November 4, 2022

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

Re: K213108
Trade/Device Name: Humerus & Ulna 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: October 5, 2022
Received: October 5, 2022

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213108

Device Name
Humerus and Ulna System

Indications for Use *(Describe)*

Specific Indications:

1. 2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate
2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate is intended for treating of Intraarticular Fracture of the distal humerus, Supracondylar fractures of the distal humerus and Non-unions of the distal humerus.

2. 2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support
2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support is intended for treating of Intraarticular fractures of the distal humerus, Supracondylar fractures of the distal humerus and Non-unions of the distal humerus.

3. 2.7/3.5mm Wise-Lock Dorsolateral Medial Distal Humerus Plate
2.7/3.5mm Wise-Lock Dorsolateral Medial Distal Humerus Plate are indicated for treating of Intraarticular fractures of the distal humerus, Supracondylar fractures of the distal humerus and Non-unions of the distal humerus.

4. 3.5mm Wise-Lock Extra-Articular Distal Humerus Plate
3.5mm Wise-Lock Extra-Articular Distal Humerus Plate are indicated for fractures of the distal humerus.

5. PHEELOS-3.5mm Wise-Lock Proximal Humerus Plate, Short
PHEELOS Short Indications
• Dislocated two-, three-, and four-fragment fractures of the proximal humerus
• Pseudarthroses in the proximal humerus
• Osteotomies in the proximal humerus

6. PHEELOS-3.5mm Wise-Lock Proximal Humerus Plate, Long
• As for PHEELOS Short, but for fractures extending to the shaft or without medial support.

7. 3.5mm Wise-Lock Proximal Humerus Plate
The 3.5mm Wise-Lock Proximal Humerus Plate is intended for fractures and fracture dislocations, osteotomies, and nonunions of the proximal humerus.3

8. 3.5mm Wise-Lock Periarticular Proximal Humerus Plate
3.5mm Wise-Lock Periarticular Proximal Humerus Plate are indicated for fractures, fracture dislocations, osteotomies, and nonunions of the proximal humerus.

9. 3.5mm Wise-Lock Olecranon Plate
3.5mm Wise-Lock Olecranon Plate is indicated for fixation of fractures, osteotomies and non-unions of the olecranon.

10. 3.5mm Wise-Lock Hook Plate
3.5mm Wise-Lock Hook Plate is indicated for fractures, osteotomies and non-unions of small bones including the ulna, radius, tibia and fibula.

11. 2.7mm Wise-Lock Screw, Self-Tapping (Hex Head)

This Screw is indicated for the fixation of bone and plate to produce compression in bones which is required to mend a bone injury.

12. 3.5mm Wise-Lock Screw, Self-Tapping (Hex Head)
This Screw is indicated for the fixation of bone and plate to produce compression in bones which is required to mend a bone injury.

13. 3.5mm Wise-Lock Screw, Self-Drilling, (Hex Head)
This Screw is indicated for the fixation of bone and plate to produce compression in bones which is required to mend a bone injury.

14. 3.5mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head)
This Screw is indicated for the fixation of bone and plate to produce compression in bones which is required to mend a bone injury.

15. 3.5mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head)
This Screw is indicated for the fixation of bone and plate to produce compression in bones which is required to mend a bone injury.

16. 3.5mm Cortical Screw, Self-Tapping, (Hex Head)
This Screw is indicated for the fixation of bone and plate to produce compression in bones which is required to mend a bone injury.

17. 4.0mm Cancellous Screw, Short Thread
This Screw is indicated for the fixation of bone and plate to produce compression in bones which is required to mend a bone injury.

18. 4.0mm Cancellous Screw, Full Thread
This Screw is indicated for the fixation of bone and plate to produce compression in bones which is required to mend a bone injury.

19. 2.7mm Cortical Screw, Self-Tapping, (Hex Head)
This Screw is indicated for the fixation of bone and plate to produce compression in bones which is required to mend a bone injury.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 6.0: 510k 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
Email Id:	info@auxein.com
Phone Number:	+91 9560557733
Dated:	04.11.2022

Person Responsible for Regulatory Compliance

Name:	Mr. Mohit Kumar
Title:	Sr. Research Engineer
Email Id:	m.kumar@auxein.com
Dated:	04.11.2022

Throughout the submission of Humerus and Ulna 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:
Humerus and Ulna System

Common or Usual Name:
Plate, Fixation, Bone (Primary)
Screw Fixation, Bone

Classification Name:
Single/multiple component metallic bone fixation appliances and accessories (Primary)
Smooth or threaded metallic bone fixation fastener

