



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Auxien Medical  
Rahul Luthra  
Director  
103, First Floor Jyoti Bhawan Commercial Complex  
Mukherjee Nagar  
New Delhi, India 110009

June 30, 2015

Re: K141680

Trade/Device Name: AUXEIN BRAND OF Bone Plates and Bone Screws & AUXEIN  
Brand of DCS Plate System AUXEIN brand of Locking Plates and  
Locking Screws

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 15, 2015

Received: May 21, 2015

Dear Mr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)

K141680

Device Name

AUXEIN BRAND OF Bone Plates and Bone Screws & AUXEIN Brand of DCS Plate System  
AUXEIN brand of Locking Plates and Locking Screws

Indications for Use (Describe)

AUXEIN Brand of Bone plates and bone screws are provided non-sterile.

AUXEIN BRAND OF Bone Plates and Bone Screws & AUXEIN Brand of DCS Plate System, AUXEIN brand of Locking Plates and Locking Screws.

AUXEIN Brand of Bone plates and bone screws are provided non-sterile. AUXEIN Brand of bone plates and bone screws are intended for treating fractures of various bones including the clavicle, pelvis, scapula, long bone ( humerus,ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, phalanges).

AUXEIN Brand of DCS plate system is used to provide fixation of fractures to the proximal femur shaft and generally indicated for use in trochanteric, petrochanteric, intertrochanteric fractures.

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

AUXEIN brand of Locking Plates and Locking screws have the same indications for use as mentioned above with additional feature of locking by way of combination threads in plates and corresponding Screws.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# AUXEIN MEDICAL

## **Premarket Notification 510(k) Summary as required by Section 807.92**

### **General Company Information as required by 807:92 (a)**

**(a.1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared**

**Submitter's Name:** Auxein Medical

**Address:**

**Office:** 103, First Floor,  
Jyoti Bhawan, Comm. Complex,  
Dr. Mukherjee Nagar,  
Delhi – 110009 (INDIA)

**Factory:** Auxein Medical Pvt. Ltd.  
Plot Number 169-170, HSIIDC,  
Industrial Area, Kundli,  
District Sonapat,  
Haryana 131028 (India)

**Contact Person Name:** Mr. Rahul Luthra

**Title:** Director

**Phone Number:** +91-9811720999

**Dated:** 10-06-2014

### **This is a bundled submission.**

Throughout the submission there is a mention of Auxein Brand of Bone Plates and Bone Screws that represents the range of products covered under this 510(k) submission.

# AUXEIN MEDICAL

**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 brand** of bone plates and bone screws & auxein brand of DCS plate system
- **Auxein brand** of locking plates and locking screws

## **Common or Usual Name:**

- Orthopaedic Bone Plates
- Orthopaedic Bone Screws

## **Classification Name:**

- PLATES, FIXATION, BONE
- SCREWS, FIXATION, BONE

## **Product Code:**

HRS, HWC

**Device Class:** II

**Review Pane:** Orthopaedic

**Regulation Number:** 21 CFR 888.3030 and 21 CFR 888.3040

## **Variants/Types:**

**Auxein Brand** of Bone Plates and Bone Screws, **Auxein Brand** of DCS Plate System and **Auxein Brand** of Locking Plates and Locking Screws are further subdivided into following categories

S. No.	Category	Types
01	Mini Fragment Plates	Locking Version
02	Small Fragment Plates	Locking Version
03	Large Fragment Plates	Locking Version
04	Bone Screws	Locking Version

# AUXEIN MEDICAL

Further Description of **Auxein Brand** Bone Plates and Bone Screws, **Auxein Brand** of DCS Plate System and **Auxein Brand** of Locking Plates and Locking Screws system

Generally there are following types of bone plates:

- Dynamic Compression Type,
- Special (for particular bones)
- Mini fragment

The aforementioned plates are used with cortical (cortex)-Locking Screws.

These bone plates are generally designed on the basis of the bone contour and anatomy.

