February 23, 2022

Trilliant Surgical
Christopher Radzicki
Engineering Manager
727 North Shepherd Drive, Suite 100
Houston, Texas 77007

Re: K212378
Trade/Device Name: Arsenal 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, NDG
Dated: January 24, 2022
Received: January 25, 2022

Dear Christopher Radzicki:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212378

Device Name
Arsenal Ankle Plating System

Indications for Use *(Describe)*
The Arsenal 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.

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
Arsenal Ankle Plating System

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

I. GENERAL INFORMATION

Date Prepared	February 21st, 2022
Submitted By	Trilliant Surgical, wholly owned subsidiary of DJO Global, Inc. 727 North Shepherd Drive Suite 100 Houston, TX 77007 Telephone: (832) 605-3167 Contact: Christopher Radzicki Email: Christopher.Radzicki@djoglobal.com
Trade Name	Arsenal Ankle Plating System
Common Name	Plate, Fixation, Bone (primary) Screw, Fixation, Bone Washer, Bolt, Nut, Non-Spinal Metallic
Classification Name	Single/multiple component metallic bone fixation appliances and accessories (primary) Smooth or threaded metallic bone fixation fastener
Class	II
Product Code	HRS, HWC, NDG
CFR Section	21 CFR Section 888.3030 (primary) 21 CFR Section 888.3040
Device Panel	Orthopedic
Predicate Devices	(Primary Predicate) Gridlock Ankle Plating System (Trilliant Surgical, K160177, HRS, HWC)
	Arsenal Plating System (Trilliant Surgical, K191009, HRS, HWC, NDG)
	Tiger Cannulated Screw System (Trilliant Surgical, K081510 & K153338, HWC)

II. DEVICE DESCRIPTION

The Arsenal Ankle Plating System consists of plates of various shapes and sizes composed of implant grade titanium alloy 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 system incorporates multiple locking and non-locking screws of various lengths and diameters, washers, and the necessary instruments to facilitate the placement of these implants.

Materials

The implants in the Arsenal Ankle Plating System are made of Titanium-6Aluminum-4Vanadium ELI per ASTM F136. Surgical instrumentation is provided to facilitate modification, insertion, and removal of the implants. The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade polymer.

Substantial Equivalence Claimed to Predicate Devices

The Arsenal Ankle Plating System is substantially equivalent to the predicate device in terms of intended use, design, materials used, mechanical safety and performance. The intended use of the Arsenal Ankle Plating System is identical to that of the predicate Gridlock Ankle Plating System (K160177) from Trilliant Surgical; the indications have been updated for clarity and do not impact the safety or effectiveness of the device as:

- There is no change from a functional/performance indication to a treatment or aesthetic indication.
- There is no change from a diagnostic indication to a screening indication (and vice versa).
- There is no change in the anatomical structure of use.
- There is no change in the patient population.
- There is no change in the clinical context or setting.

The plates of the Arsenal Ankle Plating System are manufactured from the same material as the predicate Arsenal Plating System from Trilliant Surgical (K191009). The screws of the Arsenal Ankle Plating System are manufactured from the same material as the predicate, the Arsenal Plating System from Trilliant Surgical (K191009), the Tiger Cannulated Screw System from Trilliant Surgical (K153338), and the Gridlock Ankle Plating System (K160177) from Trilliant Surgical. The washers of the Arsenal Ankle Plating System are manufactured from the same material as the predicate, the Arsenal Plating System from Trilliant Surgical (K191009).

The Arsenal Ankle Plating System is sterilized using the same methods as the listed predicate devices. The technological characteristics and intended use of the proposed device and predicates are identical: all are titanium-based plate and / or screw systems intended to fixate fractures and/or osteotomies of bones appropriate for their size in trauma and reconstructive procedures.

III. INDICATIONS FOR USE

The Arsenal 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.

IV. NON-CLINICAL TEST SUMMARY

The following tests were performed:

- Single Cycle Bend Testing referencing ASTM F382

- Axial Pullout Strength Testing referencing ASTM F543 and Guidance for Industry and Food and Drug Administration Staff for Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway
- Torsional Property Testing referencing ASTM F543 and Guidance for Industry and Food and Drug Administration Staff for Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway
- Driving Torque Testing referencing ASTM F543 and Guidance for Industry and Food and Drug Administration Staff for Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway
- Sterilization Testing referencing ISO 17665-1:2006 and AAMI TIR30:2011
- Biocompatibility Testing referencing ISO 10993-1

Additionally, an engineering analysis was conducted for the plates to demonstrate substantial equivalence to the predicate devices.

The results of these evaluations indicate that the Arsenal Ankle Plating System is equivalent to the predicate devices.

V. CLINICAL TEST SUMMARY

No clinical studies were performed.

VI. CONCLUSION

Trilliant Surgical considers the Arsenal 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, intended use, and indications for use.