March 14, 2022

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

Re: K211324
Trade/Device Name: 2.4mm Distal Radius 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: February 9, 2022
Received: February 11, 2022

Dear Gaurav Luthra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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,

For: 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

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)*
K211324

Device Name
2.4mm Radius System

Indications for Use *(Describe)*

2.4mm Wise-Lock Distal Radius System:
2.4mm Wise-Lock Distal Radius System are used for displaced extra-articular and intra-articular distal radius fractures and corrective osteotomies of the distal radius.

2.4mm Wise-Lock Proximal Radius System:
2.4mm Wise-Lock Proximal Radius System are used for extra-articular and intra-articular fractures of Proximal radius and multifragmented radial neck fractures.

2.4mm Variable Angle Distal Radius System:
2.4mm Variable Angle Distal Radius System are used for displaced extra-articular and intra-articular distal radius fractures and corrective osteotomies of the distal radius.

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 5.0: 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
Phone Number:	+91-9811720999
Dated:	2022.03.09

Person Responsible for Regulatory Compliance

Name:	Mr. Mohit Kumar
Title:	Sr. Research Engineer
Email Id:	m.kumar@auxein.com
Dated:	2022.03.09

Throughout the submission of 2.4 mm Radius 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:
2.4 mm Radius 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 Identification

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

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	K012114
Applicant	Synthes, USA
Common Name	Bone Fixation Plates
Device Name	2.4mm Distal Radius System

Reference Predicate:

510K Number	K040777, K091644
Applicant	Synthes, USA
Common Name	Bone Fixation Plates
Device Name	2.4mm Distal Radius System

510K Number	K091644
Applicant	Synthes, USA
Common Name	Bone Fixation Plates
Device Name	2.4mm Distal Radius System

510K Number	K083694, K110125
Applicant	Synthes, USA
Common Name	Bone Fixation Plate
Device Name	2.4mm VA LCP System

510K Number	K102694
Applicant	Synthes, USA
Common Name	Bone Fixation Screws
Device Name	Locking Screw

510K Number	K033975
Applicant	Synthes, USA
Common Name	Bone Fixation Screws
Device Name	Locking Screw

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 2.4mm Radius System consists of various types of bone plates, screws for implantation in the radius bone to treat the radius bone fracture.

2.4mm Wise-Lock "T" Distal Radius Dorsal Plate

- The shaft portion of the plate features a Combi & Capsule and the head portion features round holes. The plates are available with 3 & 4 shaft holes.It has 3 head Holes. This plate is available in 40.1 mm and 49.1 mm length. The plate is 2 mm thick.
- The 2.4mm Wise-Lock "T" Distal Radius Dorsal Plate are intended for fixation of complex intra-extra articular fractures and osteotomies of the distal radius and other small bones.

2.4mm Wise-Lock Distal Radius Dorsal Plate, Straight:

- The shaft portion of the plate features a Combi, capsule and round holes. The plates are available with 5 & 6 Shaft holes. It is available in 48.7 mm & 57.7 mm length. Plate thickness is 2mm.
- The 2.4mm Wise-Lock Distal Radius Dorsal Plate, Straight are intended for fixation of complex intra-extra articular fractures and osteotomies of the distal radius and other small bones.

2.4mm Wise-Lock "L" Distal Radius Dorsal Plate, (2 & 3 Head Holes), Left & Right:

- Plate features locking compression holes and round locking holes that accepts 2.4mm cortical and locking screws. Plate Thickness is 2 mm.
- There are 2 and 3 head holes. In 2 & 3 head holes, length of the plate varies from 40.1 mm to 49.1 mm.
- There is an oblique plate in this plate having 3 Head holes and it is available in 43.6 mm to 52.6 mm length.
- The 2.4mm Wise-Lock "L" Distal Radius Dorsal Plate are intended for fixation of complex intra-extra

articular fractures and osteotomies of the distal radius and other small bones.

