Auxein Medical Private Limited
Rahul Luthra
Director
Plot No.168,169,170 Phase-4
Kundli Industrial Area, HSIIDC, Sector-57
Sonipath, Haryana 131028
India

April 6, 2021

Re: K201457
Trade/Device Name: Auxein Brand Vertaux 5.5 mm Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral Pedicle Screw System
Regulatory Class: Class II
Product Code: NKB
Dated: March 3, 2021
Received: March 8, 2021

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,

Anne D. Talley -S for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201457

Device Name
Auxein Brand Vertaux 5.5 mm Pedicle Screw System

Indications for Use *(Describe)*
The Auxein Brand Vertaux 5.5 mm Pedicle Screw System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications:

•Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
•Spondylolisthesis;
•Trauma (i.e., fracture or dislocation);
•Spinal stenosis;
•Curvatures (i.e., scoliosis, kyphosis and/or lordosis);
•Tumor and pseudarthrosis

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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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 submitters 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-4, Kundli Industrial Area, HSIIDC, Sector-57, Sonepat - 131028, Haryana, India
Contact Person Name:	Mr. Rahul Luthra
Title:	Director
Phone Number:	+91-9811720999
Dated:	**04.02.2021**

Throughout the submission Auxein Brand Vertaux 5.5 mm Pedicle Screw System 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:

Auxein Brand Vertaux 5.5 mm Pedicle Screw System

Common or Usual Name:

- Pedicle screw system

Classification Name:

- Thoracolumbosacral pedicle screw system.

Product Code:
NKB

Device Class: II

Review Panel: Orthopedic

Regulation Number: 21 CFR 888.3070

Variants/Types:
Auxein Brand Vertaux 5.5 mm Pedicle Screw System consists of the following components:

S.No.	Product Description
1	**VERTAUX Mono-Axial Pedicle Screw**
2	**VERTAUX Poly-Axial Pedicle Screw**
3	**VERTAUX Pedicle Screw Cap**
4	**VERTAUX Crosslink-I**
5	**VERTAUX Crosslink-II**
6	**VERTAUX Rod**

A.3) Identification of the Predicate Device:

The identified primary predicate within this submission is as follows:
K 091442, Medtronic Sofamor Danek, USA, CD HORIZON Spinal System

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

Device Description:

Auxein Brand Vertaux 5.5 mm Pedicle Screw System consists of rods, connectors and screws for implantation in the spine. The system is available in multiple rod diameters and screw sizes.

VERTAUX Mono-axial Pedicle Screw

- The screw is threaded and the head is fixed for top loading for an easy rod introduction.
- It may be used in instrumentation procedures to affix rods and screws to the spine.
- 25 mm to 55 mm lengths & the diameter ranges from 4.5 mm to 7.0 mm.

VERTAUX Poly-axial Pedicle Screw

It may be used in instrumentation procedures to affix rods and screws to the spine.
25 mm to 55 mm lengths & the diameter ranges from 4.5 mm to 6.5 mm.

VERTAUX-Pedicle Screws Cap

- These cap is used to apply the pressure to hold the Rod inside the U-Part Head.
- Buttress threads reduce profile and improves cross-threading resistance.
- Internal set screw allows for placement and visualization.

VERTAUX -Pedicle Crosslink I & II

Vertaux Crosslink I

The Vertaux Crosslink I is used for connecting two vertaux rods providing a rigid and stable spine construct.

Vertaux Crosslink II

The intended use of vertaux cross link II is the same as used for cross link I with only change in design.
The Crosslink I is a pre assembled expandable part, while cross link II has assembly parts which are assembled during Surgery.

VERTAUX-Pedicle Rod

- Auxein pedicle screw system has a titanium rod.
- Easily contours to meet individual patient anatomy.
- These rods are available from 50mm, 60mm, 70mm, 80mm, 90mm, 100mm, 110mm, 120mm, 130mm, 140mm, 150mm, 160mm, 170mm, 180mm, 200mm, 220mm, 240mm, 250mm, 260mm, 280mm, 300mm, 350mm, 400mm, 450mm, 500mm and having dia. of 5.5mm.

These implants are sold in both non-sterile and sterile conditions. Note- Non sterile products have to be sterilized before use.

A5). Indications for Use:

The Auxein Brand Vertaux 5.5 mm Pedicle Screw System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications:

- Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies);
- Spondylolisthesis;
- Trauma (i.e., fracture or dislocation);
- Spinal stenosis;
- Curvatures (i.e., scoliosis, kyphosis and/or lordosis);
- Tumor and pseudarthrosis

A.6). Summary of Technological Characteristics as compared to the predicate devices: Substantial equivalence including comparison with predicate devices

A comparison between the Auxein Brand Vertaux 5.5 mm Pedicle Screw System 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	Same material used in New Device and Predicate device	Equivalent
3	Performance Standards	Same performance standards used in both New Device as well as predicate device	Equivalent
4	Sterilization	Same method of sterilization used in both	Equivalent

		New Device as well as Predicate device	
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-6Aluminium-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.

B: Performance Standards:

The device performance of Auxein Brand Vertaux 5.5 mm Pedicle Screw System has been demonstrated against following applicable standards-

- Static compression testing as per ASTM F 1717-18
- Static Torsional Testing of as per ASTM F 1717-18
- Fatigue Compression testing as per ASTM F 1717-18

B.2). Discussion on the clinical evaluation referenced and relied upon:

Auxein Brand of devices is of similar design and pattern as well as similar intended use. Under

such situation we have also considered the meddev guidance document MEDDEV 2.71 REV. 04: 2016 and as per that clinical evaluation/clinical equivalence has been documented in section 11.

CONCLUSION:

General, Safety and Performance conclusion:

S.No.	Parameter of Conclusion	Proposed Device	Predicate Device
1	Product Code	Auxein Brand Vertaux 5.5 mm Pedicle Screw System.	Same
2	Regulation Number	21CFR 888.3070	Same
3	Regulatory Class	Class II	Same
4	Intended Use	Auxein Brand Vertaux 5.5 mm Pedicle Screw System is intended for posterior, non-cervical fixation in skeletally mature patients as an adjunct to fusion for the following indications: • Degenerative Disc Disease (Defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) • Spondylolisthesis • Trauma (i.e. fracture or dislocation) • Spinal Stenosis • Curvatures (i.e. Scoliosis, kyphosis, and/or lordosis) • Tumor and pseudarthrosis	Same
5	Sterilization	Provided both in Non-Sterile and Sterile Conditions.	Same
6	Mechanical Test Performance	**Auxein Brand Vertaux 5.5 mm Pedicle Screw System tested -** • As per ASTM F1717-18 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.	Same

7	Material Standards	ASTM F 136 (Implants) & ASTM F899-12b (Instruments)	Same

From the data available we can justify that the Auxein Brand Vertaux 5.5 mm Pedicle Screw System has the same intended use and similar technological characteristics as the already marketed predicate device identified in A.3. of the 510(k) summary. Hence our device can be considered substantially equivalent to the predicate.