



June 10, 2020

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

Re: K192003

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: April 23, 2020  
Received: April 23, 2020

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Michael C. Owens -S** Digitally signed by  
Michael C. Owens -S  
Date: 2020.06.10  
17:23:44 -04'00'

Michael Owens  
Acting 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

## Indications for Use

510(k) Number (if known)  
K192003

Device Name  
Auxein Nailing system

### 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-isthmus 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)

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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**

|                             |                                                                                                                                                         |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Submitter's Name:</b>    | Auxein Medical Private Limited.                                                                                                                         |
| <b>Address:</b>             | Auxein Medical Private Limited,<br>Plot Number 168-169-170, Phase-IV,<br>Kundli Industrial Area, HSIIDC, Sector-57,<br>Sonapat, Haryana – 131028, India |
| <b>Contact Person Name:</b> | Mr. Rahul Luthra                                                                                                                                        |
| <b>Title:</b>               | Director                                                                                                                                                |
| <b>Phone Number:</b>        | +91-9811720999                                                                                                                                          |
| <b>Dated:</b>               | 07.03.2020                                                                                                                                              |

Throughout the submission Auxein Brand of Nails are covered under this 510(k) submission.



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**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:** Orthopedic

**Regulation Number:** 21 CFR 888.3020, 21 CFR 888.3030

**Variants/Types:**

**Auxein Nailing System is** divided in following categories.

| S. No. | Name                          |
|--------|-------------------------------|
| 01     | Expert Tibia Nailing System   |
| 02     | Expert Femoral Nailing System |
| 03     | Ga-mma Nailing System         |
| 04     | AJAX Advance nailing system   |



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|    |                           |
|----|---------------------------|
| 05 | Elastic Nailing System    |
| 06 | Humeral Nailing System    |
| 07 | Retrograde Nailing System |

The aforementioned Nails are used with End cap, locking bolt, Cannulated Anti-Rotation screw, proximal screw, Inner screw, compression screw and Cephalic Screw.

### A.3) Identification of the Predicate Device:

Following are the predicate device 510(k) with which we are declaring substantial equivalence:

Following is the range of variants covered with their corresponding predicate devices.

| S.No. | Item Description                                                              | Predicate Device                                                                                                                                           |
|-------|-------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.    | Expert Tibia Nail                                                             | K962047, SYNTHES (USA) TITANIUM CANNULATED TIBIAL NAIL (TI CTN)                                                                                            |
| 2.    | End cap for Expert Tibia Nail                                                 |                                                                                                                                                            |
| 3.    | Ø 4.4 mm locking bolt                                                         | K000089, SYNTHES (USA), Locking screws                                                                                                                     |
|       | Ø 4.8 mm Locking bolt, self-tapping                                           | K040762, SYNTHES (USA) TIBIAL NAIL SYSTEM EX                                                                                                               |
| 4.    | Expert Femoral Nail, Left                                                     | K040336, SYNTHES (USA) LATERAL ENTRY FEMORAL NAIL SYSTEM                                                                                                   |
| 5.    | Expert Femoral Nail, Right                                                    |                                                                                                                                                            |
| 6.    | Ø 6.4 mm Cannulated Anti-Rotation Screw, Self-Tapping for Expert Femoral Nail |                                                                                                                                                            |
| 7.    | End Cap for Expert Femoral Nail                                               |                                                                                                                                                            |
| 8.    | 130° Anti-Rotation Gamma Nail, Long, Left                                     | K100238 DEPUY ORTHOPAEDICS, INC<br>HFN 125 DEGREE 9-13 MM, 180MM, HFN 130 DEGREE 9-13 MM, K012190, ADVANCED ORTHOPAEDIC SOLUTION, AOS Modular Femoral Nail |
| 9.    | 130° Anti-Rotation Gamma Nail, Long, Right                                    |                                                                                                                                                            |