Product Code:
HRS (Primary)
HWC

Device Class: II

Review Panel: Orthopedic

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

Primary Product Code	Classification Name	Common Name	Regulation Number
HRS	Single/multiple component metallic bone fixation appliances and accessories	Plate, Fixation Bone	21 CFR 888.3030

Variants/Types:
Humerus and Ulna Systems consist of the following Components:

S.No.	Product Description
1.	2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate (3, 5, 7, 9, 14 Holes), Left and Right
2.	2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support (3, 5, 7, 9, 14 Holes), Left and Right
3.	2.7/3.5mm Wise-Lock Dorsolateral Medial Distal Humerus Plate, (3, 5, 7, 9, 14 Holes), Left and Right
4.	3.5mm Wise-Lock Hook Plate, (3, 4, 5 Holes)
5.	3.5mm Wise-Lock Extra-Articular Distal Humerus Plate, (4, 6, 8, 10, 12, 14 Holes), Left and Right
6.	3.5mm Wise-Lock Olecranon Plate, (2, 4, 6, 8, 10, 12 Holes), Left and Right
7.	PHEELOS-3.5mm Wise-Lock Proximal Humerus Plate, Short, (3, 4, 5 Holes)
8.	PHEELOS-3.5mm Wise-Lock Proximal Humerus Plate, Long, (5, 6, 8, 10, 12 Holes)
9.	3.5mm Wise-Lock Periarticular Proximal Humerus Plate, (2, 3, 4, 5, 6, 8, 10, 12, 14 Holes), Left and Right

10.	3.5mm Wise-Lock Proximal Humerus Plate, (5, 6, 7, 8 Holes)
Screws	
11.	2.7mm Wise-Lock Screw, Self-Tapping (Hex Head), (10-60mm) Length
12.	3.5mm Wise-Lock Screw, Self-Tapping (Hex Head), (10-80mm) Length
13.	3.5mm Wise-Lock Screw, Self-Drilling, (Hex Head), (10-60mm) Length
14.	3.5mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head), (10-60mm) Length
15.	3.5mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head), (10-60mm) Length
16.	3.5mm Cortical Screw, Self-Tapping, (Hex Head), (10-90 mm) Length
17.	4.0mm Cancellous Screw, Short Thread, (12-60 mm) Length
18.	4.0mm Cancellous Screw, Full Thread, (12-60 mm) Length
19.	2.7mm Cortical Screw, Self-Tapping, (Hex Head), Titanium (6-30 mm) Length

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.

Primary Predicate:

510K Number	K082625
Applicant	Synthes, USA
Common Name	Bone Fixation Plates
Device Name	3.5mm LCP Periarticular Proximal Humerus Plates

Other Predicate:

510K Number	K082807
Applicant	Synthes, USA
Common Name	3.5 /4.5 mm LCP System
Device Name	Synthes 3.5mm LCP Olecranon Plates

Reference Device:

510K Number	K033995
Applicant	Synthes, USA
Common Name	Bone Fixation Plates
Device Name	3.5 mm LCP Distal Humerus System

510K Number	K141680

Applicant	Auxein Medical Private Limited, India
Common Name	Bone Fixation Plates
Device Name	Auxein Bone Plates and Screws

510K Number	K082072
Applicant	Synthes, USA
Common Name	Bone Fixation Plates
Device Name	3.5 mm LCP Hook Plate

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 Humerus and Ulna System consists of various types of bone plates, Screws for implantation in the humerus and ulna bone to treat humerus and ulna bone fractures.

The Humerus and Ulna System consists of medial and postero-lateral distal humerus plates of various lengths and 2.7 mm locking screws. The plates are pre-contoured to match the anatomy of the distal humerus with a limited contact low profile design. The plate features locking compression holes which accept 2.4, 3.5, & 4.0 mm cortex screws, 2.4, 2.7 & 3.5 mm locking screws, and 4.0 mm cancellous screws. The System is available in Stainless Steel and Titanium.

These implants are sold in both non-sterile and sterile conditions.

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

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

The humerus and Ulna System contains several plates and each plate has its intended uses. The intended uses for all plates are given below:

A.5) Indications for Use:

2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate

2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate is intended for treating of Intraarticular Fracture of the distal humerus, Supracondylar fractures of the distal humerus and Non-unions of the distal humerus.

2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support

2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support is intended for treating of Intraarticular fractures of the distal humerus, Supracondylar fractures of the distal humerus and Non-unions of the distal humerus.

