



Food and Drug Administration
10903 New Hampshire Avenue
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April 19, 2017

Greens Surgical Pvt. Ltd.
Dr. Vinay Kumar
Director
209 (Second Floor), Saffron Complex
Fatehgunj
Vadodara, 390 002 IN

Re: K163383

Trade/Device Name: GREENS BRAND Locking Bone Plates and Screws Osteosynthesis
Plating System, GREENS BRAND of DHS/Dynamic Condylar Plates
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: November 21, 2016

Received: December 1, 2016

Dear Dr. Kumar:

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" (21 CFR 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,

Lori A. Wiggins -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)

K163383

Device Name

GREENS BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, GREENS Brand of DHS/Dynamic Condylar Plate Plating System

Indications for Use (Describe)

GREENS BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, GREENS Brand of DHS/Dynamic Condylar Plate Plating System are provided non-sterile.

GREENS 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).

GREENS Brand of DHS/Dynamic Condylar Plate 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: GREENS SURGICALS PVT. LTD.

Address:

Office:

209 (Second Floor), Saffron Complex, Fatehgunj, Vadodara-390
002 (INDIA)

Factory:

Plot No. 508-512, Savli Industrial Estate, GIDC Manjusr, Vadodara –
391775 Gujarat (INDIA)

Contact Person Name: Dr. Vinay Kumar

Title: Director

Phone Number: +91-2667 264 890

Dated: 21-11-2016

This is a bundled submission.

Throughout the submission there is a mention of **GREENS BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **GREENS** Brand of DHS/ Dynamic Condylar Plates Plating System that represents the range of products covered under this 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:

- **GREENS BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **GREENS** Brand of DHS/ Dynamic Condylar Plates Plating System

Common or Usual Name:

- Orthopaedic Bone Plates
- Orthopaedic Bone Screws

Classification Name:

Single/multiple component metallic bone fixation appliances and accessories

- PLATES, FIXATION, BONE
Smooth or threaded metallic bone fixation fastener
- SCREWS, FIXATION, BONE

Product Code:

HRS, HWC

Device Class: II

Review Pane: Orthopaedic

Regulation Number: 21 CFR 888.3030 and 21 CFR 888.3040

Further Description of **GREENS BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **GREENS** Brand of DHS/ Dynamic Condylar Plates 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.

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

Variants/Types:

GREENS BRAND Locking Bone Plates and Screws Osteosynthesis Plating System are further subdivided into following categories

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

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
Mini Fragment		
01.	Locking Posterolateral Distal Humerus Plate 2.7/3.5mm	Synthes 3.5mm LCP Elbow System (K033995)
02.	Locking Distal Dorsal Radius T-Plates 2.7mm	K012114 (Synthes locking distal radius plating system)
03.	Locking Volar Distal Radius Plate Extra-Articular Plates Ø 2.4mm/2.7mm Left and Right	LCP Radial Head Plating System (K040777)
04.	3.5MM Small Locking T- Plate 3.5mm	Synthes Small Fragment Dynamic Compression Locking(DCL) System(K000684)
Small Fragment		
05.	3.5mm Locking Plate	K082807 Synthes (USA) 3.5 nun and 4.5 nun Locking Compression Plate
06.	Locking Medial Distal Tibia Plate 3.5mm / 4.0mm Left & Right	Synthes (USA) Medial Distal Tibia Plate (K001945)

07.	3.5mm Locking T- Plate Oblique Angled, Left& Right	Synthes Small Fragment Dynamic Compression Locking(DCL) System (K000684)
08.	3.5MM Locking T-Plate Right Angle	Synthes Small Fragment Dynamic Compression Locking(DCL) System(K000684)
09.	3.5MM Locking Proximal Tibia Plate, Left& Right	Synthes 3.5mm Titanium LCP Proximal Tibia Plate (K030597) OR Synthes LCP Proximal Tibia Plates (K011978)
10.	3.5mm Locking Reconstruction Plate	Synthes 4.5 mm LCP Straight Reconstruction Plate (K051986)
11.	Locking Clavicle Hook Plate Ø 3.5mm, Left & Right	Synthes Clavicle Hook Plate (K061753)
12.	3.5mm Locking Periarticular Proximal Humerus Plate, Left and Right	Synthes (USA) 3.5mm LCP Periarticular Proximal Humerus Plates (K082625)
13.	3.5MM Locking Proximal Humerus Plate	Proximal Humerus Plate Long Synthes K041860
14.	3.5MM Locking Superior Anterior Clavicle Plates, Left and Right	Synthes 3.5mm LCP Clavicle Plate System (K111540)
15.	3.5MM Locking Anterolateral Distal Tibia Plate, Left and Right	Synthes (USA) 2.7mm / 3.5mm LCP Anterolateral Distal Tibia Plate (k092812)
16.	3.5MM Locking Medial Proximal Tibia Plate Left and Right	Synthes (USA) 3.5 / 4.5mm LCP® Medial Proximal Tibia Plate (K032269)
17.	3.5mm Locking Posteromedial Proximal Tibia Plate Right and Left	Synthes (USA) 3.5mm LCP Posteromedial Proximal Tibia Plates (K082628)
18.	3.5MM Locking Distal Fibula Plate, Left and Right	Synthes 2.7mm / 3.5mm LCP Distal Fibula Plate (K073460)
Large Fragment		
19.	Narrow Locking Plate Ø 4.5mm/5.0mm Screws	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
20.	Locking Reconstruction Plate,Ø 4.5mm	Synthes 4.5 mm LCP Straight Reconstruction Plate (K051986)

