January 27, 2023

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

Re: K213059
Trade/Device Name: Tibia and Fibula 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: May 5, 2022
Received: May 11, 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 Restoritive, 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)*
K213059

Device Name
Tibia and Fibula System

Indications for Use *(Describe)*

Wise-Lock Tibia & Fibula System

The Wise-Lock Tibia & Fibula System plates are intended for fracture fixation. Indications for the plates included in the system as follows:

3.5mm Wise-Lock Medial Distal Tibia Plate:
Medial distal tibia plates are indicated for treating fractures of the tibia.

3.5mm Wise-Lock Proximal Tibia Plate:
3.5mm Wise-Lock Proximal Tibia Plate indicated for treating fractures of the tibia.

3.5mm Wise-Lock Medial Proximal Tibia Plate:
The 3.5mm Wise-Lock Medial Proximal Tibia Plates are indicated to buttress metaphyseal fractures of the medial tibia plateau, split type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. The plates may also be used for fixation of the proximal quarter (lateral and medial) of the tibia as well as segmental fractures of the proximal tibia.

3.5mm Wise-Lock Posterior Medial Proximal Tibia Plate:
3.5mm Wise-Lock Posterior Medial Proximal Tibia Plates are indicated for internal fixation of posteromedial proximal tibia fractures including buttressing of fractures of the proximal, distal, and metaphyseal areas of the tibia.

3.5mm Wise-Lock Anterolateral Distal Tibia Plate:
3.5mm Wise-Lock Anterolateral Distal Tibia Plate indicated for treating fractures of the tibia.

3.5mm Wise-Lock Medial Distal Tibia Plate, Without Tab:
The 3.5mm Wise-Lock Medial Distal Tibia Plate, Without Tab is indicated for fixation of complex intra-and extra-articular fractures and osteotomies of the distal tibia.

3.5mm Wise-Lock Low Profile Medial Distal Tibia Plate, Without Tab:
The 3.5mm Wise-Lock Low Profile Medial Distal Tibia Plate, Without Tab is indicated for fixation of complex intra-and extra-articular fractures and osteotomies of the distal tibia.

3.5mm Wise-Lock Lateral Distal Fibula Plate:
The 3.5mm Wise-Lock Lateral Distal Fibula Plates are indicated for fractures, osteotomies, and non-unions of the metaphyseal and diaphyseal region of the distal fibula.

3.5mm Wise-Lock Metaphyseal Plate For Medial Distal Tibia:
The 3.5mm Wise-Lock Metaphyseal Plate For Medial Distal Tibia is indicated for fractures, osteotomies, and non-unions of the metaphyseal and diaphyseal region of the distal fibula.

3.5mm Wise-Lock Pilon Plate:
The 3.5mm Wise-Lock Pilon Plate is indicated for fixation of complex intra-and extra-articular fractures and osteotomies of the distal tibia.

3.5mm Wise-Lock Pilon Plate, Cruciform:
3.5mm Wise-Lock Pilon Plate, Cruciform is indicated for fixation of complex intra-and extra-articular fractures and osteotomies of the distal tibia.

3.5mm Wise-Lock Z-type Distal Medial Tibial Plate:
The 3.5mm Wise-Lock Z-type Distal Medial Tibial Plate is indicated for temporary internal fixation and stabilization of osteotomies and fractures, including:
Comminuted fractures
Supracondylar fractures
Intra-articular and extra-articular condylar fractures
Non-unions, and
Malunions

3.5mm Wise-Lock Z-type Proximal Lateral Tibial Plate:
The 3.5mm Wise-Lock Z-type Proximal Lateral Tibial Plate is intended for fixation of fractures and osteotomies involving the tibia. The plate is indicated for the the follow:
Treatment of non-unions, malunions and fractures of the proximal tibia, including simple, comminuted lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression and fractures with associated shaft fractures.
To buttress Metaphyseal fractures of the medial tibial plateau, split-type fractures of the medial tibial plateau, medial split fractures with associated depressions and split of depression fractures of the medial tibia plateau.
The fixation of fractures of the distal tibia including, but not limited to, ankle fractures, periarticular, intra articular and distal tibia fractures with a shaft extension, malleolar and distal fibular fractures.