2.7/3.5mm Wise-Lock Dorsolateral Medial Distal Humerus Plate

2.7/3.5mm Wise-Lock Dorsolateral Medial Distal Humerus Plate are indicated for treating of Intraarticular fractures of the distal humerus, Supracondylar fractures of the distal humerus and Non-unions of the distal humerus.

3.5mm Wise-Lock Extra-Articular Distal Humerus Plate

3.5mm Wise-Lock Extra-Articular Distal Humerus Plate are indicated for fractures of the distal humerus.

PHEELOS-3.5mm Wise-Lock Proximal Humerus Plate, Short & Long

PHEELOS Short Indications

• Dislocated two-, three-, and four-fragment fractures of the proximal humerus
• Pseudarthroses in the proximal humerus
• Osteotomies in the proximal humerus

PHEELOS long indications

• As for PHEELOS Short, but for fractures extending to the shaft or without medial support.

3.5mm Wise-Lock Proximal Humerus Plate

The 3.5mm Wise-Lock Proximal Humerus Plate is intended for fractures and fracture dislocations, osteotomies, and nonunions of the proximal humerus.

3.5mm Wise-Lock Periarticular Proximal Humerus Plate

3.5mm Wise-Lock Periarticular Proximal Humerus Plate are indicated for fractures, fracture dislocations, osteotomies, and nonunions of the proximal humerus.

3.5mm Wise-Lock Olecranon Plate

3.5mm Wise-Lock Olecranon Plate is indicated for fixation of fractures, osteotomies and non-unions of the olecranon.

3.5mm Wise-Lock Hook Plate

3.5mm Wise-Lock Hook Plate is indicated for fractures, osteotomies and non-unions of small bones including the ulna, radius, tibia and fibula.

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 Humerus and Ulna 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	Auxein Device	Predicate Device	Remarks
1.	Product Code	HWC (Primary), HRS	HWC (Primary), HRS	Identical as predicate device
2.	Regulation Number	21 CFR 888.3030 (Primary), 21 CFR 888.3040	21 CFR 888.3030 (Primary), 21 CFR 888.3040	Identical as

				predicate device
3.	Regulatory Class	Class II	Class II	Identical as predicate device
4.	Indications for use	**2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate** 2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate is intended for treating fractures of humerus bones. **2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support** 2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support is intended for treating fractures of humerus bones. **2.7/3.5mm Wise-Lock Dorsolateral Medial Distal Humerus Plate** 2.7/3.5mm Wise-Lock Dorsolateral Medial Distal Humerus Plate are indicated for intra articular fractures of the distal humerus, commninuted supracondylar fractures, osteotomies, and non-unions of the distal humerus. **3.5mm Wise-Lock Extra-Articular Distal Humerus Plate** 3.5mm Wise-Lock Extra-Articular Distal Humerus Plate are indicated for intra articular fractures of the distal	**2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate** 2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate is intended for treating fractures of humerus bones. **2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support** 2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support is intended for treating fractures of humerus bones. **3.5 mm LCP Distal Humerus System** 3.5 mm LCP Distal Humerus System are indicated for intra articular fractures of the distal humerus, commninuted supracondylar fractures, osteotomies, and non-unions of the distal humerus. **3.5mm LCP Extra-Articular Distal Humerus Plate** 3.5mm LCP Extra-Articular Distal Humerus Plate are indicated for intra articular fractures of the distal humerus, commninuted supracondylar fractures, osteotomies, and non-unions of the distal humerus. **PHEELOS-3.5mm Wise-Lock Proximal Humerus Plate, Short**	Identical as predicate device.

