



Food and Drug Administration
10903 New Hampshire Avenue
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June 17, 2016

Ortho Care
Mr. Rajeev Chhabra
Managing Partner
3/10 Kirti Nagar Industrial Area
New Delhi, 110015
INDIA

Re: K153374

Trade/Device Name: CARE BRAND Locking Bone Plate and Screws Osteosynthesis
Plating System, CARE Brand of DHS/DCS Plating 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: April 19, 2016

Received: April 21, 2016

Dear Mr. Chhabra:

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 Parts 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,

Vincent J. Devlin -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K153374

Device Name

CARE BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, CARE Brand of DHS/DCS Plating System

Indications for Use (Describe)

CARE BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, CARE Brand of DHS/DCS Plating System are provided non-sterile.

CARE BRAND Locking Bone Plates and Screws Osteosynthesis Plating System are indicated 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).

CARE Brand of DHS/DCS Plating 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.

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)

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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: Ortho Care

Address:

Office:
3/10 Kirti Nagar
Industrial Area, New
Delhi-110015 India

Factory:

Plot Number A-31, Sector A-4,
Tronica City, Loni, Ghaziabad,
201102 India

Contact Person Name: Mr. Rajeev Chhabra

Title: Managing Partner

Phone Number: +91-9810038246

Dated: 05-11-2015

This is a bundled submission.

Throughout the submission there is a mention of **CARE BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **CARE** Brand of DHS/DCS Plating System that represents the range of products covered under this 510(k) submission.

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a.2: The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known

Proprietary Name:

- **CARE BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **CARE**
Brand of DHS/DCS Plating System

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:

CARE BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, **CARE** Brand of DHS/DCS Plating System are further subdivided into following categories

S. No.	Category	Types
01	Dynamic Hip Screw Type /Dynamic Condylar Screw Type DHS and Compression Screws	Non-Locking Version
02	Large Fragment Plates	Locking Version
03	Small Fragment Plates	Locking Version
04	Mini Fragment Plates	Locking Version
05	Bone Screws	Locking and Non-Locking Version

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Further Description of **CARE BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **CARE** Brand of DHS/DCS Plating System

Generally there are following types of bone plates used with cortical (cortex) and Locking Screws. These bone plates are generally designed on the basis of the bone contour and anatomy. The Dynamic Hip Screw Plate and Dynamic Condylar Type Plates are used with Dynamic Hip Screw combined with Compression Screw and shaft with cortical (cortex) screws.

S. No.	Type	Subtype
01	Dynamic Hip Screw Type /Dynamic Condylar Screw Type	Dynamic Hip Screw Plate, Dynamic Condylar Screw Plate
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	Mini Fragment	T-Shaped

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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. No.	Subject Device	Predicate Device
1.	Dynamic Hip Screw Plate (with Dynamic Compression Holes) (Long Barrel) Dynamic Hip Screw Plate (with Dynamic Compression Holes) (Short Barrel)	Synthes Limited Contact-Dynamic Hip Screw Implant (LC-DHS)" for K923613 Synthes Titanium Limited Contact-Dynamic Hip Screw Implant (Ti LC-DHS)" for K953607
2.	Dynamic Condylar Plate with Dynamic Compression Holes (Barrel length 25 mm)	Synthes dynamic condylar screw or d.c.s. K840954
3.	Dynamic Hip Screw, Ø 12.5mm with Compression Screw	Synthes Limited Contact-Dynamic Hip Screw Implant (LC-DHS)" for K923613 Synthes Titanium Limited Contact-Dynamic Hip Screw Implant (Ti LC-DHS)" for K953607
4.	LCP Curved Narrow Plates	Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP) (K092609)
5.	Narrow Locking Plate For 4.5mm/5.0mm Screws	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
6.	Locking Reconstruction Plate 4.5mm	Synthes 4.5 mm LCP Straight Reconstruction Plate (K051986)
7.	LCP Curved Broad Plates	Synthes 3.5 mm and 4.5 mm Curved Narrow and Broad Locking Compression Plates (LCP) (K092609)
8.	Broad Locking Plate For 4.5mm/5.0mm Screws	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
9.	Locking distal femur plate – right Locking distal femur plate - left	Synthes LCP Distal Femur Plates (K062564)
10.	Proximal Lateral Tibia Locking Plate Left Proximal Lateral Tibia Locking Plate Right	K030597 Synthes 3.5 Titanium LCP Proximal Tibia Plate (For Titanium) Synthes LCP Proximal Tibia Plate (K011978) (For Stainless Steel)

