May 8, 2018

Trident Orthopedics
% Al Memmolo
Official Correspondent
6648 Surf Crest Street
Carlsbad, California 92011

Re: K171690
Trade/Device Name: Trident Extremity Fixation 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
Dated: March 28, 2018
Received: March 30, 2018

Dear Al Memmolo:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171690

Device Name
The Trident Extremity Fixation System

Indications for Use *(Describe)*
The Trident Extremity Fixation System consisting of plates and screws are intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of bone of the feet, hand, ankle and toes. Specific examples include:
- Arthrodesis of the first metatarsalcuneiform joint (Lapidus fusion procedure)
- Arthrodesis of the first metatarsalphalangeal joint (MTP fusion procedure)
- Primary and revision MTP fusion due to hallux rigidus and/or hallux valgus corrections
- Revision of failed first MTP arthroplasty implant 2nd, 3rd and 4th metatarsal weil osteotomy correction indications
- Metatarsal osteotomies to correct hallux valgus bunion indications
- Fractures of the fifth metatarsal bone in the foot
- Carpal bone fusions and fractures

Flatfoot Osteotomies:
- Lateral column lengthening (Evans osteotomy)
- Plantar flexion opening wedge osteotomy of the medial cuneiform (Cotton osteotomy)
- Medial displacement calcaneal osteotomy

Midfoot/Hindfoot Arthrodesis/Fusions
- Lisfranc arthrodesis and/or stabilization
- 1st, 2nd, 3rd and 4th Tarsometatarsal (TMT) fusions
- Navicular-Cuneiform (NC) joint fusions
- Talo-Navicular (TN) joint fusions
- Calcaneo-Cuboid (CC) joint fusions
- Medial column fusions (NC and 1st TMT)

The Trident Extremity Fixation System screws and plates are indicated for use with the Trident Plates and Screws of the same material. The locking and non-locking solid cortical screws, cannulated screws and headless screws are also indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, 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
(as required by 21 CFR 807.92)

Date Prepared	May 8, 2018
Manufacturer	Trident Orthopedics
Address	212 Copperwood Court Millersville, MD 21108
Contact Person	Al Austin
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Telephone	410-903-9038
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Trade Name	Trident Extremity Fixation System
Common Name	Bone Screw
Panel Code	Orthopaedics/87
Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Class	Class II
Regulation Number	21 CFR 888.3030
Product Code	HRS: Plate, Fixation, Bone HWC: Screw, Fixation, Bone

Predicate Devices	**510(k) #**	**Manufacturer**
Primary Predicate: Medline Foot Plates and Screws	K151235	Medline
Secondary Predicate: Vilex Cannulated Bone Screw/DuVal Cannulated Bone Screw	K991151, K991197	Vilex, Inc.
Secondary Predicate: Osteomed Cannulated Screw System	K151021	Osteomed, Corp.

Description	The Subject device is manufactured from titanium conforming to ASTM F-136. The system includes plates in various sizes as well as locking and non-locking screws to be used with the plates. The bones screws are available in diameter sizes from 3.0 mm to 7.3 mm diameter and lengths from 10 mm to 100 mm. The system also includes reusable instrumentation for delivery of the implantable components. The Subject device has a similar range of sizes as its predicate.

Indications and Intended Use	*The Trident Extremity Fixation System consisting of plates and screws are intended for use in stabilization and fixation of fresh fractures, revision procedures, joint fusion and reconstruction of bone of the feet, hand, ankle and toes. Specific examples include:* *- Arthrodesis of the first metatarsalcuneiform joint (Lapidus fusion procedure)* *- Arthrodesis of the first metatarsalphalangeal joint (MTP fusion procedure)* *- Primary and revision MTP fusion due to hallux rigidus and/or hallux valgus corrections*

	- Revision of failed first MTP arthroplasty implant *2nd, 3rd and 4th metatarsal weil osteotomy correction indications* *Metatarsal osteotomies to correct hallux valgus bunion indications* *Fractures of the fifth metatarsal bone in the foot* *Carpal bone fusions and fractures* *Flatfoot Osteotomies:* *- Lateral column lengthening (Evans osteotomy)* *- Plantar flexion opening wedge osteotomy of the medial cuneiform (Cotton osteotomy)* *- Medial displacement calcaneal osteotomy* *Midfoot/Hindfoot Arthrodesis/Fusions* *- Lisfranc arthrodesis and/or stabilization* *- 1st, 2nd, 3rd and 4th Tarsometatarsal (TMT) fusions* *- Navicular-Cuneiform (NC) joint fusions* *- Talo-Navicular (TN) joint fusions* *- Calcaneo-Cuboid (CC) joint fusions* *- Medial column fusions (NC and 1st TMT)* *The Trident Extremity Fixation System screws and plates are indicated for use with the Trident Plates and Screws of the same material. The locking and non-locking solid cortical screws, cannulated screws and headless screws are also indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation, appropriate for the size of the device.*

Technological Characteristics and Substantial Equivalence	Documentation and performance testing was provided to demonstrate that the Subject device is substantially equivalent to the Predicate Medline Foot Plates and Screws (K151235) and the Predicate Vilex Cannulated Bone Screw/DuVal Cannulated Bone Screw (K991151, K991197). The Subject device is substantially equivalent to the predicate devices in intended use, indications for use, materials, technological characteristics, and labeling.

Performance Data	Bench testing confirmed that the Subject device performed as intended and is at least equivalent to the predicate devices. Static 4-Point bending (ASTM F382-14) was conducted on the plates. Axial Pullout, Axial Pushout, Torque to Failure (ASTM F543) Static Three-Point Bend, and Dynamic Three-Point Bend (ASTM F1264) were performed on the screws.

Conclusion	Based on the intended use, indications for use, technological characteristics, materials, and comparison to predicate devices, the Subject device has been shown to be substantially equivalent to legally marketed predicate devices.