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

August 25, 2021

Re: K210792
Trade/Device Name: Auxein Nailing System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, JDS
Dated: March 15, 2021
Received: March 15, 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,

Michael Owens
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210792

Device Name
Auxein Nailing System (Sterile)

Indications for Use *(Describe)*
Device Name: Auxein Nailing System are categorized to the following system:
1. Expert Tibia Nailing System 2. Expert Femoral Nailing System 3. Gamma Nailing System 4. AJAX Advance nailing system 5. Elastic Nailing System 6. Humeral Nailing System 7. Retrograde Nailing System

INDICATION FOR USE:

1. AUXEIN Brand of Expert Tibia Nailing System- consists of variety of Bone nails and bone screws. Expert Tibia Nail System is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post-isthmic fractures; and tibial malunions and non- unions.

2. AUXEIN Brand of Expert Femoral Nailing System -is intended to stabilize femoral shaft fractures, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions.

3. AUXEIN Brand of Gamma Nailing System -The Gamma Nail with Anti -Rotation Screw is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, including non-union, malunion and tumor resections. The Long Nail system is additionally indicated to treat pertrochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas, impending pathological fractures, long subtrochanteric fractures, ipsilateral femoral fractures, proximal or distal non-unions, malunions, revision procedures and tumor resections.

4. AUXEIN Brand of AJAX Advance Nailing System, end cap and screws is intended to treat stable and unstable proximal femoral fracture including Pertrochanteric fractures, Intertrochanteric fractures and High sub trochanteric fractures and combination of these fractures.

5. The AUXEIN MEDICAL's Elastic Intramedullary Nail System is indicated for fixation of diaphyseal fractures where the canal is narrow or flexibility of the implant is important. This includes upper extremity fractures in all patients and lower extremity fractures in children above the age of 6 years and any patient below 65 kg. This system is also intended to treat metaphyseal and epiphyseal fractures, such as radial neck fractures.

6. AUXEIN Brand of Humeral Nailing System is indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures, proximal humeral fractures with diaphyseal extension, diaphyseal fractures of the humeral shaft, and impending pathologic humeral fractures.

7. AUXEIN Brand of Retrograde Nailing System This nails are indicated for simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of long bones being treated."

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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510K Number: *K210792*

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:	10/03/2021

Throughout the submission Auxein Nailing 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 Nailing System

Common or Usual Name:

Rod, Fixation, Intramedullary and Accessories

Nail, Fixation, Bone

Classification Name:

● Intramedullary Fixation Rod.

● Single/multiple component metallic bone fixation appliances and accessories.

Product Code:

HSB, JDS

Device Class: II

Review Panel: Orthopaedic

Regulation Number: 21 CFR 888.3020, 21 CFR 888.3030

510K Number: *K210792*

Variants/Types:

An intramedullary rod, also known as an intramedullary nail (IM nail) or inter-locking nail is a metal rod forced into the medullary cavity of a bone. IM nails have long been used to treat fractures of long bones of the body.

The device is made from a Titanium alloy, Ti-6Al-4V ELI (ASTM F136).

(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.	Auxein Nailing System	K192003, Auxein Nailing System, (Primary Predicate) K011857, Synthes USA PFNA-II Blade, (Reference Predicate)

Note: K011857, Synthes USA PFNA-II Blade is a Reference predicate device for (Ajax Blade)

(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:

Nail Fixation

Auxein Brand of Expert Tibia Nail system consists of various shapes and sizes of sterile nails featuring proximal & distal holes, end caps & locking bolts of different sizes. The nails and screws are fabricated from titanium. The system contains several modules based on the size of the device and application site such as fixation/reconstruction of bones. The diameter of the nails varies from 8mm to 12mm; the length varies from 255mm to 375mm. The screw implants are in corresponding diameter of 4.4mm & 4.8mm diameters with lengths varying as per the requirements and minimum length: 24mm to maximum length 90mm.

Auxein Brand of Expert Femoral Nail system consists of various shapes and sizes of sterile nails featuring proximal & distal holes, end caps, locking screw & Anti-rotation screw of different sizes. The nails and screws are fabricated from titanium. The system contains several modules based on the size of the device and application site such as fixation/reconstruction of bones.The diameter of the nails varies from 9mm to 13mm; the length varies from 320mm to 440mm.The screw implants are in corresponding diameter of 4.8mm, 6.4mm & 10.5mm diameters with lengths varying as per the requirements and minimum length: 25mm to maximum length 130mm.

Auxein Brand of Ga-mma Nailing system consists of various shapes and sizes of sterile nails featuring proximal & distal holes, end caps, Inner screw, locking bolts, Anti-rotation

screw & Cephalic screw of different sizes. The nails and screws are fabricated from titanium. The system contains several modules based on the size of the device and application site such as fixation/reconstruction of bones. The diameter of the nails varies from 9mm to 13mm; the length varies from 180mm to 480mm. The screw implants are in corresponding diameter of 4.8mm, 6.4mm & 10.5mm diameters with lengths varying as per the requirements and minimum length: 26mm to maximum length 120mm.