S. No.	Type	Subtype
01	Mini Fragment	T-Shaped
02	Small and Large Fragment	T-Shaped, Hook, Angled Plates. Reconstructions plates
03	Dynamic compression	Small DCP, Narrow DCP, Lengthening Narrow, Broad DCP, Lengthening Broad Plates
04	DCS	DCS Plate

# AUXEIN MEDICAL

## A3) 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.N.	Item Description	Predicate Device
1.	2.4mm Wise-Lock "T" Distal Radius Dorsal Plate, (3 Head Holes)	K012114 (Synthes locking distal radius plating system)
2.	2.4mm Wise-Lock Distal Radius Volar Plate, Extra-Articular, Left, (4 Head Holes)	LCP Radial Head Plating System (K040777)
3.	2.4mm Wise-Lock Distal Radius Volar Plate, Extra-Articular, Right, (4 Head Holes)	LCP Radial Head Plating System (K040777)
4.	2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate, Left Direction	Synthes 3.5mm LCP Distal Humerus System (K033995)
5.	2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate, Right Direction	Synthes 3.5mm LCP Distal Humerus System (K033995)
6.	2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support, Left Direction	Synthes 3.5mm LCP Distal Humerus System (K033995)
7.	2.7/3.5mm Wise-Lock Dorsolateral Distal Humerus Plate with Lateral Support, Right Direction	Synthes 3.5mm LCP Distal Humerus System (K033995)
8.	2.7/3.5mm Wise-Lock Medial Distal Tibia Plate, Left Direction	Synthes Medial Distal Tibia Plate (K001945)
9.	2.7/3.5mm Wise-Lock Medial Distal Tibia Plate, Right Direction	Synthes Medial Distal Tibia Plate (K001945)
10.	PHEELOS - Wise-Lock Proximal Humerus Plate	Synthes (USA) LCP® Proximal Humerus Plates, Long (K041860)
11.	3.5mm Wise-Lock Small Dynamic Compression Plate with LC under cuts	Synthes 3.5 and 4.5mm Locking Compression Plate System

		(K082807)
12.	3.5mm Wise-Lock Proximal Humerus Plate	Proximal humerus plate long Synthes K041860
13.	3.5mm Wise-Lock Small 'T' Plate, Oblique Angled - Left Direction	Synthes Small Fragment Dynamic Compression Locking( DCL) System (K000684)
14.	3.5mm Wise-Lock Small 'T' Plate, Oblique Angled - Right Direction	Synthes Small Fragment Dynamic Compression Locking( DCL) System (K000684)
15.	3.5mm Wise-Lock Small 'T' Plate, Right Angled (3 Head Holes)	Synthes Small Fragment Dynamic Compression Locking( DCL) System(K000684)
16.	Wise-Lock Small 'T' Plate, Right Angled (4 Head Holes)	Synthes Small Fragment Dynamic Compression Locking( DCL) System(K000684)
17.	3.5mm Wise-Lock Proximal Tibia Plate, Left Direction	Synthes 3.5mm Titanium LCP Proximal Tibia Plate (K030597) OR Synthes LCP Proximal Tibia Plates (K011978)
18.	3.5mm Wise-Lock Proximal Tibia Plate, Right Direction	Synthes 3.5mm Titanium LCP Proximal Tibia Plate (K030597) OR Synthes LCP Proximal Tibia Plates (K011978)
19.	3.5mm Wise-Lock Anterolateral Distal Tibia Plates, Left	Synthes (USA) 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates (K092812)
20.	3.5mm Wise-Lock Anterolateral Distal Tibia Plates, Right	Synthes (USA) 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plates (K092812)
21.	3.5mm Wise-Lock Clavicle Hook Plate, Left Direction	Synthes Clavicle Hook Plate (K061753)
22.	3.5mm Wise-Lock Clavicle Hook Plate, Right Direction	Synthes Clavicle Hook Plate (K061753)



# AUXEIN MEDICAL

23.	4.5/5.0mm Wise Lock Broadly Curved Plates	Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad
		Locking Compression Plates (LCP) (K092609)
24.	4.5/5.0mm Wise-Lock Reconstruction Plates	Synthes 4.5 mm LCP Straight Reconstruction Plate (K051986)
25.	4.5/5.0mm Wise Lock Broad Locking Compression Plate	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
26.	4.5/5.0mm Wise Lock Narrow Locking Compression Plate	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
27.	4.5/5.0mm Wise lock Distal Femur Plate	Synthes LCP Distal Femur Plates (K062564)
28.	4.5/5.0mm Wise Lock Lateral Tibia Plate	Synthes LCP Proximal Tibia Plate (K011978)
29.	4.5/5.0mm Wise Lock Proximal Femur plate	Synthes (USA) LCP Proximal Femur Plate and Screws (K030858)
30.	2.4mm Wise Lock Screw	Synthes 2.4mm titanium locking screw (K033975)
31.	2.7 mm Wise Lock Screw	Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684)
32.	3.5mm Wise lock screw	Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684)
33.	5.0mm Wise lock Screw	Synthes Large Fragment Dynamic Compression Locking (DCL) System (K000682)