		humerus, commninuted supracondylar fractures, osteotomies, and non-unions of the distal humerus. **PHEELOS-3.5mm Wise-Lock Proximal Humerus Plate, Short & Long** PHEELOS-3.5mm Wise-Lock Proximal Humerus Plate, Short & Long are intended for treating fractures of humerus bones. **3.5mm Wise-Lock Proximal Humerus Plate** The 3.5mm Wise-Lock Proximal Humerus Plate is intended for treating fractures of humerus bones. **3.5mm Wise-Lock Periarticular Proximal Humerus Plate** 3.5mm Wise-Lock Periarticular Proximal Humerus Plate are indicated for fractures, fracture dislocations, osteotomies, and nonunions of the proximal humerus. **3.5mm Wise-Lock Olecranon Plate** 3.5mm Wise-Lock Olecranon Plate is indicated for fixation of fractures, osteotomies and non-unions of the olecranon. **3.5mm Wise-Lock Hook Plate** 3.5mm Wise-Lock Hook Plate is indicated for fractures, osteotomies and	**& Long** PHEELOS-3.5mm Wise-Lock Proximal Humerus Plate, Short & Long are intended for treating fractures of humerus bones. **3.5mm Wise-Lock Proximal Humerus Plate** The 3.5mm Wise-Lock Proximal Humerus Plate is intended for treating fractures of humerus bones. **3.5mm LCP Periarticular Proximal Humerus Plates** 3.5mm LCP Periarticular Proximal Humerus Plate are indicated for fractures, fracture dislocations, osteotomies, and nonunions of the proximal humerus, particularly in osteopenic bone. **3.5mm LCP Olecranon Plate** The Synthes 3.5 mm Locking Compression Plate (LCP) System is indicated for fixation of fractures, osteotomies and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, fibula, particularly in osteopenic bone for adult patients. **3.5 mm LCP Hook Plate** 3.5mm LCP Hook Plate is indicated for fractures, osteotomies and non-unions of small bones including the ulna, radius, tibia and fibula, particularly in osteopenic bone.	

		non-unions of small bones including the ulna, radius, tibia and fibula.		
5.	Material	Titanium Alloy and Stainless Steel.	Titanium Alloy and Stainless Steel.	Confirm to the same material standard
6.	Performance Standards	The performance testing was done on the subject device as per the standard ASTM F382 and F543.	The performance testing was done on the predicate device as per the standard ASTM F382 and F543.	Identical as predicate device.
7.	Sterilization	Gamma Sterilization Method and Non-Sterile used in subject device.	Gamma Sterilization Method and Non-Sterile used in predicate device.	Identical as predicate device.
8.	Shelf-life	5 Years (For Sterilized Product)	5 Years (For Sterilized Product)	Identical as predicate device.
9.	Single Use/Reuse	Single Use	Single Use	Identical as predicate device.
10.	Operating Principle	The plate is fixed to the bone by application of screws on both sides of the fracture.	The plate is fixed to the bone by application of screws on both sides of the fracture.	Identical as predicate device.
11.	Dimensional Verification	The same dimensions are found in both new devices as well as Predicate devices.		Identical as predicate device.

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:

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:

- **ASTM F136/ISO 5832-3:** Standard specification for wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.
- **ASTM F899-12:** Standard Specification for Wrought Stainless Steels for surgical instruments.
- **ASTM F138/ISO 5832-1:** Standard Specification for Wrought-18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants.

Note: We have used Grade 304 of Stainless steel (SS 304) Material for instruments as per ASTM F899-12b, Stainless Steel (Grade 316L) as per ISO 5832-3/ASTM F138 for Stainless Steel Implants and Titanium Alloy (Ti-6Al-4V) Grade 5 as per ISO 5832-1/ASTM F136 for Titanium Implants.

We have verified the purchased material and are in compliance to these standards and copies of the relevant test results are attached in Vol_005_Appendix D Implant Material Report and Vol_006_ Appendix E ASTM F899 Report of the technical dossier.

Summary of Biocompatibility

The device in its final finished form has been evaluated for biocompatibility according to ISO 10993.

Mechanical performance

- ASTM F382, Standard Specification and Test Method for Metallic Bone Plates.
- ASTM F543, Standard Specification and Test Method for Metallic Medical Bone Screws.

The following tests were performed with the predicate device:

Plate

- 4-Point Static Test: Conforms

Screw

- Driving Torque Test: Conforms
- Torsion Test: Conforms
- Axial Pull-out Test: Conforms

The results of this testing indicate that the Humerus and Ulna System is equivalent to the predicate device.

Sterilization, shelf-life and packaging for sterile product

- ISO 11137-1:2006, sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
- ISO 11137-2:2012, 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(en), 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 Sterilization of medical devices - Microbiological methods- Part 1: Estimation of population of microorganisms on products.
- ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods- Part 2: Tests of sterility performed in the validation of a sterilization process.
- ISO 11607-1:2006/AMD1:2014 Packaging for terminally sterilized medical devices - part 1:requirements for materials, sterile barrier systems and packaging system.
- ISO 11607-2:2006/AMD1:2014 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.
- ASTM F1980:2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
- ASTM F88/F88M:2015 Standard test method for seal strength of flexible barrier materials.
- ASTM F1929:2015 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 Humerus and Ulna is as safe, and as effective and perform the same indications for use as those of already marketed predicate devices identified in A.3. of 510(k) summary.