Auxein Brand of Humeral Nailing system consists of various shapes and sizes of sterile nails featuring proximal & distal holes, end caps, locking bolt, compression screw, and proximal screw of different sizes. The nails and screws are fabricated from titanium. The system contains several modules based on the size of the device and application site such as fixation/reconstruction of bones. The diameter of the nails varies from 6mm to 9mm; the length varies from 180mm to 320mm. The screw implants are in corresponding diameter of 3.5mm & 4.5mm diameters with lengths varying as per the requirements and minimum length: 20mm to maximum length 70mm.

Auxein Brand of AJAX Advance Nailing system consists of various shapes and sizes of sterile nails featuring proximal & distal holes, end caps, locking bolts, Cephalic screw, Ajax Blade, and inner screw of different sizes. The nails and screws are fabricated from titanium. The system contains several modules based on the size of the device and application site such as fixation/reconstruction of bones. The diameter of the nails varies from 9mm to 12mm; the length varies from 170mm to 420mm.The screw implants are in corresponding diameter of 4.9mm & 10.5mm diameters with lengths varying as per the requirements and minimum length: 26mm to maximum length 120mm.

Auxein Brand of Elastic Nailing system consists of various shapes and sizes of sterile nails featuring end caps of different sizes. The nails and screws are fabricated from titanium. The system contains several modules based on the size of the device and application site such as fixation/reconstruction of bones. The diameter of the nails varies from 1.5mm to 4.0mm; the total length of 440mm. The end caps are in corresponding diameter ranges from 1.5mm to 4.0mm diameters with length of 14mm & 25mm.

Auxein Brand of Retrograde Nailing system consists of various shapes and sizes of sterile nails featuring proximal & distal holes, end caps & locking bolts of different sizes. The nails and screws are fabricated from titanium. The system contains several modules based on the size of the device and application site such as fixation/reconstruction of bones. The diameter of the nails varies from 9.5 to 12mm; the length varies from 180mm to 360mm. The screw implants are in corresponding diameter of 5.0mm diameters with lengths varying as per the requirements and minimum length: 32mm to maximum length 80mm.

Auxein Nailing System covered same products as of covered in K192003. In this addition Auxein Nailing System is offering sterile version of the nailing devices.

The device is made from a Titanium alloy, Ti-6Al-4V ELI (ASTM F136).

However, we are adding a new device i.e. Ajax Blade in this submission. The associated Instruments with the newly added device are tabulated below.

S.No.	***Item Description***	***Material***
1.	Inner Screwdriver, Hex 4.0mm	Stainless Steel as Per ASTM 899
2.	Inner Screw Holder, Hex 4.0mm	Stainless Steel as Per ASTM 899

3.	Container for AJAX Cephalic Screw Instrument Set	Stainless Steel as Per ASTM 899

These implants will be supplied in Sterile State (Gamma Irradiation) Only.

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

Indications for Use:

AUXEIN Brand of Expert Tibia Nailing System

AUXEIN Brand of Expert Tibia Nailing System- consists of variety of Bone nails and bone screws. Expert Tibia Nail System is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post-isthmic fractures; and tibial malunions and non- unions.

AUXEIN Brand of Expert Femoral Nailing System

AUXEIN Brand of Expert Femoral Nailing System -is intended to stabilize femoral shaft fractures, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions.

AUXEIN Brand of Gamma Nailing System

AUXEIN Brand of Gamma Nailing System -The Gamma Nail with Anti -Rotation Screw is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, including non-union, malunion and tumor resections. The Long Nail system is additionally indicated to treat pertrochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas, impending pathological fractures, long subtrochanteric fractures, ipsilateral femoral fractures, proximal or distal non-unions, malunions, revision procedures and tumor resections.

AUXEIN Brand of AJAX Advance Nailing System,

AUXEIN Brand of AJAX Advance Nailing System, end cap and screws is intended to treat stable and unstable proximal femoral fracture including Pertrochanteric fractures, Intertrochanteric fractures and High sub trochanteric fractures and combination of these fractures.

The AUXEIN MEDICAL's Elastic Intramedullary Nail System

The AUXEIN MEDICAL's Elastic Intramedullary Nail System is indicated for fixation of diaphyseal fractures where the canal is narrow or flexibility of the implant is important. This includes upper extremity fractures in all patients and lower extremity fractures in children above the age of 6 years and any patient below 65 kg. This system is also intended to treat metaphyseal and epiphyseal fractures, such as radial neck fractures.

AUXEIN Brand of Humeral Nailing System-

AUXEIN Brand of Humeral Nailing System is indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures, proximal

humeral fractures with diaphyseal extension, diaphyseal fractures of the humeral shaft, and impending pathologic humeral fractures..

AUXEIN Brand of Retrograde Nailing System

AUXEIN Brand of Retrograde Nailing System This nails are indicated for simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of long bones being treated."

