following standards:

Material Standards:

The material standards are the essential part to be complied with first, as it is the basis of manufacturing metallic surgical implants.

We have complied with the following material standards:

- **ASTM F136/ISO 5832-3**: Standard specification for wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.
- **ASTM F2848-17:** Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns.
- **ASTM F899-20:** Standard Specification for Wrought Stainless Steels for surgical instruments.

Note: We have used Grade 304 of Stainless steel (SS 304) Material for instruments as per ASTM F899-20, UHMWPE for Suture as per ASTM F2848-17 and Titanium Alloy (Ti- 6Al-4V) Grade 5 for Titanium Implants.

Summary of Biocompatibility

The device in its final finished form has been evaluated for biocompatibility according to ISO 10993-3.

Conclusion of Mechanical performance

The following are the mechanical tests that have been performed on the Subject device (i.e. Auxilock Titanium Screw-In Suture Anchor) and Predicate device (i.e. Smith & Nephew's Twinfix Suture Anchor):

1. Insertion Test
2. Pull-Out Tensile Static Test and Pull-Out Tensile Fatigue Test.

Sterilization, shelf-life and packaging for sterile product

Sterilization: ETO Sterilization

The ETO sterilization has been performed to sterilize this medical device. EO penetrates the packaging, making contact with all accessible surfaces of the product to deliver the required sterility assurance level (SAL).

Trace levels of EO and ethylene chlorohydrin (ECH) may remain on products after an EO sterilization process. To detect these traces, EO residual test was done. ISO 10993-7 outlines the specific limits of EO and ECH that must not be exceeded in order to ensure product and patient safety.

- ISO 11135: 2014, Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ISO 17665-1:2006, Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.
- ISO/TS 17665-2:2009, Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1.
- ISO/TS 17665-3:2013 (en), Sterilization of health care products — Moist heat — Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization.
- ISO 11140-1:2014, Sterilization of health care products — Chemical indicators — Part 1: General requirements.
- ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods- Part 1: Estimation of population of microorganisms on products.
- ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods- Part 2: Tests of sterility performed in the validation of a sterilization process.

Packaging of the Product: Tyvek Packaging

The integrity of the final package is maintained at least for the claimed shelf-life of the medical device.

The tyvek pouch is used for the packaging of Auxilock Titanium Screw-In Suture Anchor. The double sterile barrier is used for the packaging.

We have followed the below standards for packaging of the device:

- ISO 11607-1:2006/AMD1:2014 Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging system.
- ISO 11607-2:2006/AMD1:2014 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.

Shelf-life: 5 years

The stability study has been done to determine the shelf life.

We have followed the below standards for performing shelf-life of the device:

- ASTM F1980:2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- ASTM F88/F88M:2015 Standard test method for seal strength of flexible barrier materials.
- ASTM F1929:2015 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging

by Dye Penetration.

Safety in MRI Not Evaluated

The Auxilock Titanium Screw-In Suture Anchor has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Auxilock Titanium Screw-In Suture Anchor in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Bacterial Endotoxin

- USP <85> Bacterial Endotoxin Test.
- USP <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests.

Bacterial Endotoxin Test (BET): We perform Bacterial Endotoxin Test of every sterile batch products by using acceptance criteria as endotoxin testing limit must be <20EU/Device (as the products are general medical devices for implantation). The testing is done by using Limulus amebocyte lysate (LAL) test. The testing procedure is performed as per the standards USP 85 and ANSI/AAMI ST72:2019.

Conclusion:

There are no significant differences between the subject device and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, and operational principles as internal fixation components. From the data available we can justify that the Auxilock Titanium Screw-In Suture Anchor is as safe, and as effective and performs the same indications for use as that of already marketed predicate devices identified in 510(k) summary.