December 11, 2017

Trilliant Surgical
Jon Olson
President, CEO
6721 Portwest Drive, Suite 160
Houston, Texas 77024

Re: K172405
Trade/Device Name: Sniper Staple System, Non-sterile
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: JDR
Dated: November 8, 2017
Received: November 8, 2017

Dear Jon 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K172405

Device Name
Trilliant Sniper Staple System

Indications for Use *(Describe)*

The Trilliant Sniper Staple System is indicated for fixation of fractures and osteotomies of the hand, foot, and bones appropriate for the size of the device.

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
Sniper Staple System

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

I. GENERAL INFORMATION

Date Prepared	December 11, 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	Sniper Staple System
Common Name	Bone staple
Device	Staple, Fixation, Bone
Regulatory Description	Single/multiple component metallic bone fixation appliances and accessories.
Class	II
Product Code	JDR
CFR Section	21 CFR Section 888.3030
Device Panel	Orthopedic
Predicate Device	Sniper Staple System, Sterile (Trilliant Surgical LTD, K162354)

II. DEVICE DESCRIPTION

The Sniper Staple System consists of different-sized staples composed of Nitinol (Nickel-Titanium alloy) intended for fixation of fractures and osteotomies of the hand, foot, and bones appropriate for the size of the device. The system will be offered non-sterile in a tray for sterilization at the user's facility prior to use.

Materials

Nitinol per ASTM F2063

Substantial Equivalence Claimed to Predicate Devices

The Sniper Staple System is substantially equivalent to the primary predicate device in terms of intended use, design, materials used, mechanical safety and performance. The Sniper Staple System is sterilized to the same sterility assurance level as the predicate device. The technological characteristics of the proposed device and the predicate are identical: both are U-shaped metallic fixation devices made from Nitinol that use two legs and a single bridge to fixate bone segments.

III. Indications for Use

The Trilliant Sniper Staple System is indicated for fixation of fractures and osteotomies of the hand, foot, and bones appropriate for the size of the device.

IV. Non-Clinical Test Summary

The following tests were performed:

- Elastic Static Bending Strength per ASTM F564-10 (2015), *Standard Specification and Test Methods for Metallic Bone Staples*, specifically Annex IV – Test Method for Elastic Static Bending of Metallic Bone Staples.
- Pull-Out Fixation Strength per ASTM F564-10 (2015), *Standard Specification and Test Methods for Metallic Bone Staples*, specifically Annex II – Test Method for Pull-Out Fixation Strength of Metallic Bone Staples.
- Transformation temperature testing per ASTM F2082 (2016), *Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery*
- Corrosion resistance testing per ASTM F2129 (2017), *Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices*

The results of these evaluations indicate that the Sniper Staples are safe and equivalent to the predicate device.

V. Clinical Test Summary

No clinical studies were performed.

VI. Conclusions: Non-Clinical and Clinical

Trilliant Surgical LTD considers the Sniper Staple 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.

VII. Other device submission references

Multiple device submissions from Trilliant Surgical were used to demonstrate acceptable biocompatibility of the subject device. The reference submissions are as follows:

510(K) Number	Device Name	Decision Date	Manufacturer
K081510	Tiger Cannulated Screw System	08/04/2008	Trilliant
K121452	Gridlock Plating System	08/20/2012	Trilliant
K153338	Tiger Cannulated Screw System	01/14/2016	Trilliant
K123926	Metasurg Nitinol Staple	05/03/2013	Metasurg