November 30, 2023

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

Re: K221787
Trade/Device Name: Auxein's Patient Specific Implant
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT, KTW, HRS, HWC
Dated: March 20, 2023
Received: March 22, 2023

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,

Limin Sun -S

Limin Sun, Ph.D.,
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K221787

Device Name
Auxein's DHS/DCS Plate System

Indications for Use *(Describe)*
The DHS/DCS Plate System is intended for use in treating fractures of femoral head (Dynamic Hip Plates) and condylar part of the femur (Dynamic Condylar Plates).

Specific indications, which are dependent on the angle of the plate, include:

130°-135°: fractures of the trochanter region, simple and multifragmentary pertrochanteric, intertrochanteric.

95°: distal and intercondylar fractures of the femur.

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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510(k) 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:	+91-9811720999
Email Id:	rahul@auxein.com
Dated:	2023.11.30

Secondary Contact

Name:	Mr. Mohit Kumar
Title:	Manager-Regulatory Affairs
Email Id:	m.kumar@auxein.com
Dated:	2023.11.30

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's DHS/DCS Plate System

Common or Usual Name:
Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component

Classification Name:
Single/multiple component metallic bone fixation appliances and accessories

Primary Product Code:
KTT

Additional Product Code:
HRS, KTW, HWC

Device Class: II

Review Panel: Orthopedic

Regulation Number:
21 CFR 888.3030 (Primary)
21 CFR 888.3040

Variants/Types:
Auxein's DHS/DCS Plate System consists of the following Components:

S.No.	Product Description
DHS/DCS Plates	
1.	Wise-Lock Dynamic Hip System (DHS) Plate
2.	4.5/5.0mm Wise-Lock Trochanter Stabilizing Plate for DHS-Adjustable
3.	135° Wise-Lock DHS Plate, Short Barrel
4.	95° Wise-Lock DCS Plate
5.	95° Condylar Blade Plate
6.	130°Angled Blade Plate
7.	135° Dynamic Hip Compression Plate, Short Barrel
8.	Dynamic Hip Compression Plate
9.	95° DCS Plate
Screws	
1.	DHS/DCS Screw
2.	DHS/DCS Compression Screw
3.	4.5mm Cortical Screw, Self-Tapping, (Hex Head)
4.	5.0mm Wise-Lock Screw, Self-Tapping, (Hex Head)
5.	6.5mm Cancellous Screw, 16mm Thread
6.	6.5mm Cancellous Screw, 32mm Thread
7.	6.5mm Cancellous Screw, Full Thread

A.3) Identification of the Predicate Device:
Following are the predicate device 510(k)s which we are declaring substantial equivalence:

Primary Predicate Device

510k Number	K071852

Applicant	aap Implantate AG (Germany)
Common Name	Appliance, fixation, nail/blade/plate combination, single component
Device Name	Dynamic Hip Screw

Additional Predicate Devices

510k Number	K052677
Applicant	Synthes (USA)
Device Name	Synthes Universal Locking Trochanter Stabilization Plate (ULTSP)

510k Number	K840954
Applicant	Synthes (USA)
Device Name	Dynamic Condylar Screw Or D.C.S.

510k Number	K914546
Applicant	Synthes (USA)
Device Name	Angled Blade Plate

510k Number	K791619
Applicant	Synthes (USA)
Device Name	Dynamic Hip Screw (DHS)/DCS Compression Screw

Reference Device

510k Number	K213059
Applicant	Auxein Medical Private Limited, India
Common Name	Orthopaedic bone plates, Orthopaedic bone screws
Device Name	Tibia and Fibula system

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:

The Auxein's DHS/DCS Plate System offers a variety of treatment options depending on the fracture site and the patient. The DHS/DCS Plate System is composed of plates, compression screw and bone screws. The devices are made from either Stainless Steel as per ASTM F138-19 or Titanium alloy as per ASTM F136-13(2021)e1.

These implants will be available either in sterile or non-sterile state.

Note- Non sterile products have to be sterilized before use.

The system is indicated for use in skeletally mature patients only. All implants are for single use only.

A.5) Indications for Use:

The DHS/DCS Plate System is intended for use in treating fractures of femoral head (Dynamic Hip Plates) and condylar part of the femur (Dynamic Condylar Plates).

Specific indications, which are dependent on the angle of the plate, include:

- **130°-135°:** fractures of the trochanter region, simple and multifragmentary pertrochanteric, intertrochanteric.
- **95°:** distal and intercondylar fractures of the femur.

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 DHS/DCS Plate System and predicate devices has been performed which has resulted in demonstration of similarities in dimensional and performance criteria.

The subject implants are similar to the predicates because they are made from the same materials. The subject plates have similar plate lengths, thickness, and widths. The subject plates are also compatible with the same types of screws and same sized screws as the predicates. The subject and predicates differ in their specific geometries (e.g., tolerances, locking thread profile, screw hole sizes and patterns on the plate).

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

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:

Summary of Biocompatibility

The device has been evaluated for biocompatibility according to ISO 10993.

Conclusion of Non-Clinical Testing

The device's performance of has been demonstrated against the following standards:

Bone Plates

ASTM F384-17: Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices.

- Static four point bend test
- Fatigue four point bend test

The Auxein's DHS/DCS Plate System was mechanically tested for static and fatigue four point bend, with test results similar to those of predicates. The performance of the subject device was assessed through tests. According to the results, the Auxein's DHS/DCS Plate System is considered substantially equivalent to the predicate device.

Sterilization, shelf-life and packaging for sterile product

- ISO 11137-1:2006/Amd 2:2018, sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- ISO 11137-2:2013/Amd 1:2022, Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose.
- ISO 11137-3:2017, Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects of development, validation and routine control.
- 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, 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/Amd 1:2021, Sterilization of medical devices - Microbiological methods- Part 1: Estimation of population of microorganisms on products.
- ISO 11737-2:2019, Sterilization of medical devices - Microbiological methods- Part 2: Tests of sterility performed in the validation of a sterilization process.
- ISO 11607-1:2019, Packaging for terminally sterilized medical devices - part 1:requirements for materials, sterile barrier systems and packaging system.
- ISO 11607-2:2019, Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.
- ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- ASTM F88/F88M-21, Standard test method for seal strength of flexible barrier materials.
- ASTM F1929-15, 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.

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 Auxein's DHS/DCS Plate System 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.