October 10, 2024

Greens Surgicals Pvt. Ltd.
Dr. Vinay Kumar
Director
Plot No. 508-512, Savli Industrial Estate, GIDC Manjusar
Vadodara, Gujarat 391 775
India

Re: K230325
Trade/Device Name: GREENS BRAND Posterior, Non-cervical Pedicle Screw Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Thoracolumbosacral pedicle screw system
Regulatory Class: Class II
Product Code: NKB
Dated: September 9, 2024
Received: September 9, 2024

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ronald P. Jean -S

for Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K230325

Device Name
GREENS BRAND Posterior, Non-cervical Pedicle Screw Spinal System

Indications for Use *(Describe)*
The GREENS BRAND Posterior, Non-cervical Pedicle Screw Spinal System is a pedicle screw fixation system intended for immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:
• Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
• Spondylolisthesis
• Trauma (e.g., fracture or dislocation)
• Deformity or curvature (e.g., scoliosis, kyphosis, and/or lordosis)
• Tumor
• Spinal stenosis
• Pseudarthrosis
• Failed previous fusion
Paediatric Use:
When used for posterior non-cervical screw fixation in paediatric patients, the GREENS BRAND Posterior, Non-cervical Pedicle Screw Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, it is intended to treat paediatric patients diagnosed with the following conditions:
• Spondylolisthesis
• Spondylolysis
• Fracture caused by tumor and/or trauma.
Paediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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Pre-market 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

510(k) submitter	:	**Greens Surgicals Pvt. Ltd.**
Head office Address	:	TF-1 E & F, Third Floor, Lotus Aura-I, Near IOCL Petrol Pump, Sama Savli Main Road, Vadodara – 390 008 Gujarat, INDIA
Manufacturing Unit Address	:	Plot No. 508-512,Savli Industrial Estate, GIDC Manjusar, Vadodara - 391 775 Gujarat, INDIA
Contact person name	:	Dr. Vinay Kumar
Title	:	Director
Phone number	:	+91 9099757575
Dated	:	09-09-2024

Throughout the submission there is a mention of GREENS Brand Posterior, Non cervical Pedicle Screw Spinal 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:

- GREENS BRAND Posterior, Non-cervical Pedicle Screw Spinal System.

Common or Usual Name:

- Thoracolumbosacral pedicle screw system

Product Code: NKB

Device Class: II

Review Panel: Orthopaedic

Regulation Name and Number: 21CFR 888.3070; Thoracolumbosacral pedicle screw system

Description of **GREENS BRAND Posterior, Non cervical Pedicle Screw Spinal System**

Polyaxial Screw: This screw is used in various spinal fixation situations in conjunction with other hardware to create a rigid construct. The polyaxial screw consists of a body, bushing, and ball head screw.

Inner screw, Rod complete the spinal construct. The body portion of the screw rotates about the ball head on the screw, which provides increased motion over a fixed post of the polyaxial screw. An increase in motion facilitates the capture of rods that are not perfectly aligned.

Straight Rods: Rods are used to connect pedicle screws and create a rigid structure.

Inner Screw: Inner screws are used to secure the bone screw and rod interface

A3) Identification of the Predicate Device:

Following are the predicate devices with which we are declaring substantial equivalence :

Primary predicate device:

Stryker Xia 4.5mm Evolution Polyaxial Screw (K121342)

Additional predicate devices:

CD HORIZON® Multi- Axial Screw (K152457)

Zimmer Vital Polyaxial Screw (K150896)

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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 Posterior, Non cervical Pedicle Screw Spinal System
The posterior non-cervical pedicle screw spinal system consists of a body, bushing, and ball head screw. Inner Screw, rods complete the spinal construct. The body portion of the screw rotates about the ball head on the screw, which provides increased motion over a fixed post of the polyaxial screw. An increase in motion facilitates the capture of rods that are not perfectly aligned.

The Screws, Rods are fabricated from Titanium alloy.

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

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

Indications for Use:

The GREENS BRAND Posterior, Non-cervical Pedicle Screw Spinal System is a pedicle screw fixation system intended for immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine:

- Degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (e.g., fracture or dislocation)
- Deformity or curvature (e.g., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Spinal stenosis
- Pseudarthrosis
- Failed previous fusion

Paediatric Use:
When used for posterior non-cervical screw fixation in paediatric patients, the GREENS BRAND

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Posterior, Non-cervical Pedicle Screw Spinal System is indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Additionally, it is intended to treat paediatric patients diagnosed with the following conditions:

- Spondylolisthesis
- Spondylolysis
- Fracture caused by tumor and/or trauma.

Paediatric pedicle screw fixation is limited to a posterior approach and is intended to be used with autograft and/or allograft.

a6). Summary of Technological Characteristics as compared to the predicate devices:

Substantial equivalence including comparison with predicate devices

A comparison between the **GREENS BRAND Posterior, Non cervical Pedicle Screw Spinal System** and predicate devices has been performed which has demonstrated substantial equivalence of indications for use, material, mechanical performance, and dimensions compared to predicate devices.

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

We have complied to following material standard

1. ASTMF136: Standard specification for wrought Titanium-6 Aluminium-4 Vanadium ELI (Extra low interstitial) Alloy for surgical implant applications.

B: Performance Standards:

The device performance of subject devices has been demonstrated using the following performance testing:

ASTM F1717

- Static compression bending
- Static torsion
- Dynamic compression bending

ASTM F1798

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- Axial grip
- Flexion-extension

b2). Discussion on the clinical evaluation referenced and relied upon:

Clinical information was not necessary to demonstrate substantial equivalence.

CONCLUSION:

General, Safety and Performance conclusion:

From the available data we can justify that the GREENS BRAND Posterior, Non-cervical Pedicle Screw Spinal System is substantially equivalent to previously cleared predicate devices identified in a3.of this 510(k) summary.