August 22, 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: K213109
Trade/Device Name: Auxilock Draw Tight Suture-Based 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: July 1, 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,

Laura C. Rose -S

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)*
K213109

Device Name
Auxilock Draw Tight Suture-Based Anchor

Indications for Use *(Describe)*

The Auxilock Draw Tight Suture-Based Anchor is indicated for attachment of soft tissue to bone. This product is intended for the following indications:

Shoulder
Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, Superior Labrum, Anterior to Posterior Lesion Repair.

Knee
Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.

Foot/Ankle
Lateral Stabilization, Medial Stabilization, Mid foot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.

Elbow
Tennis Elbow Repair, Biceps Tendon Reattachment.

Hand/Wrist
Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Triangular Fibrocartilage Complex Tear.

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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510k Summary

Pre Market Notification 510(k) Summary as required by section 807.92
General Company Information as required by 807.92 (a)
A.1: The Submitter's Name, address, telephone number, a contact person, and the date the summary was prepared.

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:	22.08.2022

Person Responsible for Regulatory Compliance

Name:	Mr. Mohit Kumar
Title:	Management Representative
Mail Id:	m.kumar@auxein.com
Dated:	22.08.2022

Throughout the submission of Auxilock Draw Tight Suture-Based Anchor is covered under 510(k) Submission.

A.2: The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Proprietary Name:
Auxilock Draw Tight Suture-Based 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

A.3) Identification of the Predicate Device:
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.

510(k) Number	**K122805**
Applicant	Parcus Medical LLC.
Common Name	Suture Anchor
Device Name	Parcus Draw Tight Anchor

A.4) A description of the device that is the subject of the pre market notification submission, such as might be found in the labelling or promotional material for the device

Device Description:
AUXILOCK® Draw tight anchor is made with UHMWPE suture anchor body and PEEK OPTIMA eyelet tip. The Auxilock Draw Tight Anchors are designed for use in attachment of soft tissue to bone. The construct of the Draw Tight Anchors is such that when inserted into the bone and deployed via the included suture, a suture ball is created in the prepared socket that provides the necessary fixation. The Draw Tight Anchors are designed to accommodate both sliding and fixed sutures to be used for soft tissue fixation. The anchor is designed to deliver efficiency and promote ease of use. The anchor can be used for rotator cuff repair surgeries. The AUXILOCK® Draw tight suture based anchor provides a small footprint and also asserts subcortical fixation for anchor insertion. The Draw tight anchor is available in 1.8mm and 3.2mm diameter with various combination of BioBraid and suture tapes. The drill guide and anchor driver combination is well-designed to improve the performance and reliability. The Auxilock Draw Tight Suture-Based Anchor consists of the following types of implants:

- AUXILOCK® 1.8mm Draw Tight Suture-Based Anchor with One #2 BioBraid: White/Blue
- AUXILOCK® 1.8mm Draw Tight Suture-Based Anchor with One 1.6mm Suture Tape: White/Blue
- AUXILOCK® 3.2mm Draw Tight Suture-Based Anchor with Two #2 BioBraid: White/Blue &

White/Black

- AUXILOCK® 3.2mm Draw Tight Suture-Based Anchor with One #2 BioBraid And One 1.6mm Suture tape: White/Black & White/Blue

The Auxilock Suture is a dyed or non-dyed braided suture construct made of UHMWPE. The proposed suture is braided flat with round ends, and is available in precut lengths in straight and loop configurations, and with or without needles. Suture ends are stiffened with cyanoacrylate. The Suture constructs meet USP standards for suture. The Suture is available in straight and loop configurations; and sizes #2 for suture, and 1.6mm (width) for tape.

AUXILOCK® BioBraid Suture

AUXILOCK® BioBraid Sutures are braided sterile sutures prepared from Ultra High Molecular Weight Polyethylene (UHMWPE). Sutures are non-absorbable and do not impose any significant changes in tensile strength retention known to occur in vivo. BioBraid sutures are available in a variety of colour combinations for easy suture management in complicated repairs.

Suture color additives

The UHMWPE sutures when made up of tracers can be with blue polypropylene (pigment β-Cu-phthalocyanine blue) or polyamide black (pigment hematein).

The color additive FD&C Blue 2, color additive Black logwood and color additive phtalocyanine are according to FDA and it is approved for use in medical applications (§74.3102 – FDA), (§73.1410 –FDA) and (§74.3045 – FDA) respectively.

AUXILOCK® BioBraid Suture Tape

AUXILOCK® BioBraid Suture Tape made from UHMPWE has a width of 1.6mm. The suture tape design accommodates the tape in the centre with a suture on the either sides of the tape.

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

Surgical instrumentation is included in Auxilock Draw Tight Suture-Based Anchor to allow the placement and attachment of the Anchors with bone. Various drill bits, drill, anchor driver, Awl, Threading device, Tray, Containers and other components are included with the Auxilock Draw Tight Suture-Based Anchor. These Instruments are made from Stainless steel (SS 304) Material.

A.5) Indications for Use:

Auxilock Draw Tight Suture-Based Anchor:

The Auxilock Draw Tight Suture-Based Anchor is indicated for attachment of soft tissue to bone. This product is intended for the following indications:

Shoulder: Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, Superior Labrum, Anterior to Posterior Lesion Repair.

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair.

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Mid foot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair.

