Trilliant Surgical
Jon Olson
President
727 N Shepherd Dr. STE 100
Houston, Texas 77007

October 26, 2018

Re: K181898
Trade/Device Name: Two-Step Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTY
Dated: September 19, 2018
Received: September 20, 2018

Dear Mr. 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Jesse Muir -S
2018.10.26 12:17:00 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181898

Device Name
Two-Step Implant System

Indications for Use *(Describe)*
The Two-Step Implant System is intended for fixation of osteotomies and reconstruction of the bones of the foot and hand during procedures to correct deformities of the toes and fingers. Indications include: hammer toe deformity, claw toe deformity, mallet toe deformity, and other deformities of the foot and hand.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW ***

The urden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
ffice of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not re uired to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
Two-Step Implant System

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

I. GENERAL INFORMATION

Date Prepared	September 19th, 2018
Submitted By	Trilliant Surgical 727 N. Shepherd Drive, Suite 100 Houston, TX 77007 Telephone: (800) 495-2919 Fax: (877) 778-3864 Contact: Gabriel Kern Email: gkern@trilliantsurgical.com
Trade Name	Two-Step Implant System
Regulatory Class	Class II
CFR Section, Product Code, Classification Name, and Common Name	21 CFR Section 888.3040, Product Code HWC, Screw, Fixation, Bone, threaded metallic bone fixation fastener, bone screw 21 CFR Section 888.3040, Product Code HTY, Pin, Fixation, Smooth, smooth metallic bone fixation fastener, k-wire
Device Panel	Orthopedic
Primary Predicate Device	Hammer Toe Implant (Trilliant Surgical, K122959)
Secondary Predicate Devices	Tiger Headless Cannulated Screws (Trilliant Surgical, K112737)
	Trilliant Surgical K-Wires (Trilliant Surgical, K121008)
	KMedic External Fixation Devices - (Teleflex Medical Group, K030336)

II. DEVICE DESCRIPTION

The Two-Step Implant System is used for fixation of the bones of the foot and hand. The system includes a cannulated, threaded, spaded implant that is offered in multiple threaded diameters, lengths, and spade diameters. The system includes k-wire implants in multiple sizes. Available implants and instrumentation can be packaged in a sterilization tray as a single system. System instrumentation includes spade pilot drills, spade drivers, thread pilot drills, reamers, impactor, and handles to facilitate the placement of the implants. The Two-Step Implant System implants and k-wires are intended for single use only.

III. Indications for Use

The Two-Step Implant System is intended for fixation of osteotomies and reconstruction of the bones of the foot and hand during procedures to correct deformities of the toes and fingers. Indications include: hammer toe deformity, claw toe deformity, mallet toe deformity, and other deformities of the foot and hand.

IV. Technological Comparison to Predicate Devices

The Two-Step Implant System has the same technological characteristics as one or more predicate devices in terms of design, material, performance, and energy source.

V. Non-Clinical Performance Summary

Performance testing is presented per methods developed from ASTM F543 to demonstrate equivalence to predicates in terms of established performance specifications.

VI. Clinical Test Summary

No clinical studies were performed.

VII. Conclusions

Based upon the similarities in indications for use, technology, materials, and performance, Trilliant Surgical considers the Two-Step Implant System to be as safe and effective as predicate devices and performs as well as predicate devices.

VIII. Substantial Equivalence Claimed to Predicate Devices

The Two-Step Implant System is substantially equivalent to the predicate devices in terms of intended use, technological characteristics, and performance specifications.