DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 19, 2017

Greens Surgicals 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,

for
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

Indications for Use

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

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)*

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

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GREENS SURGICALS PVT. LTD.

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 Manjusar, 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.

Help (./help/index.html)

DRLM Home (mainMenu.htm) > View Your Registrations and Listings

Registration Information

Facility

Registration Number
3013846070

FEI Number
3013846070

Registration Status
Active

Registration Status Reason
Registration number assigned

Initial Importer
N

Facility Name
GREENS SURGICALS PRIVATE LIMITED

Facility Address
PLOT NUMBER 508 TO 512, SAVLI INDUSTRIAL ESTATE , GIDC, MANJUSAR
VADODARA , GUJARAT , 391775 , INDIA

Owner/Operator

Owner/Operator Number
10055543

Contact Name
VINAY KUMAR

Business Name
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Official Correspondent

Contact Name
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U.S.Agent

Contact First Name
RAVI PAREKH

Contact Last Name

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MR

Business Name

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Phone Number
270 -7765394

Fax Number
-

Registration Status

Expiration Date
2021-12-31

PIN - PCN
50316478 - 21473708

Previous (drlm.htm?_flowExecutionKey=_c6A6BB53A-9C58-68F1-4048-B7B2FFE01BD9_k7CE255AA-D008-573F-9BD0-B6A102C12040&_eventId=back)