K121452

510(k) Summary
for the Gridlock Plating System

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

AUG 20 2012

1. GENERAL INFORMATION

Date Prepared: May 11, 2012

Trade Name: Gridlock Plating System

Common Name: bone plate

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Class: II

Product Code: HRS / HWC

CFR section: 21 CFR section 888.3030 / 888.3040

Device panel: Orthopedic

Legally Marketed Predicate Device: OsteoMed Foot Plating System – K091614

Submitter: Trilliant Surgical LTD
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Houston, TX 77007

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2. DEVICE DESCRIPTION

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

Materials:

CP Titanium per ASTM F67
Titanium alloy per ASTM F136

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The Gridlock Plating System is substantially equivalent to the predicate device in terms of intended use, design, materials used, mechanical safety and performances.

4. 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.

5. NON-CLINICAL TEST SUMMARY

The following tests were performed:

Plates

- Static four point bending per ASTM F382 (Annex A1)
- Dynamic bending per ASTM F382 (Annex A2)

Screws

- Static Axial Pull-out per ASTM F543
- Driving Torque per ASTM F543
- Torque to Failure per ASTM F543

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

6. CLINICAL TEST SUMMARY

No clinical studies were performed

7. CONCLUSIONS NONCLINICAL AND CLINICAL

This summary includes the conclusions drawn from the nonclinical tests (discussed above) that demonstrate that Gridlock Plating System is as safe, as effective, and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Trilliant Surgical Limited
% The OrthoMedix Group, Incorporated
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AUG 2 0 2012

Re: K121452
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: August 9, 2012
Received: August 14, 2012

Dear Mr. 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121452

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INDICATIONS FOR USE

510(k) Number (if known): _____

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 and screws 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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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