4.5/5.0mm Wise-Lock Proximal Lateral Tibia Plate:
The 4.5/5.0mm Wise-Lock Proximal Lateral Tibia Plate is indicated for treatment of nonunions, malunions, tibial osteotomies (4.5mm plate only), and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures.

4.5/5.0mm Wise-Lock Medial Proximal Tibia Plate:
The 4.5/5.0mm Wise-Lock Medial Proximal Tibia Plates are indicated to buttress metaphyseal fractures of the medial tibia plateau, split type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. The plates may also be used for fixation of the proximal quarter (lateral and medial) of the tibia as well as segmental fractures of the proximal tibia. The 4.5mm version may also be used for fixation of nonunions and malunions of the medial proximal tibia and tibia shaft, as well as opening and closing wedge tibial osteotomies.

4.5/5.0mm Wise-Lock Proximal Tibia Plate:
4.5/5.0mm Wise-Lock Proximal Tibia Plate is indicated for treatment of non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft fractures.

AV-Wise Lock Ankle System
The AV-Wise Lock Ankle System is intended for fixation of the ankle in adults and adolescents (12-21) in which the growth plates have fused. Indications for plates included in the system are as follows:

Medial and Anteromedial Distal Tibia Plates are indicated for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia,

Distal Tibia T Plates and Distal Tibia L Plates are indicated to buttress partial articular fractures and bone fragments of the distal tibia, and

Lateral Distal Fibula Plates are indicated for fixation of osteotomies, fractures, nonunions, malunions, and replantations of

bones and bone fragments of the diaphyseal and metaphyseal regions of the distal fibula.

AV-Wise Lock Proximal Tibia Plates

The AV-Wise Lock Proximal Tibia Plates are indicated to treat fractures of the proximal tibia in adults and adolescents in which the growth plates have fused including: simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures. Plates can also be used for treatment of nonunions, malunions, tibial osteotomies.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510k Summary

Pre Market Notification 510(k) Summary as required by section 807.92
General Company Information as required by 807.92 (a)

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:	+91-9560557733
Email Id:	info@auxein.com
Dated:	**27.01.2023**

Person Responsible for Regulatory Compliance

Name:	Mr. Mohit Kumar
Title:	Sr. Research Engineer
Email Id:	m.kumar@auxein.com
Dated:	27.01.2023

Proprietary Name:
Tibia and Fibula 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:
Tibia and Fibula Systems consist of the following Components:

S.No.	Item Description
Wise-Lock Tibia & Fibula System Plates	
1.	3.5mm Wise-Lock Medial Distal Tibia Plate, (4, 6, 8, 10, 12, 14 Holes), Left and Right
2.	3.5mm Wise-Lock Proximal Tibia Plate, (4, 6, 8, 10, 12, 14, 16 Holes), Left and Right
3.	3.5mm Wise-Lock Medial Proximal Tibia Plate, (4, 6, 8, 10, 12, 14, 16, 18, 20 Holes), Left and Right
4.	3.5mm Wise-Lock Posterior Medial Proximal Tibia Plate, (1, 2, 4, 6, 8, 10 Holes)
5.	3.5mm Wise-Lock Anterolateral Distal Tibia Plate, (5, 7, 9, 11, 13, 15, 17, 19, 21 Holes), Left and Right
6.	3.5mm Wise-Lock Medial Distal Tibia Plate, Without Tab, (4, 6, 8, 10, 12, 14 Holes), Left and Right
7.	3.5mm Wise-Lock Low Profile Medial Distal Tibia Plate, Without Tab, (4, 6, 8, 10, 12, 14 Holes), Left and Right
8.	3.5mm Wise-Lock Lateral Distal Fibula Plate, (3, 4, 5, 6, 7, 9, 11 Holes), Left and Right
9.	3.5mm Wise-Lock Metaphyseal Plate For Medial Distal Tibia, (4, 5, 6, 7, 8, 9, 10, 12, 14, 16, 18, 20 Holes), Left and Right
10.	3.5mm Wise-Lock Pilon Plate, (7, 9 Holes)
11.	3.5mm Wise-Lock Pilon Plate, Cruciform, (7, 9 Holes)
12.	3.5mm Wise-Lock Z-type Distal Medial Tibial Plate, (6, 8, 10, 14, 18 Holes), Left and Right
13.	3.5mm Wise-Lock Z-type Proximal Lateral Tibial Plate, (6, 8, 10, 12, 14, 16 Holes), Left and Right
14.	4.5/5.0mm Wise-Lock Proximal Lateral Tibia Plate, (5, 7, 9, 11, 13 Holes), Left and Right
15.	4.5/5.0mm Wise-Lock Medial Proximal Tibia Plate, (4, 6, 8, 10, 12, 14, 16 Holes), Left and Right
16.	4.5/5.0mm Wise-Lock Proximal Tibia Plate, (4, 6, 8, 10, 12, 14, Holes), Left and Right
AV-Wise Lock Ankle System Plates	
17.	2.7/3.5mm AV-Wise Lock Anteromedial Distal Tibia Plate, (4, 6, 8, 10, 12, 14, 16 Holes),

	Left & Right
18.	2.7/3.5mm AV-Wise Lock Medial Distal Tibia Plate, (4, 6, 8, 10, 12, 14, 16 Holes), Left & Right
19.	2.7mm AV-Wise Lock Distal Tibia L-Plate, (4, 6 Holes), Left & Right
20.	2.7mm AV-Wise Lock Distal Tibia T-Plate, (4, 6 Holes)
21.	2.7mm AV-Wise Lock Lateral Distal Fibula Plate, (3, 4, 5, 6 ,7, 9, 11, 13, 15 Holes), Left & Right
22.	2.7/3.5mm AV-Wise Lock Anterolateral Distal Tibia Plate, (4, 6, 8, 10, 12, 14, 16 , 18 Holes), Left & Right
AV-Wise Lock Proximal Tibia System Plate	
23.	3.5mm AV-Wise Lock Proximal Tibia Plate, Small Bend, (4, 6, 8, 10, 12, 14 Holes), Left & Right
24.	3.5mm AV-Wise Lock Proximal Tibia Plate, Large Bend, (4, 6, 8, 10, 12, 14 Holes), Left & Right
Screws	
25.	2.7mm Wise-Lock Screw, Self-Tapping (Hex Head), (10-60 mm) Length
26.	3.5mm Wise-Lock Screw, Self-Tapping (Hex Head), (10-80 mm) Length
27.	3.5mm Wise-Lock Screw, Self-Drilling, (Hex Head), (10-60 mm) Length
28.	3.5mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head), (10-60 mm) Length
29.	3.5mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head), (10-60 mm) Length
30.	3.5mm Cortical Screw, Self-Tapping, (Hex Head), (10-90 mm) Length
31.	4.0mm Cancellous Screw, Short Thread, (12-60 mm) Length
32.	4.0mm Cancellous Screw, Full Thread, (12-60 mm) Length
33.	4.5mm Cortical Screw, Self-Tapping, (Hex Head), (12-60 mm) Length
34.	5.0mm Wise-Lock Screw, Self-Tapping, (Hex Head), (12-90 mm) Length
35.	5.0mm Wise-Lock Screw, Self-Tapping & Self-Drilling, (Hex Head), (12-90 mm) Length
36.	5.0mm Wise-Lock Cancellous Screw, Full Thread, Self-Tapping, (Hex Head), (20-110 mm) Length
37.	5.0mm Wise-Lock Cancellous Screw, Short Thread, Self-Tapping, (Hex Head), (20-110 mm) Length
38.	5.0mm Wise-Lock Cannulated Screw, Full Thread, Self-Tapping, (20-120 mm) Length
39.	5.0mm Wise-Lock Cannulated Screw, Partial Thread, Self-Tapping, (30-100 mm) Length
40.	6.5mm Cancellous Screw, 16mm Thread, (25-120 mm) Length
41.	6.5mm Cancellous Screw, 32mm Thread, (35-120 mm) Length
42.	6.5mm Cancellous Screw, Full Thread, (35-120 mm) Length
43.	2.7mm Cortical Screw, Self-Tapping, (Hex Head), Titanium, (6-30 mm) Length
44.	2.7mm AV-Wise Lock Screw, Self-Tapping, (Star Head), (6-70mm) Length
45.	2.7mm Cortical Screw, Self-Tapping, (Star Head), (6-70mm) Length
46.	2.7mm Wise-Lock Screw, Self-Tapping, (Star Head), (6-70mm) Length
47.	3.5mm AV-Wise Lock Screw, Self-Tapping, (10-95mm) Length

