August 20, 2021

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

Re: K203029
Trade/Device Name: Auxilock Titanium Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, MBI
Dated: July 14, 2021
Received: July 20, 2021

Dear Mr. 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,

Pooja Panigrahi -S

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)*
K203029

Device Name
Auxilock Titanium Interference Screw

Indications for Use *(Describe)*

The Auxilock Titanium Interference Screw is indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5.0: *510K Summary*

Premarket 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 Pvt. Ltd.*** Plot No. 168-169-170, Phase- IV, Kundli Industrial Area, HSIIDC, Sector-57, Sonepat-131028, Haryana.
Contact Person Name:	Mr. Rahul Luthra
Title:	Director
Phone Number:	+91-9811720999
Dated:	21/08/2021

Throughout the submission Auxilock Titanium Interference Screw is covered under 510(k) Submission.

(A.2) ***The name of the device, including the trade or proprietary name if applicable, thecommon or usual name, and the classification name, if known***

Proprietary Name:

Auxilock Titanium Interference Screw

Common or Usual Name:

Interference Screws

Classification Name:

Fastener, Fixation, Non-Degradable, Soft tissue.

Product Code:

HWC, MBI

Device Class: II

Review Panel: Orthopaedic

Regulation Number: 21 CFR 888.3040

Variants/Types:

An Auxilock titanium Interference screw is a cannulated, threaded, tapered fastener for use in Interference fixation of ligaments and tendons in patients requiring ligament or tendon-repair.

The device is made from a Titanium alloy, Ti-6Al-4V ELI (ASTM F136) and is available in sizes ranging from 7 to 12 mm in diameter and 20 to 35 mm in length.

(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.

S.No.	Item Description	Predicate Device
1.	Auxilock Titanium Interference Screw	K083619, Parcus Titanium Interference Screw

Reference Device: K201457, Auxien Brand Vertaux 5.5 mm Pedicle Screw System

(A.4). *A description of the device that is the subject of the premarket notificationsubmission, such as might be found in the labelling or promotional material for the device.*

Device Description:

Auxein Brand Auxilock titanium Interference screw is cannulated, threaded, tapered fastener for use in Interference fixation of ligaments and tendons in patients requiring ligament or tendon-repair.

The device is made from a Titanium alloy, Ti-6Al-4V ELI (ASTM F136) and is available in sizes ranging from 7 to 12 mm in diameter and 20 to 35 mm in length.

Each variant of Auxilock Titanium Interference Screw are sold both in non-sterile and sterile (EO & Gamma Sterile) conditions.

Non-sterile version of Auxilock Titanium Interference Screw have to be sterilized before use.

(A.5) *A statement of the intended use of the device.*

Indications for Use:

Auxilock Titanium Interference Screw is indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.

(A.6). *Summary of Technological Characteristics as compared to the predicate devices:*

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Substantial equivalence including comparison with predicate devices.

A comparison between the Auxilock Titanium Interference screw 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	Predicate Device Versus New Device(Auxein Brand)	Remarks
1.	Indications for use	Similar intended use in New Device and Predicate device.	Equivalent
2.	Material	Conform to same material standard.	Equivalent
3.	Performance Standards	Same performance standards used in both New Device as well as predicate device.	Equivalent
4.	Sterilization	Predicate device is supplied in Non-sterile and EO sterile but our device will be supplied in Non-Sterile, Gamma Sterile and EO Sterile.	Equivalent
5.	Dimensional Verification	Same dimensions found in both New Device as well as Predicate device.	Equivalent

(B.1)*. Discussion on the non-clinical testing performed*

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

Material Standards

B: Performance Standards

A: 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.

1. ASTM F 136: Standard specification for wrought Titanium - 6Aluminum - 4Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.

2. ASTM F 899-12: Standard Specification for Wrought Stainless Steels for surgical instruments.

We have verified the purchased material compliance to these standards and copies of the relevant test results are attached herewith.

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B: Performance Standards:

The device performance of Auxilock Titanium Interference Screw system has been demonstrated against following applicable standards.

- ASTM F 543-17
- Custom Fatigue Testing

(B.1). ***Summary of performance testing:***

The pull out strength, Torsional Strength, Screw In and Out and Pull Out Based Fatigue test were measured for the smallest dia. i.e. 7 mm Auxilock Titanium Interference Screws. The above test were also performed for the samples of Titanium Interference Screw of Parcus Medical and results of these test demonstrated that there were no significant differences between both the devices.

Bacterial endotoxins for the implantable components are determined using LAL testing to meet endotoxin limit specifications.

Biocompatibility testing of the samples has been conducted as per EN ISO 10993-1.

We have performed accelerated and real-time studies as per EN ISO 11607-1:2009.

Reference device for shelf-life and packaging is already approved by USFDA **(K201457)** and the scoped device (Auxilock Titanium Interference Screw) contains same packaging material as that of K201457.

Conclusion:

General, Safety and Performance conclusion:

S.No.	Parameter of Conclusion	Proposed Device	Predicate Device
1.	Product Code	MBI, HWC	Same
2.	Regulation Number	21 CFR 888.3040.	Same
3.	Regulatory Class	Class II	Same
4.	Intended Use	The Auxilock Titanium Interference Screw is indicated for use in the fixation of ligaments and tendons in patients requiring ligament or tendon repair.	Similar Intended Use
5.	Sterilization	Same method of sterilization used in both New Device as well as Predicate device.	Same
6.	Mechanical Test Performance	Pull out strength, Torsional Strength, Screw In and Out and Pull Out Based Fatigue test.	Same

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7.	Material Standards	ASTM F 136 & ASTM F 899-12b.	Same

From the data available we can justify that the Auxilock Titanium Interference screw is as safe, and as effective and performs as same indications for use as that of already marketed predicate devices identified in A.3. of 510(k) summary.