|     |                                                    |                                                                                           |
|-----|----------------------------------------------------|-------------------------------------------------------------------------------------------|
| 10. | 130° Anti-Rotation Ga-mma Nail, Short              | K100238 DEPUY ORTHOPAEDICS, INC<br>HFN 125 DEGREE 9-13 MM, 180MM, HFN 130 DEGREE 9-13 MM, |
| 11  | Inner Screw For Anti-Rotation Ga-mma Nail - Long   |                                                                                           |
| 12  | Inner Screw For Anti-Rotation Ga-mma Nail - Short  |                                                                                           |
| 13  | Ø6.4mm Cannulated Anti-Rotation Screw              |                                                                                           |
| 14  | 130° Ga-mma Nail Type-II, Short                    |                                                                                           |
| 15  | 130° Ga-mma Nail, Type-II, Long, Left              |                                                                                           |
| 16  | 130° Ga-mma Nail, Type-II, Long, Right             |                                                                                           |
| 17  | End Cap For Ga-mma Nail Type-II                    |                                                                                           |
| 18  | End Cap For Ø10.5mm Cephalic Screw For Ga-mma Nail |                                                                                           |
| 19  | Ø4.8mm Locking Bolt, Self Tapping, For Ga-mm Nail  | K962047 SYNTHES (USA) TITANIUM CANNULATED TIBIAL NAIL (TI CTN)                            |
| 20  | Ø10.5mm Cephalic Screw For Ga-mma Nail             | K100238 DEPUY ORTHOPAEDICS, INC<br>HFN 125 DEGREE 9-13 MM, 180MM, HFN 130 DEGREE 9-13 MM, |
| 21  | Inner Screw For Ga-mma Nail Type-II                |                                                                                           |
| 22  | 130° AJAX Advance Nail, Short,                     |                                                                                           |
| 23  | 130° AJAX Advance Nail, Long, Left                 |                                                                                           |
| 24  | 130° AJAX Advance Nail, Long, Right                |                                                                                           |
| 25  | 125° AJAX Advance Nail, Short,                     |                                                                                           |
| 26  | 125° AJAX Advance Nail, Long, Left                 |                                                                                           |
| 27  | 125° AJAX Advance Nail, Long, Right,               |                                                                                           |

|    |                                                                   |                                                                                                                                                                                         |
|----|-------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 28 | AJAX Ø 4.9mm Locking Bolt, Self-Tapping                           | K970097, SYNTHES(USA) PROXIMAL FEMORAL NAIL (PFN) SYSTEM<br><br>K131548,SYNTHES (USA), Synthes Trochanteric Fixation Nail - Advanced System, used as predicate for Ajax Cephalic screws |
| 29 | Ajax Cephalic Screws                                              |                                                                                                                                                                                         |
| 30 | End Cap (For Cephalic Screws)                                     |                                                                                                                                                                                         |
| 31 | Inner Screws for Ajax Cephalic Screws                             |                                                                                                                                                                                         |
| 32 | Ajax Nail end cap( for cephalic Screws)                           |                                                                                                                                                                                         |
| 33 | Titanium Elastic Nail                                             | K032687 ACE NANCY NAIL DEPUY ORTHOPAEDICS, INC. 700 ORTHOPAEDIC DRIVE Warsaw, IN 46581 -0988                                                                                            |
| 34 | End cap for Titanium Elastic Nail, Size- 1                        |                                                                                                                                                                                         |
| 35 | End cap for Titanium Elastic Nail, Size- 2                        |                                                                                                                                                                                         |
| 36 | Reconstruction Nail,Cannulated                                    | K120807, SYNTHES MULTILOC HUMERAL NAILING SYSTEM                                                                                                                                        |
| 37 | Ø 3.5mm Locking Bolt                                              |                                                                                                                                                                                         |
| 38 | End Cap for Reconstruction cannulated intramedullary Humeral Nail |                                                                                                                                                                                         |
| 39 | Reconstruction cannulated intramedullary Humeral Nail             |                                                                                                                                                                                         |
| 40 | 4.5 mm Locking Bolt for Intramedullary Cannulated Humeral Nail    |                                                                                                                                                                                         |
| 41 | 4.5 mm proximal Screw                                             |                                                                                                                                                                                         |
| 42 | Intramedullary Cannulated Humeral Nail                            | K033071,SYNTHES (USA) CANNULATED TITANIUM HUMERAL NAIL SYSTEM                                                                                                                           |
| 43 | End Cap for Intramedullary Cannulated Humeral Nail                |                                                                                                                                                                                         |
| 44 | Compression Screw for Intramedullary Cannulated Humeral Nail      |                                                                                                                                                                                         |