48.	3.5mm Cortical Screw, Self-Tapping, (Star Head), (10-90mm) Length
49.	3.5mm Wise-Lock Screw, Self-Tapping, (Star Head), (10-95mm) Length

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 device:

510K Number	K013248
Applicant	Synthes, USA
Device Name	3.5mm LCP Medial Distal Tibia Plate

Reference Predicate device:

510K Number	K073460
Applicant	Synthes, USA
Device Name	3.5/2.7 mm LCP Distal Fibula Plates

510K Number	K141680
Applicant	Auxein Medical Pvt. Ltd. India
Device Name	Bone Plates

510K Number	K020602
Applicant	Synthes, USA.
Device Name	3.5mm LCP Pilon Plate

510K Number	K111039
Applicant	Zimmer
Device Name	Zimmer Periarticular Locking Plate System

510K Number	K061098
Applicant	Zimmer
Device Name	EBI OptiLock Periarticular Plating System

510K Number	K052390
Applicant	Synthes, USA
Device Name	Synthes LCP Proximal Tibia Plates Line Extension

510K Number	K050646
Applicant	Synthes, USA
Device Name	Synthes (USA) 3.5/4.5mm LCP Medial Proximal Tibia Plates

510K Number	K030597, K011978
Applicant	Synthes (USA)
Device Name	3.5mm Titanium LCP Proximal Tibia Plate, Stainless Steel LCP Proximal Tibia plate

510K Number	K120854
Applicant	Synthes, USA
Device Name	Synthes VA LCP Ankle Trauma System

510K Number	K120689
Applicant	Synthes, USA
Device Name	Synthes 3.5 mm VA-LCP Proximal Tibia Plate System

510K Number	K050646
Applicant	Synthes,USA
Device Name	Synthes (USA) 3.5/4.5mm LCP Medial Proximal Tibia Plates

510K Number	K082624
Applicant	Synthes,USA
Device Name	Synthes (USA) 3.5mm LCP Posteromedial Proximal Tibia Plates

510K Number	K120360
Applicant	Ortho Solutions Limited, U.K
Device Name	4.0mm Cancellous Screw, Short thread

Device Description:

The Tibia and Fibula System consists of three types of bone Plates system i.e. *Wise-Lock Tibia & Fibula Plates*, *AV-Wise Lock Ankle Plates*, *AV-Wise Lock Proximal Tibia Plat*e and screws for implantation in the tibia and fibula bone to treat tibia and fibula bone fractures. The bone plates are available in Stainless steel and Titanium material and also in left and right directional configuration.

There are 16 types of bone plates in Wise-lock tibia and fibula bone plate, 6 bone plates in AV-Wise Lock Ankle bone plates and 2 bone plates in AV-Wise Lock Proximal Tibia bone plate system. There are 25 types of bone screws associated with these bone plates.

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.

Indications for Use

Wise-Lock Tibia & Fibula System

The Wise-Lock Tibia & Fibula System plates are intended for fracture fixation. Indications for the plates included in the system as follows:

3.5mm Wise-Lock Medial Distal Tibia Plate:
Medial distal tibia plates are indicated for treating fractures of the tibia.

