

**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.

**Premarket Notification 510(k) Summary as required by Section 807.92****General Company Information as required by 807:92 (a)**

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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

**Address**

PLOT 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

**Address**

PLOT 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**

2024-12-31

**PIN - PCN**

50406792 - 24579415

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## Establishment Registration & Device Listing

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



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## Establishment Registration & Device Listing

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Proprietary Name:	GREENS
Classification Name:	SCREW, FIXATION, BONE
Product Code:	<u>HWC</u>
Device Class:	2
Regulation Number:	<u>888.3040</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