2.4mm Wise-Lock Distal Radius Volar Plate, Left & Right (5 Head Holes):

- The shaft portion of the plate features Combi holes and the head portion features round holes. The plates are available with 5 head holes for both the left and right side. The system consists of a variety of bone plates and fixed angle bone screws. These plates are available in 45 mm, 63 mm, 26 mm in length and 2mm thick.
- The 2.4 mm Wise Lock Distal Radius Volar Plate are Intended for extra-articular and intra-articular fractures of the proximal radius and for multi-fragmented radial neck fractures.

2.4mm Wise-Lock Distal Radius Volar Plate, Extra-articular (4 & 5 Head Holes), Left & Right:

- The shaft portion of the plate features Combi holes and the head portion features round holes. The plates are available with 4 & 5 head holes for both the left and right side. The system consists of a variety of bone plates and fixed angle bone screws.
- Plate having 4 head holes are available in 48.6 mm & 66.6 mm length and the plates having 5 Head Holes are available in 49.1 mm and 67.1 mm length.
- The 2.4mm Wise-Lock Distal Radius Volar Plate, Extra-articular implants are intended for extra-articular and intra-articular fractures of the proximal radius and for multi-fragmented radial neck fractures.

2.4mm Wise-Lock Volar Buttress Plate, left & Right (5 Head Holes):

- Volar Plates are pre contoured for anatomic fit on the volar aspect of the distal radius. Volar Plates are pre contoured for anatomic fit on the volar aspect of the distal radius. Plate available with 5 head holes & 3 shaft holes. The plates are left & right configured.
- Length of the plate is 55.6 mm.
- 2.4mm Wise- Lock Volar Buttress Plate are intended for extra-articular and intra-articular fractures of the proximal radius and for multi-fragmented radial neck fractures.

2.4mm Wise-Lock Volar Column Distal Radius Plate, Left & Right (8 & 9 Head Holes):

- Plate features locking compression holes and round locking holes that accepts 2.4mm cortical and locking screws. Plate available with 5 head holes & 3 shaft holes. The plates are left & right configured.
- 8 head holes plate are available in 49 mm, 58 mm, 67 mm length and 9 head holes plates are available in 49.6 mm, 58.6 mm & 67.6 mm length. Plate thickness is 2.20 mm.
- The 2.4mm Wise-Lock Volar Column Distal Radius Plate are intended for fixation of complex intra and extra-articular fractures of and osteotomies of the distal radius and other small bones.

2.4mm Wise-Lock Proximal Radius Plate for Radius Head Rim (5 Head Holes), Left & Right:

- Plate features locking compression holes and round locking holes that accepts 2.4mm cortical and locking screws and available with 2,3 & 4 shaft holes. The plates are left & right configured.
- This Plate is available in 36.2 mm, 46 mm and 55.58 mm length. Plate Thickness is 1.7 mm.
- The 2.4mm Wise-Lock Proximal Radius Plate for Radial Head Rim implants is indicated for extra-articular and intra-articular fractures of the proximal radius and for multi-fragmented radial neck fractures.

2.4mm Wise-Lock Proximal Radius Plate for Radial Head Neck (5 Head Holes):

- Plate features locking compression holes and round locking holes that accepts 2.4mm cortical and locking screws and available with 2, 3 & 4 shaft holes.
- This plate is available in 31.40 mm, 41.20 mm and 51.0 mm length having 1.7 mm plate thickness.
- The 2.4mm Wise-Lock Proximal Radius Plate for Radial Head Neck are intended for extra-articular and intra-articular fractures of the proximal radius and for multi-fragmented radial neck fractures.

2.4mm Wise-Lock distal radius volar plate extra-long (4 head holes):

- Volar Plates are precontoured for anatomic fit on the volar aspect of the distal radius. Plate features locking compression holes and round locking holes that accepts 2.4mm cortical and Wise-lock screws and available with 4 head holes & 8,10,12 shaft holes, Plates are left & right configured.
- Available in 99mm, 119mm, 139mm length with 2 mm plate thickness.
- The 2.4mm Wise-Lock Distal Radius Volar Plate, Extra-Long implant components are temporary implants that are intended for extra-articular and intra-articular fractures of the proximal radius and for multi-fragmented radial neck fractures.