21.	Broad Locking Plate Ø 4.5mm/5.0mm Screws	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
22.	Locking Distal Femur Plate, Right Locking Distal Femur Plate, Left	Synthes LCP Distal Femur Plates (K062564)
23.	Proximal Lateral Tibia Locking Plate, Left Proximal Lateral Tibia Locking Plate. Right	Synthes LCP Proximal Tibia Plate (K011978)
24.	Locking Proximal Femur Plate 4.5/5.0/6.5mm Left & Right	Synthes (USA) LCP Proximal Femur Plate and Screw (K030858)
25.	Locking Philos Proximal Humeral Plate - Long Locking Philos Proximal Humeral Plate - Short	Synthes (USA) LCP® Proximal Humerus Plates, Long (K041860) Synthes LCP Proximal Humerus Plates K011815
26.	Broad LC DCP Plate, 4.5mm	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
27.	Narrow LC DCP Plate 4.5mm	Synthes 3.5 and 4.5mm Locking Compression Plate System (K082807)
28.	Dynamic Hip Screw (Non-Locking) Plate (with Dynamic Compression Holes) (Long Barrel) Dynamic Hip Screw (Non-Locking) 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
29.	Dynamic Condylar Plate with Dynamic Compression Holes (Barrel length 25 mm)	Synthes dynamic condylar screw or D.C.S. K840954
30.	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
Locking and Non-Locking Screw		
31.	Locking Head Screw, Ø 2.4mm - Self Tapping	Synthes Locking Distal Radius Plating System (K012114)
32.	Locking Head Screw, Ø 2.7mm - Self Tapping	Synthes 2.4mm/2.7mm variable angle LCP Forefoot/Midfoot System K100776
33.	Locking Head Screw, Ø 3.5mm - Self Tapping	Synthes Small Fragment Dynamic

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		Compression Locking (DCL) System (K000684)
34.	Cortex Screw Ø 3.5mm, Self Tapping	Synthes Cortical Screws K112583
35.	Cortex Screw Ø 4.5mm, Self Tapping	Synthes Cortical Screws K112583
36.	Locking Head Screw, Ø 5.0mm - Self Tapping	Synthes Large Fragment Dynamic Compression Locking (DCL) System (K000682)
37.	Cancellous Screw, Ø6.5mm, 16mm Thread, 32mm Thread and Full Thread	Synthes (USA) 6.5 mm Cancellous Screws (K061621)

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:

GREENS BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, **GREENS** Brand of DHS/ Dynamic Condylar Plates 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

- Large Fragment Plates
- Small Fragment Plates
- Mini Fragment Plates
- Hip Plates (DHS and Dynamic Condylar Plate)

The thickness of the plates varies from 1.0mm to 6mm; and 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 140mm.

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

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

Indications for Use:

GREENS BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, **GREENS** Brand of DHS/ Dynamic Condylar Plates Plating System are provided non-sterile.

GREENS 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).

GREENS Brand of DHS/ Dynamic Condylar Plates 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 **GREENS BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **GREENS** Brand of DHS/ Dynamic Condylar Plates 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 (GREENS 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 **GREENS BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **GREENS** Brand of DHS/ Dynamic Condylar Plates 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:

GREENS BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, **GREENS** Brand of DHS/ Dynamic Condylar Plates 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 **GREENS BRAND** Locking Bone Plates and Screws Osteosynthesis Plating System, **GREENS** Brand of DHS/ Dynamic Condylar Plates 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.