November 16, 2017

Trilliant Surgical, LTD
Jonathan Olson
President
6721 Portwest Drive, Suite 160
Houston, Texas 77024

Re: K172178
Trade/Device Name: Minimally Invasive Bunion 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
Dated: October 10, 2017
Received: October 10, 2017

Dear Jonathan Olson:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172178

Device Name
Minimally Invasive Bunion Plating System

Indications for Use *(Describe)*
The Minimally Invasive Bunion Plating System is intended for fixation of osteotomies and corrective procedures of the hallux and associated disorders such as hallux valgus.

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.

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510(k) Summary
Minimally Invasive Bunion Plating System

In accordance with 21 CFR 807.92(c) of the Federal Code of Regulations, the following 510(k) summary is submitted for the Minimally Invasive Bunion Plating System.

I. GENERAL INFORMATION

Date Prepared	July 14th, 2017
Submitted By	Trilliant Surgical LTD 6721 Portwest Dr. Suite 160 Houston, TX 77024 Telephone: 713-388-6055 Contact: Jon Olson Email: jolson@trilliantsurgical.com
Trade Name	Minimally Invasive Bunion Plating System
Common Name	bone fixation plate
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Class	II
Product Code	HRS
CFR Section	21 CFR Section 888.3030
Device Panel	Orthopedic
Primary Predicate Device	Gridlock Plating System (Trilliant Surgical LTD, K121452)
Secondary Predicate Device	Mini MaxLock Extreme Plating System – ISO Plate (OrthoHelix/Tornier, K121437)

II. DEVICE DESCRIPTION

The Minimally Invasive Bunion Plating System consists of left and right plates composed of implant grade titanium intended for fixation of osteotomies and corrective procedures of the hallux and associated disorders such as hallux valgus. The system will incorporate both locking and non-locking screws, cannulated screws, and the necessary instruments to facilitate the placement of these implants.

Materials

CP Titanium per ASTM F67

Substantial Equivalence Claimed to Predicate Devices

The Minimally Invasive Bunion Plating System is substantially equivalent to the predicate device in terms of intended use, design, materials used, mechanical safety and performance. The plates of the Minimally Invasive Bunion Plating System are manufactured from the same material and utilize the same screws as the predicate Gridlock Plating System. The Minimally Invasive Bunion Plating System is sterilized using the same methods as the predicate Gridlock Plating System. The technological

characteristics of the proposed device and the predicates are similar: all are titanium based plate and screw systems intended to fix fractures and/or osteotomies of bones appropriate for their size.

III. Indications for Use

The Minimally Invasive Bunion Plating System is intended for fixation of osteotomies and corrective procedures of the hallux and associated disorders such as hallux valgus.

IV. Non-Clinical Test Summary

The following tests were performed:

- Single Cycle Bend Testing referencing ASTM F382
- Dynamic Bend Testing referencing ASTM F382

The results of these evaluations indicate that the Minimally Invasive Bunion Plating System is equivalent to the predicate devices.

V. Clinical Test Summary

No clinical studies were performed.

VI. **Conclusions: Non-Clinical and Clinical**

Trilliant Surgical LTD considers the Minimally Invasive Bunion 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.