3.5mm Wise-Lock Proximal Tibia Plate:
3.5mm Wise-Lock Proximal Tibia Plate indicated for treating fractures of the tibia.

3.5mm Wise-Lock Medial Proximal Tibia Plate:
The 3.5mm Wise-Lock Medial Proximal Tibia Plates are indicated to buttress metaphyseal fractures of the medial tibia plateau, split type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. The plates may also be used for fixation of the proximal quarter (lateral and medial) of the tibia as well as segmental fractures of the proximal tibia.

3.5mm Wise-Lock Posterior Medial Proximal Tibia Plate:
3.5mm Wise-Lock Posterior Medial Proximal Tibia Plates are indicated for internal fixation of posteromedial proximal tibia fractures including buttressing of fractures of the proximal, distal, and metaphyseal areas of the tibia.

3.5mm Wise-Lock Anterolateral Distal Tibia Plate:
3.5mm Wise-Lock Anterolateral Distal Tibia Plate indicated for treating fractures of the tibia.

3.5mm Wise-Lock Medial Distal Tibia Plate, Without Tab:
The 3.5mm Wise-Lock Medial Distal Tibia Plate, Without Tab is indicated for fixation of complex intra-and extra-articular fractures and osteotomies of the distal tibia.

3.5mm Wise-Lock Low Profile Medial Distal Tibia Plate, Without Tab:
The 3.5mm Wise-Lock Low Profile Medial Distal Tibia Plate, Without Tab is indicated for fixation of complex intra-and extra-articular fractures and osteotomies of the distal tibia.

3.5mm Wise-Lock Lateral Distal Fibula Plate:
The 3.5mm Wise-Lock Lateral Distal Fibula Plates are indicated for fractures, osteotomies, and non-unions of the metaphyseal and diaphyseal region of the distal fibula.

3.5mm Wise-Lock Metaphyseal Plate For Medial Distal Tibia:
The 3.5mm Wise-Lock Metaphyseal Plate For Medial Distal Tibia is indicated for fractures, osteotomies, and non-unions of the metaphyseal and diaphyseal region of the distal fibula.

3.5mm Wise-Lock Pilon Plate:
The 3.5mm Wise-Lock Pilon Plate is indicated for fixation of complex intra-and extra-articular fractures and osteotomies of the distal tibia.

3.5mm Wise-Lock Pilon Plate, Cruciform:
3.5mm Wise-Lock Pilon Plate, Cruciform is indicated for fixation of complex intra-and extra-articular fractures and osteotomies of the distal tibia.

3.5mm Wise-Lock Z-type Distal Medial Tibial Plate:
The 3.5mm Wise-Lock Z-type Distal Medial Tibial Plate is indicated for temporary internal fixation and stabilization of osteotomies and fractures, including:

- Comminuted fractures
- Supracondylar fractures
- Intra-articular and extra-articular condylar fractures
- Non-unions, and
- Malunions

3.5mm Wise-Lock Z-type Proximal Lateral Tibial Plate:
The 3.5mm Wise-Lock Z-type Proximal Lateral Tibial Plate is indicated for fixation of fractures and osteotomies involving the tibia. The plate is indicated for the the follow:
Treatment of non-unions, malunions and fractures of the proximal tibia, including simple, comminuted lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression and fractures with associated shaft fractures.
To buttress Metaphyseal fractures of the medial tibial plateau, split-type fractures of the medial tibial plateau, medial split fractures with associated depressions and split of depression fractures of the medial tibia plateau.
The fixation of fractures of the distal tibia including, but not limited to, ankle fractures, periarticular, intra articular and distal tibia fractures with a shaft extension, malleolar and distal fibular fractures.

4.5/5.0mm Wise-Lock Proximal Lateral Tibia Plate:
The 4.5/5.0mm Wise-Lock Proximal Lateral Tibia Plate is indicated for treatment of nonunions, malunions, tibial osteotomies (4.5mm plate only), and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures.