Elbow: Tennis Elbow Repair, Biceps Tendon Reattachment.

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Triangular Fibrocartilage Complex Tear.

A.6) Summary of Technological Characteristics as compared to the predicate devices:
Substantial equivalence including comparison with predicate devices.
A comparison between the Auxein's Draw Tight Suture-Based 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	Auxein's Draw Tight Suture-Based Anchor	Predicate device	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	II	II	Identical as Predicate device
4.	Indications for use	The Auxilock Draw Tight Suture-Based Anchor is indicated for attachment of soft tissue to bone. This product is intended for the following indications: **Shoulder:** Rotator Cuff Repair, Acromioclavicular Separation	The Parcus Draw Tight Anchor is indicated for attachment of soft tissue to bone. This product is intended for the following indications: **Shoulder:** Rotator Cuff Repair, Acromioclavicular Separation Repair, Bankart Lesion Repair,	Identical as Predicate device

		Repair, Bankart Lesion Repair, Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, Superior Labrum, Anterior to Posterior Lesion Repair.. **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair. **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Mid foot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair. **Elbow:** Tennis Elbow Repair, Biceps Tendon Reattachment. **Hand/Wrist:** Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, Triangular Fibrocartilage Complex Tear.	Biceps Tenodesis, Capsular Shift or Capsulolabral Reconstruction, Deltoid Repair, SLAP Lesion Repair. **Knee:** Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Posterior Oblique Ligament Repair, Extra Capsular Reconstruction, Iliotibial Band Tenodesis, Patellar Ligament and Tendon Avulsion Repair. **Foot/Ankle:** Lateral Stabilization, Medial Stabilization, Mid foot Reconstruction, Achilles Tendon Repair, Hallux Valgus Reconstruction, Metatarsal Ligament Repair. **Elbow:** Tennis Elbow Repair, Biceps Tendon Reattachment. **Hand/Wrist:** Scapholunate Ligament Reconstruction, Ulnar or Radial Collateral Ligament Reconstruction, TFCC.	
5.	Material	Peek OPTIMA as per ASTM F2026-17 and UHMWPE as per ASTM F2848-17 used in New Device.	Peek OPTIMA as per ASTM F2026-17 and UHMWPE as per ASTM F2848-17 used in Predicate Device.	Conform to the Identical material standard
6.	Performance Standards	Bench testing of proposed device.	Bench testing for predicate device.	Identical as Predicate device
7.	Sterilization	Provided in Sterile conditions (EO Sterilization).	Provided in Sterile conditions (EO Sterilization).	Identical as

				Predicate device
8.	Single Use/Reuse	Single Use	Single Use	Identical as Predicate device
9.	Operating Principle	It can be used for single incision, soft tissue, or bone-tendon-bone fixation.	It can be used for single incision, soft tissue, or bone-tendon-bone fixation.	Identical as Predicate device
10.	Shelf-Life	5 Years	5 Years	Same as Predicate device
11.	Dimensional Verification	The same dimensions are found in both new Devices as well as Predicate devices.		Same as Predicate device

B.1) 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

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 F2026-17: Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.
- ASTM F2848-17: **S**tandard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns.
- ASTM F899-12: 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 F899-12 and PEEK OPTIMA as per ASTM F2026-17 for Implants.

We have verified the purchased material and are in compliance to these standards and copies of the relevant test results are attached in Vol_005_Appendix D Implant Material Report and Vol_006_ Appendix E ASTM F899 Report of the technical dossier.

Summary of Biocompatibility

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

Summary Performance Data:

The pull out strength (Static & Fatigue Loading) was measured for the Auxilock Draw Tight Suture-Based Anchors and Predicate device. The results were reviewed and side by side comparisons were done with the Parcus predicate device and it demonstrated that there were no significant differences between the Auxilock Draw Tight Suture-Based Anchors and the predicate devices.

Sterilization, shelf-life and packaging for sterile product

- ISO 11138-8:2021, Sterilization of health care products — Biological indicators — Part 8: Method for validation of a reduced incubation time for a biological indicator.
- 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 11135-1:2007, Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- ISO/TS 11135-2:2008, Sterilization of health care products — Ethylene oxide — Part 2: Guidance on the application of ISO 11135-1.
- 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.
- 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.
- 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.

Bacterial Endotoxin

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

Summary of Bacterial Endotoxin Test:

Bacterial Endotoxin test was performed on Auxilock Draw Tight Suture-Based Anchor by using Limulus Amoebocyte Lysate (LAL) test. The Endotoxin testing limit was less or equal to 20EU/Device. The test was performed according to standard USP32 chapter 85.

Summary of Shelf-Life Study:

The shelf life study (accelerated Stability Study) was conducted on an Auxilock Draw Tight Suture-Based Anchor. As per the expiry assumption of 5 years, we have performed this study at 60°C and calculated that the accelerated stability study will be continued for 8 months. The bioburden test, sterilization, sterility test, visual inspection, dimensional check, Material integrity and package integrity test were performed on the subject device before starting the study and after the completion of the study. After completion of the study, the accelerated stability study was found to be satisfactory. Hence, we have concluded that the expiry of 5 years, which we have assumed complies. ASTM F1980:2016 was used as reference standard for performing this test.

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 Draw Tight Suture-Based Anchor is as safe, and as effective and performs the same indications for use as that of already marketed predicate devices identified in A.3. of 510(k) summary.