2.4mm Variable Angle Two-Column Volar Distal Radius Plate (6 & 7 head Holes):

- The shaft portion of the plate features Combi holes and the head portion features locking star holes. The plates are available with 6 & 7 head holes and 2, 3, 4, 5 Shaft holes for both the left and right side. The system consists of a variety of bone plates and fixed angle bone screws. It is available in Titanium alloy as well as Stainless steel. Plate thickness is 2.3 mm.
- There are three types of plates i.e. Narrow head, Standard head & Wide head.
- Narrow Head:It have 6 hole head and width of 19.5 mm.
- Standard Head: It have 6 hole head and width of 22 mm.
- Wide Head: It have 7 hole head and width of 25.5 mm.
- Anatomically contoured Volar Distal radius plates designed to address both simple and complex fractures, Variable Angle Holes in the head of the plate combined with Variable Angle Locking Screws offer a locked construct to support the articular surface and reduce the need for bone graft.
- 2.4mm Variable Angle Two-Column Volar Distal Radius Plate are intended for fixation of complex intra and extra-articular fractures and osteotomies of the distal radius and other small bones.

2.4mm Variable Angle Volar Rim Distal Radius plate (6 & 7 Head Holes):

- The shaft portion of the plate features Combi holes and the head portion features locking star holes. The plates are available with 6 & 7 head holes and 3, 4, 5, 6, 7, 8 Shaft holes for both the left and right side. The system consists of a variety of bone plates and fixed angle bone screws. It is available in Titanium alloy as well as Stainless steel.
- Plate Length is 57 mm and thickness is 2.05mm.
- 2.4mm Variable Angle Volar Rim Distal Radius plate are intended for fixation of fracture of complex intra and extra-articular fractures of the distal radius and small bones in adults, skeletally mature adolescents, and the following adolescents distal radius fractures: intra-articular fractures exiting the epiphysis, intra-articular fractures exiting the metaphysis, physeal crush injuries, and any injuries which cause growth arrest to the distal radius.

2.7 mm Cortical Screw, Self-Tapping, Hex Head

- This screw is available in Titanium, for use in combi holes, used to provide compression or neutral fixation, 6 mm to 30 mm lengths (2 mm increments).

2.4 mm Cortical Screw, Self-Tapping, Hex Head

- This screw is available in Titanium, used in round or Combi holes, Low-profile head in the plate holes, used to provide compression or neutral fixation, 6 mm to 30 mm lengths (2 mm increments).

2.4 mm Wise-Lock Screw, Self-Tapping, Hex Head

- This screw is available in Titanium, threaded, conical head locks securely into the threaded holes in the plate to provide angular stability, locked screws allow uni cortical screw fixation and load transfer to the near cortex, 6 mm to 30 mm lengths (2 mm increments).

2.4 mm Wise-Lock Screw, Self-tapping, Star Head

- This screw is available in Titanium and Stainless Steel, Threaded, conical head locks securely into the threaded holes in the plate to provide angular stability, Locked screws allow uni cortical screw fixation and load transfer to the near cortex, 6 mm to 30 mm lengths (2 mm increments).

2.4mm Variable Angle Screw, Self-Tapping, Star head

- This screw is available in Titanium and Stainless Steel, Threaded, Rounded head locks securely into the threaded variable angle holes in the plate to provide angular stability, Gives the surgeon the ability to create a fixed-angle construct with a freedom of +/-15 degree off-axis screw angulation, 6 mm to 30 mm lengths (2 mm increments).

2.4 mm Cortical Screw, Self-Tapping, Star Head

- This screw is available in Titanium and Stainless Steel, For use in round or Combi holes, Low-profile head in the plate holes, Used to provide compression or neutral fixation, 6 mm to 30 mm lengths (2 mm increments).