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|    |                                     |                                                                                        |
|----|-------------------------------------|----------------------------------------------------------------------------------------|
| 45 | Retrograde Femoral Nail             | K051557, SMITH & NEPHEW, INC TRIGEN RETROGRADE FEMORAL, SUPRACONDYLAR AND TIBIAL NAILS |
| 46 | End Cap For Retrograde Femoral Nail |                                                                                        |
| 47 | 5.0 MM Locking Bolt Retrograde Nail |                                                                                        |

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

**Device Description:**

**Nail Fixation**

**Auxein Brand of Expert Tibia Nail system** consists of various shape and sizes of nails featuring proximal & distal holes, End cap & 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 8 mm to 12 mm; the length varies from 255 mm to 375 mm.

The screw implants are in corresponding diameter of 4.4 mm & 4.8 mm diameters with lengths varying as per the requirements and minimum length: 18 mm to maximum length 90 mm.

**Auxein Brand of Expert Femoral Nail system** consists of various shape and sizes of nails featuring proximal & distal holes, End cap, 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 9 mm to 13 mm; the length varies from 320 mm to 440 mm.

The screw implants are in corresponding diameter of 4.8 mm, 6.4 mm diameters with lengths varying as per the requirements and minimum length: 25 mm to maximum length 130 mm.

**Auxein Brand of Ga-mma Nailing system** consists of various shape and sizes of nails featuring proximal & distal holes, End cap, 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 9 mm to 13 mm; the length varies from 180 mm to 440 mm.

The screw implants are in corresponding diameter of 4.8 mm, 6.4mm & 10.5 mm diameters with lengths varying as per the requirements and minimum length: 26 mm to maximum length 120 mm.

**Auxein Brand of Humeral Nailing system** consists of various shape and sizes of nails featuring proximal & distal holes, End cap, 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 7mm to 9 mm; the length varies from 180 mm to 320 mm.

The screw implants are in corresponding diameter of 3.5 mm & 4.5 mm diameters with lengths varying as per the requirements and minimum length: 20 mm to maximum length 70mm.

**Auxein Brand of AJAX Advance Nailing system** consists of various shape and sizes of nails featuring proximal & distal holes, End cap, locking bolts, Cephalic screw, 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 9 mm to 12 mm; the length varies from 170 mm to 420 mm.

The screw implants are in corresponding diameter of 4.9 mm & 10.5 mm diameters with lengths varying as per the requirements and minimum length: 26 mm to maximum length 120 mm.

**Auxein Brand of Elastic Nailing system** consists of various shape and sizes of nails featuring end cap 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 1.5 mm to 4.0 mm; the total length of 440 mm.

The end caps are in corresponding diameter ranges from 1.5 mm to 4.0 mm diameters with length of 14 mm & 25 mm.

**Auxein Brand of Retrograde Nailing system** consists of various shape and sizes of nails featuring proximal & distal holes, End cap & 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 10 mm to 12 mm; the length varies from 180 mm to 360 mm.

The screw implants are in corresponding diameter of 5.0 mm diameters with lengths varying as per the requirements and minimum length: 32 mm to maximum length 80 mm.

