K123525

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510(k) Summary
for the Gridlock Plating System

FEB 15 2013

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the Gridlock Plating System

1. GENERAL INFORMATION

Date Prepared: November 12, 2012

Trade Name: Gridlock Plating System

Common Name: bone plate & screws

Classification Name: Single/multiple component metallic bone fixation appliances and accessories
Smooth or threaded metallic bone fixation fastener

Class: II

Product Code: HRS / HWC

CFR section: 21 CFR section 888.3030 / 888.3040

Device panel: OrthopedicOrthopedic

Legally Marketed Predicate Device: Gridlock Plating System (K121452)
OsteoMed Foot Plating System (K091614)

Submitter: Trilliant Surgical LTD
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2. DEVICE DESCRIPTION

Gridlock Plating System consists of various shape and size plates for the management of orthopedic osteotomies, reconstruction, and trauma. Features include a low profile, limited contact, capability of dynamic/manual compression, and angulated-locking threaded screw holes. The system also consists of multiple locking/standard screw lengths and diameters and the necessary instruments to facilitate the placement of these implants.

Change from Predicate:

This Special 510(k) is submitted in order to gain clearance for the Gridlock MPJ plates.

Materials:

CP Titanium per ASTM F67
Titanium alloy per ASTM F136

3. INTENDED USE

The Gridlock Plating System is intended for use in trauma and reconstructive procedures of the small bones in the hand/foot, ankle, and other bones appropriate for the size of the device.

The plates (implant), screws (implant), olive wires (instrument), and guide wires (instrument) are intended for single use only.

4. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS / SUBSTANTIAL EQUIVALENCE

The Gridlock Plating System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances. Two bone plates have been added to the Gridlock Plating System. These two plates are for use in treating the first metatarsal phalangeal joint and are manufactured from the same material, use the same screws and instruments, and are packaged and sterilized the using the same methods as the predicate Gridlock plates.

5. NON-CLINICAL TEST SUMMARY

The following tests were performed:

- Static and dynamic compression testing per ASTM F382-99, Standard Test Method for Determining the Bending Fatigue Properties of Metallic Bone Plates, Annexes 1 and 2

The results of this testing indicate that the current Gridlock Plating System is equivalent to predicate devices.

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

Trilliant Surgical LTD considers the current Gridlock Plating System to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

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

February 15, 2013

Trilliant Surgical Ltd
% The Orthomedix Group, Incorporated
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K123525
Trade/Device Name: Gridlock 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: December 14, 2012
Received: January 30, 2013

Dear J.D. Webb:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Erin D. Keith

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): __K123525_

Device Name: _Gridlock Plating System_____

Indications for Use:

The Gridlock Plating System is intended for use in trauma and reconstructive procedures of the small bones in the hand/foot, ankle, and other bones appropriate for the size of the device.

The plates (implant), screws (implant), olive wires (instrument), and guide wires (instrument) are intended for single use only.

Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael C. Owens

Division of Orthopedic Devices