DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 3, 2017

Truemed Group LLC
% Ms. Lara Luzak
Senior Regulatory Specialist
Registrar Corp.
144 Research Drive
Hampton, Virginia 23666

Re: K162507
Trade/Device Name: Arzzt 3.5 / 4.5 Small & Large Fragments 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: July 5, 2017
Received: July 6, 2017

Dear Ms. Luzak:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162507

Device Name
Arzzt 3.5 / 4.5 Small & Large Fragments System

Indications for Use *(Describe)*
The Arzzt 3.5/4.5 Small & Large Fragment Systems is indicated for fixation of fractures, osteotomies, and non-unions of the humerus, radius, ulna, femur, and tibia.

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.

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2002 Timberloch Place Suite 200
The Woodlands, TX 77380
Telephone: 832 442 2310

Premarket Notification 510(k) Summary

1.	Submitter's Name:	Truemed Group LLC
2.	Contact Person:	Jorge Trujillo Zavala 2002 Timberloch Place Suite 200 The Woodlands, TX 77380 Telephone: 832 442 2310
3.	Date Prepared:	April 21, 2016
4.	Device Name:	Arzzt 3.5 / 4.5 Small & Large Fragments System
5.	Common Name:	Osteosynthesis plates and screws
6.	Classification Name:	• Plate, Fixation, Bone and accessories per 21 CFR section 888.3030 • Screw, Fixation, Bone and accessories per 21 CFR section 888.3040
7.	Product Codes:	HRS, HWC
8.	Devices Classification:	Class II
9.	Regulation Numbers:	21 CFR 888.3030 21 CFR 888.3040
10.	Predicate Device (Primary):	- Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications **K082807**
11.	Device Description:	The Arzzt 3.5/4.5 Small & Large Fragments System consist of a variety of plates designed for specific bone areas, with orifices to receive either locking or non-locking screws. The screws are can be total or partially threaded and cannulated or not, some are self-tapping and they can be with or without locking features. All plates and screws may be manufactured in either stainless steel or titanium.
12.	Intended Use:	The Arzzt 3.5/4.5 Small & Large Fragment System is indicated for fixation of fractures, osteotomies, and non-unions of the humerus, radius, ulna, femur, and tibia.

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13. Test Performed:

We performed engineering analyses comparing the static bending and static torsional yield strengths of the Arzzt blocking plates to the predicate devices proving to be as strong as the predicate devices. For the screws, we performed engineering analyses comparing the maximum shear stress and thread of the Arzzt blocking and cortical screws to the predicate device.

14. Standards:

- ASTM F-983-86 Standard Practice for Permanent Marking of Orthopedic Implant Components
- ASTM F543-07 Standard Specifications And Test Methods For Metallic Medical Bone Screws
- ISO 5832-1:2007 Implants for surgery -- Metallic materials -- Part 1: Wrought stainless steel
- ISO 5832-3:1996. Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy

The Arzzt Plates & Screw System met the requirements of the above standards.

15. Substantial Equivalence:

The Arzzt 3.5 / 4.5 Small & Large Fragments System has an equivalent intended use, target population, anatomical sites, materials, biocompatibility, as well performance and properties as Synthes (USA) 3.5 mm and 4.5 mm Locking Compression Plate (LCP) System with Expanded Indications and other predicates devices for fixation of bone fractures.

In considering the technological characteristics of the device compared to the predicate device, the Arzzt 3.5 / 4.5 Small & Large Fragments System has a solid design and the engineering analyses performed on the product demonstrate that the performance and properties are of Arzzt Plates & Screw System are substantially equivalent to the predicate device.