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

April 22, 2016

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

Re: K160177
Trade/Device Name: Gridlock Ankle 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: January 23, 2016
Received: January 27, 2016

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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 -S

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K160177

Device Name

Gridlock Ankle Plating System

Indications for Use *(Describe)*

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

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

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

*5*10(k) Summary: Gridlock Ankle Plating System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations

Date Prepared	April 19, 2016
Submitted By	Trilliant Surgical LTD 6721 Portwest Dr, Suite 160 Houston, TX 77024 1-800-495-2919 Tele
Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele 512-692-3699 Fax e-mail: jdwebb@orthomedix.net
Trade Name	Gridlock Ankle 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	Orthopedic
Primary Predicate Device	Acumed Ankle Plating System (K143385)
Secondary Predicate Devices	Wright ORTHOLOC® 3Di Ankle Fracture System (K102429) Gridlock Plating System (K121452) Integra Cannulated Screw System (K040860)
Device Description	Gridlock Ankle 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.
Materials	CP Titanium per ASTM F67 Titanium alloy (Ti-6Al-4V) per ASTM F136

Substantial Equivalence Claimed to Predicate Devices	The Gridlock Ankle Plating System is substantially equivalent to the predicate devices in terms of intended use, design, materials used, mechanical safety and performances.
Indications for Use	The Gridlock Ankle Plating System is intended for use in trauma and reconstructive procedures of the small bones in the hand/foot, ankle, distal tibia, fibula, and other bones appropriate for the size of the device. The plates (implant), screws (implant), washers (implant), olive wires (instrument), and guide wires (instrument) are intended for single use only.
Non-clinical Test Summary	The following analyses were conducted: • Screw Torque to Failure (ASTM F543) • Plate 4-Point Bending (ASTM F382) The results of these evaluations indicate that the Gridlock Ankle Plating System is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Trilliant Medical LTD considers Gridlock Ankle Plating System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.