4.5/5.0mm Wise-Lock Medial Proximal Tibia Plate:
The 4.5/5.0mm Wise-Lock Medial Proximal Tibia Plates are indicated to buttress metaphyseal fractures of the medial tibia plateau, split type fractures of the medial tibia plateau, medial split fractures with associated depressions and split or depression fractures of the medial tibia plateau. The plates may also be used for fixation of the proximal quarter (lateral and medial) of the tibia as well as segmental fractures of the proximal tibia. The 4.5mm version may also be used for fixation of nonunions and malunions of the medial proximal tibia and tibia shaft, as well as opening and closing wedge tibial osteotomies.

4.5/5.0mm Wise-Lock Proximal Tibia Plate:
4.5/5.0mm Wise-Lock Proximal Tibia Plate is indicated for treatment of non-unions, malunions, and fractures of the proximal tibia, including simple, comminuted, lateral wedge, depression, medial wedge, bicondylar, combinations of lateral wedge and depression, and fractures with associated shaft

fractures.

AV-Wise Lock Ankle System

The AV-Wise Lock Ankle System is intended for fixation of the ankle in adults and adolescents (12-21) in which the growth plates have fused. Indications for plates included in the system are as follows:

- Medial and Anteromedial Distal Tibia Plates are indicated for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal tibia,

- Distal Tibia T Plates and Distal Tibia L Plates are indicated to buttress partial articular fractures and bone fragments of the distal tibia, and

- Lateral Distal Fibula Plates are indicated for fixation of osteotomies, fractures, nonunions, malunions, and replantations of bones and bone fragments of the diaphyseal and metaphyseal regions of the distal fibula.

AV-Wise Lock Proximal Tibia Plates

The AV-Wise Lock Proximal Tibia Plates are indicated to treat fractures of the proximal tibia in adults and adolescents in which the growth plates have fused including: simple, comminuted, lateral wedge, depression, medial wedge, bicondylar combination of lateral wedge and depression, periprosthetic, and fractures with associated shaft fractures. Plates can also be used for treatment of nonunions, malunions, tibial osteotomies.

Summary of Technological Characteristics as compared to the predicate devices

A comparison between the Auxein's Tibia and Fibula 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	The bone plates are indicated for use in fracture treatment of Tibia	The bone plates are indicated for use in fracture treatment of Tibia	Identical as predicate device

		and fibula bone.	and fibula bone.	
5.	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.	Conform to the same material standard as predicate device
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 subject 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 subject 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

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 and has substantially equivalent performance as the predicate:

a. Material Standards:

The material standards are the essential part to be complied with first, as it is the basis of

manufacturing metallic surgical implants.
We have complied with the following material standards:

- ASTM F136/ISO 5832-3: Standard specification for wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.
- ASTM F899-20: 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 F899-20, Stainless Steel (Grade 316L) for Stainless Steel Implants and Titanium Alloy (Ti-6Al-4V) Grade 5 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.

b. Performance Standards:
The device performance of Auxein's Tibia and Fibula System has been demonstrated against the following applicable standards:

- ASTM F543-17
- ASTM F382-17

Summary of Biocompatibility
The device in its final, finished form has been evaluated for biocompatibility according to ISO 10993-3.

Conclusion of Performance bench 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 device:
Plate

- Four-Point Static Test: Conforms
- Four-Point Fatigue Test: Conforms

Screw

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

The results of this testing indicate that the Tibia and Fibula System is equivalent to a 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

Bacterial Endotoxin test was performed on bone plates System by using Limulus Amoebocyte Lysate (LAL) test. The Endotoxin testing limit was less or equal to 20EU/Device. The test was performed according to standard USP 32 chapter 85.

- USP <85> Bacterial Endotoxin Test.
- USP <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests.

Shelf Life

The stability study has been done to determine the shelf life.

We have followed the below standards for performing shelf-life of the device:

- 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.

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 Tibia and Fibula System is as safe, and as effective and performs the same indications for use as that of already marketed predicate devices.