# AUXEIN MEDICAL

**a4). 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:**

### **Plate Fixation System**

**Auxein Brand** of Bone Plates and Bone Screws, **Auxein Brand** of DCS Plate System, **Auxein Brand** of Locking Plates and Locking Screws system consists of various shape and sizes of plates featuring compression and locking holes, full-threaded-cortical, locking self-tapping screws, compression and dynamic screws,

The plates and screws are fabricated from stainless steel and titanium.

The system contains several modules based on the size of the device and application site such as fixation/reconstruction of small fragment bones, forefoot, mid-foot, rear-foot, ankle, or other bones appropriate for the size of the device. The plate implants are in many models available: like, Reconstruction Plates, , T- Plates, , Anatomical Plates, Clavicle Hook Plates.

These all are mainly divided into

- Mini Fragment Plates
- Small Fragment Plates
- Large Fragment Plates
- DCS Plates.

The thickness of the plates varies from 1.0mm to 6mm; and the number of the holes varies from 2 to 22.

The screw implants are in corresponding diameter ranges from 2.4mm, 2.7mm, 3.5mm, 5.0mm diameters with lengths varying as per the requirements and minimum length: 6 mm to maximum length 90mm

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

# AUXEIN MEDICAL

## **A5). (5) A statement of the intended use of the device**

### **Indications for Use:**

- AUXEIN Brand of Bone plates and bone screws are provided non-sterile.

AUXEIN BRAND OF Bone Plates and Bone Screws & AUXEIN Brand of DCS Plate System,

AUXEIN brand of Locking Plates and Locking Screws.

AUXEIN Brand of Bone plates and bone screws are provided non-sterile. AUXEIN Brand of bone plates and bone screws are intended for treating fractures of various bones including the clavicle, pelvis, scapula, long bone ( humerus,ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals, phalanges).

AUXEIN Brand of DCS plate system is used to provide fixation of fractures to the proximal femur shaft and generally indicated for use in trochanteric, pertrochanteric, intertrochanteric fractures. The system is indicated for use in adult patients only. All implants are for single use only.

AUXEIN brand of Locking Plates and Locking screws have the same indications for use as mentioned above with additional feature of locking by way of combination threads in plates and corresponding Screws.

# AUXEIN MEDICAL

## a6). Summary of Technological Characteristics as compared to the predicate devices:

### Substantial equivalence including comparison with predicate devices

A comparison between the **Auxein Brand** of Bone Plates and Bone Screws, **Auxein Brand** of DCS Plate System, **Auxein Brand** of Locking Plates and Locking 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	Same dimensions found in both New Device as well as Predicate device	Equivalent

## **b1). 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 to 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 F 138: Standard Specification for Wrought 18 chromium-14Nickel-2.5Molybdenum stainless steel bar and wire for surgical implants.
3. ASTM F 139: Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants

We have verified the purchased material compliance to these standards and copies of the relevant test results were provided in the submission.

### **B: Performance Standards:**

The device performance of **Auxein Brand** of Bone Plates and Bone Screws, **Auxein Brand** of DCS Plate System and **Auxein Brand** of Locking Plates and Locking Screws has been demonstrated against following applicable standards

- ASTM F 382,
- ASTM F 384 and
- ASTM F 543.

#### **For Bone Plates:**

As per ASTM F 382 and ASTM F 384 Static Four Point Bend Test: Conforms,  
Dynamic Four Point Bend Test: Conforms

#### **For Bone Screws:**

As per ASTM F 543 :Torsional Properties: Conforms, Driving Torque : Conforms,  
Pull-out Test: Conforms

**b2). Discussion on the clinical evaluation referenced and relied upon:**

**Auxein Brand** of devices are of similar design and pattern as well as similar intended use. Clinical information was not necessary to demonstrate substantial equivalence.

**CONCLUSION:**

**General, Safety and Performance conclusion:**

From the available data available we can justify that the **Auxein Brand** of Bone Plates and Bone Screws, **Auxein Brand** of DCS Plate System and **Auxein Brand** of Locking Plates and Locking Screws are as safe, as effective and perform as same indications for use as that of already marketed predicate devices identified in a3. of 510(k) summary.

Hence our devices can be considered safe and effective for their intended use.