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 20, 2017

Trilliant Surgical LTD
% J.D. Webb
Authorized Contact Person
The Orthomedix Group, Inc.
1001 Oakwood Blvd
Round Rock, Texas 78681

Re: K162354
Trade/Device Name: Sniper Staple System
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: March 6, 2017
Received: March 8, 2017

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 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,

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)*

K162354

Device Name
Sniper Staple System

Indications for Use *(Describe)*

The Trilliant Surgical 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)

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)*

510(k) Summary: Sniper Staple System

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

Date Prepared	April 7, 2917
Submitted By	Trilliant Surgical, LTD 6721 Portwest Dr. Suite 160 Houston, TX 77024 Tele: 713-388-6055 Contact: Jon Olson email: jolson@trilliantsurgical.com
Regulatory Contact	J.D. Webb 1001 Oakwood Blvd Round Rock, TX 78681 512-388-0199 Tele e-mail: jdwebb@orthomedix.net
Trade Name	Sniper Staple System
Common Name	bone staple
Classification Name	Staple, Fixation, Bone
Class	II
Product Code	JDR
CFR Section	21 CFR section 888.3030
Device Panel	Orthopedic
Primary Predicate Device	MemoFix Super Elastic Nitinol Staple System (Metasurg (Integra), K123926)
Secondary Predicate Devices	Super Staple Classic (Metric Medical Devices, K123363) Smith and Nephew Richards Staple, (pre-amendment device)
Device Description	The Sniper Staple is a mechanical osteosynthesis device allowing for fixation and compression of the bone fragments in order to encourage early bone healing. The staple is fabricated from a nickel-titanium alloy (Nitinol) and possesses super-elastic properties at room temperature. The staple offering is composed of staples consisting of a 1.5 mm x 1.2 mm diameter “U” shaped wire. The “U” shaped staple is available in 8 mm x 8 mm and 10 mm x 10 mm sizes.
Materials	Nickel-titanium alloy (Nitinol) per ASTM F2063
Summary of Technological Characteristics	The rationale for substantial equivalence is based on consideration of the following characteristics: **Intended Use:** The subject device and the predicate devices are intended for bone fixation. **Indications for Use:** The subject device and the predicates have equivalent indications for use. **Materials:** The subject device and predicate devices are manufactured from Nitinol **Design Features:** The subject device has similar design features to that of the predicates. **Dimensions:** The dimensions of the subject device and the predicates are equivalent.

	Sterilization: The subject device and one of the predicate devices are provided sterile by gamma irradiation.
Indications for Use	The Trilliant Surgical Sniper Staple System is indicated for fixation of fractures and osteotomies of the hand, foot, and bones appropriate for the size of the device.
Non-clinical Test Summary	The following analyses were conducted: ● Four-point Bending (ASTM F564) ● Pull-out Testing (ASTM F564) ● Bend and Free Recovery Testing per ASTM F2082 ● Corrosion testing per ASTM F2129 ● Pyrogenicity was evaluated using the Limulus amebocyte lysate (LAL) assay. The testing demonstrated that the subject device meets the recommended maximum endotoxin level of 20 EU per device. The results of these evaluations indicate that the Sniper Staple is equivalent to predicate devices.
Clinical Test Summary	No clinical studies were performed
Conclusions: Non-clinical and Clinical	Trilliant Surgical 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.