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

Substantial equivalence including comparison with predicate devices.

A comparison between the Auxein Nailing 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	Identical Indications for use.	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 (Gamma)	Earlier the predicate device was supplied Non-sterile but the now device will be supplied Sterile.	Equivalent
5.	Dimensional Verification	Same dimensions are found in both New Devices as well as Predicate device.	Equivalent

(C.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-6 Aluminum-4 Vanadium 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's performance of Auxein Nailing System has been demonstrated against following applicable standards.

- ASTM F 543-17
- ASTM F1264
- ASTM F384
- Custom Fatigue Testing

(B.1). ***Discussion on the clinical evaluation referenced and relied upon:***

Auxein Nailing System is of similar design and pattern as well as similar intended use.

Conclusion:

General, Safety and Performance conclusion:

S.No.	Parameter of Conclusion	Proposed Device	Predicate Device
1.	Product Code	HSB, JDS	Same
2.	Regulation Number	21 CFR 888.3020, 21 CFR 888.3030	Same
3.	Regulatory Class	Class II	Same
4.	Intended Use	**AUXEIN Brand of Expert Tibia Nailing System** AUXEIN Brand of Expert Tibia Nailing System- consists of variety of Bone nails and bone screws. Expert Tibia Nail System is intended to stabilize fractures of the proximal and distal tibia and the tibial shaft; open and closed tibial shaft fractures; certain pre- and post-isthmic fractures; and tibial malunions and non-unions. **AUXEIN Brand of Expert Femoral Nailing**	Same

		System AUXEIN Brand of Expert Femoral Nailing System -is intended to stabilize femoral shaft fractures, subtrochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions. **AUXEIN Brand of Ga-mma Nailing System** AUXEIN Brand of Gamma Nailing System -The Gamma Nail with Anti -Rotation Screw is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric fractures, intertrochanteric fractures, high subtrochanteric fractures and combinations of these fractures, including non-union, malunion and tumor resections. The Long Nail system is additionally indicated to treat pertrochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas, impending pathological fractures, long subtrochanteric fractures, ipsilateral femoral fractures, proximal or distal non-unions, malunions, revision procedures and tumor resections. **AUXEIN Brand of AJAX Advance Nailing System,** AUXEIN Brand of AJAX Advance Nailing System, end cap and screws is intended to treat stable and unstable proximal femoral fracture including Pertrochanteric fractures, Intertrochanteric fractures and High sub trochanteric fractures and combination of these fractures. **The AUXEIN MEDICAL's Elastic Intramedullary Nail System** The AUXEIN MEDICAL's Elastic	

		Intramedullary Nail System is indicated for fixation of diaphyseal fractures where the canal is narrow or flexibility of the implant is important. This includes upper extremity fractures in all patients and lower extremity fractures in children above the age of 6 years and any patient below 65 kg. This system is also intended to treat metaphyseal and epiphyseal fractures, such as radial neck fractures. **AUXEIN Brand of Humeral Nailing System** AUXEIN Brand of Humeral Nailing System is indicated for fractures of the proximal humerus, including 2-part surgical neck fractures, 3-part fractures, and 4-part fractures, proximal humeral fractures with diaphyseal extension, diaphyseal fractures of the humeral shaft, and impending pathologic humeral fractures. **AUXEIN Brand of Retrograde Nailing System** AUXEIN Brand of Retrograde Nailing System This nails are indicated for simple long bone fractures; severely comminuted, spiral, large oblique and segmental fractures; nonunions and malunions; polytrauma and multiple fractures; prophylactic nailing of impending pathologic fractures; reconstruction, following tumor resection and grafting; supracondylar fractures; bone lengthening and shortening. Interlocking intramedullary nails are indicated for fixation of fractures that occur in and between the proximal and distal third of long bones being treated."	
5.	Sterilization (Gamma)	Earlier the predicate device was supplied Non-Sterile but the now scope device will be supplied Sterile (Gamma Irradiation).	Same
6.	Mechanical Test Performance	• ASTM F543 • ASTM F384	Same

		● Screw-Cut Out Test ● ASTM F1264	
7.	Material Standards	ASTM F136 & ASTM F 899-12b.	Same

From the data available we can justify that the Auxein Nailing System 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. Hence our devices can be considered safe and effective for their intended use.

Non Clinical Testing

Gap assessment was performed between the previously cleared 510k and the new submission. Since this submission includes sterile version of products as new additions and no other technical changes are being included. No additional risk for mechanical testing and biocompatibility testing was identified.

We have performed the Mechanical Testing as per ASTM F384 and Screw Cut-Out test for the Ajax Blade.

The sterilization method was validated using the below standards:

- **ASTM F1980-**Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- **ISO 11737-2:2019-**Sterilization of health care products—Microbiological methods—Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.

Conclusion

Bases upon the non-clinical testing, the Auxein Nailing System has been demonstrated to be substantially equivalent to the predicate device and is safe and effective for its intended use.