2.7 mm Cortical Screw, Self-Tapping, Star Head

- This screw is available in Titanium and Stainless Steel, for use in Combi holes in the shaft , Used to provide compression or neutral fixation, 6 mm to 30 mm lengths (2 mm increments).

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.

A.5) A statement of the intended use of the device.
Indications for Use:

2.4mm Wise-Lock Distal Radius System:
2.4mm Wise-Lock Distal Radius System are used for displaced extra-articular and intra-articular distal radius fractures and corrective osteotomies of the distal radius.

2.4mm Wise-Lock Proximal Radius System:
2.4mm Wise-Lock Proximal Radius System are used for extra-articular and intra-articular fractures of Proximal radius and multifragmented radial neck fractures.

2.4mm Variable Angle Distal Radius System:
2.4mm Variable Angle Distal Radius System are used for displaced extra-articular and intra-articular distal radius fractures and corrective osteotomies of the distal radius.

A.6) Summary of Technological Characteristics as compared to the predicate devices:
Substantial equivalence including comparison with predicate devices.
A comparison between the 2.4 mm Radius 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	Subject Device (Auxein)	Predicate Device	Remarks
1.	Product Code	HWC (Primary), HRS	HWC (Primary), HRS	Same as predicate device
2.	Regulation Number	21 CFR 888.3030 (Primary), 21 CFR 888.3040	21 CFR 888.3030 (Primary), 21 CFR 888.3040	Same as predicate device
3.	Regulatory Class	Class II	Class II	Same as predicate device
4.	Indications for use	**2.4mm Wise-Lock Distal Radius System:** 2.4mm Wise-Lock Distal Radius System are used for displaced extra-articular and intra-articular distal radius fractures and corrective osteotomies of the distal radius. **2.4mm Wise-Lock Proximal Radius System:** 2.4mm Wise-Lock Proximal Radius System are used for extra-articular and intra-articular fractures of Proximal radius and multifragmented radial neck fractures.	**2.4mm LCP Distal Radius System:** 2.4mm LCP Distal Radius System are used for displaced extra-articular and intra-articular distal radius fractures and corrective osteotomies of the distal radius. **2.4mm LCP Proximal Radius System:** 2.4mm LCP Proximal Radius System are used for extra-articular and intra-articular fractures of Proximal radius and multifragmented radial neck fractures. **2.4mm VA LCP Radius**	Same as predicate device.

		2.4mm Variable Angle Distal Radius System: 2.4mm Variable Angle Distal Radius System are used for displaced extra-articular and intra-articular distal radius fractures and corrective osteotomies of the distal radius.	**System:** 2.4mm VA LCP Radius System are used for displaced extra-articular and intra-articular distal radius fractures and corrective osteotomies of the distal radius.	
2.	Material	Titanium Alloy as per ASTM F136 and Stainless Steel as per ASTM F138.	Titanium Alloy as per ASTM F136 and Stainless Steel as per ASTM F138.	Same as predicate device.
3.	Mechanical 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.	Same as predicate device.
4.	Sterilization	Gamma Sterilization Method and Non-Sterile used in subject device.	Gamma Sterilization Method and Non-Sterile was used in the predicate devices.	Same in predicate device.
5.	Dimensional Verification	Same dimension as of Predicate device.		Same as predicate device.
6.	Shelf-life	5 Years	5 Years	Same as predicate device
7.	Single Use/Reuse	Single Use	Single Use	Same as predicate device
8.	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.	Same 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 Raw materials have been evaluated for biocompatibility according to ISO 10993-3.

Conclusion of Non-Clinical Testing
- 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 and subject device:
Plate
- 4-Point Static Test: Conforms
- 4-Point Fatigue Test: Conforms

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

The conclusion of this non-clinical indicates that the 2.4mm Radius System is equivalent to the predicate devices.

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 2.4mm Radius System is as safe, and as effective and performs the same indications for use as that of already marketed predicate devices identified in A.3. of 510(k) summary.