October 9, 2024

Auxein Medical Pvt. Ltd
℅ Gaurav Luthra
Director
Auxein Medical Pvt. Ltd.
Auxein Medical Pvt. Ltd. Plot No. 168-169-170 Sector 57
Phase IV, HSIIDC Kundli
Sonepat, Haryana 131028
India

Re: K240181
Trade/Device Name: Clavicle and Scapula System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: September 13, 2024
Received: September 13, 2024

Dear Gaurav 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240181

Device Name

Clavicle and Scapula System

Indications for Use *(Describe)*

3.5mm Wise-Lock Scapula Medial Border Plate
Indicated to provide fixation during fractures, fusions, and osteotomies for the Scapula.

3.5mm Wise-Lock Clavicle Hook Plate
Indicated for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint.

2.7 / 3.5mm Wise-Lock Superior Anterior Clavicle Plate with Lateral Extension
Indicated for fixation of fractures, malunions, non-unions, and osteotomies for the clavicle.

3.5mm Wise-Lock S Clavicle Plate
Indicated to provide fixation for fractures, fusion, or osteotomies for the clavicle.

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) #: K240181

510(k) Summary

Prepared on: 2024-10-08

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Auxein Medical Private Limited
Applicant Address	Auxein Medical Pvt. Ltd. Plot No. 168-169-170, Phase-4, Kundli Industrial Area, HSIIDC, Sector-57, Sonepat-131028, Haryana, India
Applicant Contact Telephone	+91-9717586969
Applicant Contact	Mr. Gaurav Luthra
Applicant Contact Email	gaurav@auxeinmedical.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Clavicle and Scapula System
Common Name	Single/multiple component metallic bone fixation appliances and accessories (primary), Smooth or threaded metallic bone fixation fastener
Classification Name	Plate, Fixation, Bone (primary); Screw, Fixation, Bone
Regulation Number	888.3030 (primary), 888.3040
Product Code(s)	HRS (primary), HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K051083	Acumed Scapula Congruent Bone Plate System	HRS
K061753	Synthes (USA) Clavicle Hook Plate	HRS
K073186	SYNTHES 3.5mm LCP Clavicle Plate System	HRS
K012655	Acumed Congruent Bone Plate System	HRS
K203414	DePuy Synthes 2.7mm VA LCP Clavicle Plate System, DePuy S	HRS
K213059	Tibia and Fibula System	HRS
K213108	Humerus & Ulna System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

Clavicle and Scapula System consists various types of bone plates, Screws for implantation & fixation of Clavicle and Scapula bone fractures. The plates are designed to match the anatomy of the Clavicle and Scapula bones with a limited contact low profile design. Scapula Plates are featured with only locking holes and combi-holes. However, Clavicle plates are featured with locking holes, combi-holes, compression holes as well as static holes for better fixation of implant. All the plates and screws included in the system are available in both Stainless Steel as per ASTM F138 and Titanium material as per ASTM F136. The Scapula System consists of a medial

border plate. It also consist of 3.5mm cortical screws, 3.5 mm Wise-lock screws, and 4.0 mm Cancellous screws for the fixation of bone plate to the bone. Similarly, the Clavicle system consists of Hook plate, superior anterior plate, and S Clavicle plate for fixation of clavicle bone. In this system for fixation of bone plate to the bone various lengths of 2.7 & 3.5mm cortical screws, 2.7 & 3.5 mm wise lock screws and 2.7 & 3.5mm AV wise lock screw are used.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

3.5mm Wise-Lock Scapula Medial Border Plate
Indicated to provide fixation during fractures, fusions, and osteotomies for the Scapula.

3.5mm Wise-Lock Clavicle Hook Plate
Indicated for fixation of lateral clavicle fractures and dislocations of the acromioclavicular joint.

2.7 / 3.5mm Wise-Lock Superior Anterior Clavicle Plate with Lateral Extension
Indicated for fixation of fractures, malunions, non-unions, and osteotomies for the clavicle.

3.5mm Wise-Lock S Clavicle Plate
Indicated to provide fixation for fractures, fusion, or osteotomies for the clavicle.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indication of both the subject device and predicate are identical.

Technological Comparison

21 CFR 807.92(a)(6)

The technological characteristic of the subject device like design, material, principle of operation and its indication for use is also substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Static and dynamic four point bend test (ASTM F382, ASTM F384) has been performed on both the Auxein's device and predicate device for the substantial equivalence.

N/A

The test report of both the subject device and predicate device has been reviewed and compared with each other on each parameter and there is no any significant changes between them.