**These implants are sold non-sterile, the products have to be sterilized prior to use.**

## **A5). 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** - Expert Femoral Nail 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** - The Gamma Nail with Anti-Rotation Screw is intended to treat stable and unstable proximal fractures of the femur including per trochanteric fractures, intertrochanteric fractures, high sub trochanteric fractures and combinations of these fractures, including non-union, malunion and tumor resections. The Long Nail system is additionally indicated to treat per trochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas, impending pathological fractures, long sub trochanteric fractures, ipsilateral femoral fractures, proximal or distal non-unions, malunions, revision procedures and tumor resections.
- **AUXEIN Brand of AJAX Advance Nailing System**, end cap and screws is intended to treat stable and unstable proximal femoral fracture including Per trochanteric fractures, Intertrochanteric fractures and High sub trochanteric fractures and combination of these fracture.
- **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



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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** - This Nail 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** - 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 Brand of Nails, screws, 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    |
|--------|--------------------------|----------------------------------------------------------------------------------|------------|
| 01     | Indications for use      | Similar intended use in New Device and Predicate device                          | Equivalent |
| 02     | Material                 | Same material used in New Device and Predicate device                            | Equivalent |
| 03     | Performance Standards    | Same performance standards used in both New Device as well as predicate device   | Equivalent |
| 04     | Sterilization            | Same method of sterilization used in both New Device as well as Predicate device | Equivalent |
| 05     | Dimensional Verification | Similar 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 to first, as it is the basis of manufacturing metallic surgical implants.

We have complied with 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 F899-12b 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 is attached herewith

### B: Performance Standards:

The device performance of Auxein Brand of Nails, screws, has been demonstrated against following applicable standards

- ASTM F 1264
- ASTM F 384
- ASTM F 543
- **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 MEDDEV2.71 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 |
|--------|-------------------------|------------------------------------|------------------|
| 01     | Product Code            | HSB<br>JDS                         | Same             |
| 02     | Regulation Number       | 21 CFR 888.3020<br>21 CFR 888.3030 | Same             |

|    |                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                      |
|----|------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------|
| 03 | Regulatory Class | Class II                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Same                 |
| 04 | Intended Use     | <ul style="list-style-type: none"> <li>• <b>AUXEIN Brand of Expert Tibia Nailing System</b>- 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-isthmus fractures; and tibial malunions and non- unions.</li> <li>• <b>Auxein Brand of Expert Femoral Nailing System</b> - Expert Femoral Nail is intended to stabilize femoral shaft fractures, sub trochanteric fractures, ipsilateral neck/shaft fractures, impending pathologic fractures, non-unions and malunions.</li> <li>• <b>Auxein Brand Gamma Nailing system</b> - The Gamma Nail with Anti-Rotation Screw is intended to treat stable and unstable proximal fractures of the femur including per trochanteric fractures, intertrochanteric fractures, high sub trochanteric fractures and combinations of these fractures, including non-union, malunion and tumor resections. The Long Nail system is additionally indicated to treat per trochanteric fractures associated with shaft fractures, pathologic fractures in osteoporotic bone (including prophylactic use) of the trochanteric and diaphyseal areas, impending pathological fractures, long sub trochanteric fractures, ipsilateral femoral fractures, proximal or distal non-unions, malunions, revision procedures and tumor resections.</li> </ul> | Similar Intended Use |

|  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  |
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|  |  | <ul style="list-style-type: none"> <li>• <b>Auxein Brand of AJAX Advance Nailing System</b>, end cap and screws is intended to treat stable and unstable proximal femoral fracture including Per trochanteric fractures, Intertrochanteric fractures and High sub trochanteric fractures and combination of these fracture.</li> <li>• <b>The AUXEIN MEDICAL'S Elastic Intramedullary Nail System</b> 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.</li> <li>• <b>AUXEIN Brand of Humeral Nailing System</b><br/>- This Nail 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.</li> </ul> |  |
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- AUXEIN Brand of Retrograde Nailing System** - This nail 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.



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|    |                             |                                                                                                                                                          |      |
|----|-----------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| 05 | Sterilization               | Provided Non-Sterile and to be sterilized using Autoclaving Method to achieve SAL of $10^{-6}$                                                           | Same |
| 06 | Mechanical Test Performance | <b>For Nails &amp; Screws:</b><br>As per ASTM F 1264, ASTM F 384, ASTM F 543 Standard Specification and Test Methods for Intramedullary Fixation Devices | Same |
| 07 | Material Standards          | ASTM F 136 & ASTM F 899-12b                                                                                                                              | Same |

The data described above completely supports the substantial equivalence of the Auxein brand of nailing system to the predicate devices listed.