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11.	Locking Femoral Proximal Lateral Plates L/R 5 Holes To 13 Holes, Left Locking Femoral Proximal Lateral Plates L/R 5 Holes To 13 Holes, Right	Synthes (USA) LCP Proximal Femur Plate and Screws (K030858)
12.	Locking Humeral Distal Dorsal Plates L/R Without Support 2.7/3.5, Left & Right	Synthes 3.5mm LCP Distal Humerus System (K033995)
13.	Locking Humeral Distal Dorsal Plates L/R With Lateral Support 2.7/3.5, Left & Right	Synthes 3.5mm LCP Distal Humerus System (K033995)
14.	Distal Tibial Locking Plate 2.7/3.5, Left	Synthes Medial Distal Tibia Plate (K001945)
15.	Distal Tibial Locking Plate 2.7/3.5, Right	Synthes Medial Distal Tibia Plate (K001945)
16.	Locking philos proximal humeral plate - Long Locking philos proximal humeral plate - Short	Synthes (USA) LCP® Proximal Humerus Plates, Long (K041860)
17.	Small Locking Plate For Dia 3.5mm Screws	Synthes 3.5 and 4.5mm Locking Compression Plate System with expended indications (K082807)
18.	Locking Proximal Humeral Plate - long Locking Proximal Humeral Plate - short	Proximal humerus plate long Synthes K041860
19.	Locking T-Plate Oblique angled For Dia 3.5mm Screws, Left	Synthes Small Fragment Dynamic Compression Locking(DCL) System (K000684)
20.	Locking T-Plate Oblique angled For Dia 3.5mm Screws, Right	Synthes Small Fragment Dynamic Compression Locking(DCL) System (K000684)
21.	Locking T-Plate Right Angle FOR Dia 3.5mm Screws, 3 Hole Head	Synthes Small Fragment Dynamic Compression Locking(DCL) System(K000684)
22.	Locking T-Plate Right Angle FOR Dia 3.5mm Screws, 4 Hole Head	Synthes Small Fragment Dynamic Compression Locking(DCL) System(K000684)
23.	LCP Proximal Tibial Plate 3.5, Left	Synthes 3.5mm Titanium LCP Proximal Tibia Plate (K030597) OR Synthes LCP Proximal Tibia Plates (K011978)
24.	LCP Proximal Tibial Plate 3.5, Right	Synthes 3.5mm Titanium LCP Proximal Tibia Plate (K030597) OR Synthes LCP Proximal Tibia Plates (K011978)

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25.	LCP Clavicle Hook Plate, Left	Synthes Clavicle Hook Plate (K061753)
26	LCP Clavicle Hook Plate, Right	Synthes Clavicle Hook Plate (K061753)
27.	Locking Distal Dorsal Radius T-Plates 2.7mm, 3Holes	K012114 (Synthes locking distal radius plating system)
28	Locking Distal Dorsal Radius T-Plates 2.7mm, 4Holes	LCP Radial Head Plating System (K040777)
29.	Locking Compression EXTRA-ARTICULAR VOLAR DISTAL RADIUS PLATES 2.4 HEAD 4HOLES, Left and Right with Shaft having 3 Holes, 4 Holes and 5 Holes	LCP Radial Head Plating System (K040777)
30.	Locking Head Screw, Dia - 2.4mm - Self Tapping	Synthes 2.4mm titanium locking screw (K040777)
31.	Locking Head Screw, Dia - 2.7mm - Self Tapping	Synthes LCP Modular Foot plate (K050110)
32.	Locking Head Screw, Dia - 3.5mm - Self Tapping	Synthes Small Fragment Dynamic Compression Locking (DCL) System (K000684)
33.	Locking Head Screw, Dia - 5.0mm - Self Tapping	Synthes Large Fragment Dynamic Compression Locking (DCL) System (K000682)
34.	Cortex Screw Ø 3.5mm, Self Tapping	Synthes Cortical Screws K112583
35.	Cortex Screw Ø 4.5mm, Self Tapping	Synthes Cortical Screws (K112583)

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

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Device Description:

CARE BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, **CARE** Brand of DHS/DCS Plating 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 models 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

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

The number of the holes varies from 2 to 22.

The Locking 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.

The Non-locking screw implants are in 3.5mm and 4.5mm diameter and length range from 10mm to 74mm.

CARE Brand of DHS/DCS Plating System consist of DHS/DCS Plates, lag Screw, compression screw, and 4.5 Cortex screw (Standard and Self Tapping). The DHS plates are available with barrel length 25mm (short barrel) and 38mm (Standard barrel) and barrel angels varies from 130° to 150°. The DHS/DCS Screw is available in total length from 50 to 120 mm, thread length 22mm, shaft diameter 7 mm and outer diameter of 12.5. The thread of DHS/DCS Screw has a buttress type. The DHS/DCS Compression Screw can be used to achieve fracture compression. Its dimension is available with thread length 36mm and outer diameter 3.8 mm.

These devices are not indicated for use in spine.

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

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

Indications for Use:

- **CARE BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **CARE** Brand of DHS/DCS Plating System are provided non-sterile.
- CARE BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System are indicated 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).
- CARE** Brand of DHS/DCS Plating 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.

A6). Summary of Technological Characteristics as compared to the predicate devices:

Substantial equivalence including comparison with predicate devices

A comparison between the **CARE BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **CARE** Brand of DHS/DCS Plating 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	Predicate Device Versus New Device (Care 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

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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 **CARE BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **CARE** Brand of DHS/DCS Plating System 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:

CARE BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, **CARE** Brand of DHS/DCS Plating System 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 **CARE BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **CARE** Brand of DHS/DCS Plating System 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 these devices can be considered safe and effective for their intended use.