

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.

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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

Legal Name**Facility Address**PLOT NUMBER 508 TO 512, SAVLI INDUSTRIAL ESTATE, GIDC, MANJUSAR
VADODARA, GUJARAT, 391775, INDIA**DUNS Number****Foreign Trade Zone**

N

Facility URL**Other Business Trade Name(s)**

1. GREENS

Establishment located on a campus

Owner/Operator

Owner/Operator Number

10055543

Contact Name

VINAY KUMAR

Business Name

GREENS SURGICALS PRIVATE LIMITED

AddressPLOT NUMBER 508 TO 512, SAVLI INDUSTRIAL ESTATE, GIDC, MANJUSAR
VADODARA, GUJARAT, 391775, INDIA**Phone Number**

91 - 265 - 2783892

Fax Number

91 - 266 - 7264890

E-mail

vinaygreens@gmail.com

DUNS Number

Official Correspondent

Contact Name

VINAY KUMAR

Business Name

GREENS SURGICALS PRIVATE LIMITED

AddressPLOT NUMBER 508 TO 512, SAVLI INDUSTRIAL ESTATE, GIDC, MANJUSAR
VADODARA, GUJARAT, 391775, INDIA**Phone Number**

91 - 265 - 2783892

Fax Number

91 - 266 - 7264890

E-mail

vinaygreens@gmail.com

DUNS Number

U.S.Agent

Contact First Name

RAVI

Contact Last Name	PAREKH
Title	MR
Business Name	
Full Address	112 BUTTERCUP COURT RADCLIFF , KENTUCKY , 40160 , UNITED STATES
E-mail	rparekh_usfda@greensurgicals.com
Phone Number	270 -7765394
Fax Number	-

Registration Status
Expiration Date 2026-12-31
PIN - PCN 50479419 - 26664274

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Proprietary Name:	GREENS
Classification Name:	PLATE, FIXATION, BONE
Product Code:	<u>HRS</u>
Device Class:	2
Regulation Number:	<u>888.3030</u>
Medical Specialty:	Orthopedic
Registered Establishment Name:	<u>GREENS SURGICALS PRIVATE LIMITED</u>
Registered Establishment Number:	3013846070
Premarket Submission Number:	<u>K163383</u>
Owner/Operator:	<u>Greens Surgicals Private Limited</u>
Owner/Operator Number:	10055543
Establishment Operations:	Manufacturer

Establishment Registration & Device Listing

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Proprietary Name:	GREENS
Classification Name:	SCREW, FIXATION, BONE
Product Code:	HWC
Device Class:	2
Regulation Number:	888.3040
Medical Specialty:	Orthopedic
Registered Establishment Name:	GREENS SURGICALS PRIVATE LIMITED
Registered Establishment Number:	3013846070
Premarket Submission Number:	K163383
Owner/Operator:	Greens Surgicals Private Limited
Owner/Operator Number:	10055543
Establishment Operations:	Manufacturer



Establishment Registration & Device Listing

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Proprietary Name:	Greens Surgicals Pvt. Ltd.
Classification Name:	THORACOLUMBOSACRAL PEDICLE SCREW SYSTEM
Product Code:	NKB
Device Class:	2
Regulation Number:	888.3070
Medical Specialty:	Orthopedic
Registered Establishment Name:	GREENS SURGICALS PRIVATE LIMITED
Registered Establishment Number:	3013846070
Premarket Submission Number:	K230325
Owner/Operator:	Greens Surgicals Private Limited
Owner/Operator Number:	10055543
Establishment Operations:	Manufacturer

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