June 10, 2019

Truemed Group LLC
Nina Rodriguez
Coordinator
2002 Timberloch Place Suite 200
The Woodlands, Texas 77380

Re: K182650
Trade/Device Name: Arzzt Distal Radius and Ulna 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: May 2, 2019
Received: May 6, 2019

Dear Nina Rodriguez:

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,

Shumaya Ali, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182650

Device Name

Arzzt Distal Radius and Ulna System

Indications for Use *(Describe)*
The Arzzt Distal Radius and Ulna System is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

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

TRUEMED GROUP

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:	September 12th, 2018
4.	Device Name:	Arzzt Distal Radius and Ulna System
5.	Common Name:	Osteosynthesis plates and screws
6.	Classification Name:	• Plate, Fixation, Bone and accessories per 21 CFR section 888.3030
7.	Product Codes:	HRS, HWC
8.	Devices Classification:	Class II
9.	Regulation Numbers:	21 CFR 888.3030 21 CFR 888.3040
10.	Predicate Devices:	Primary Predicate: Synthes Locking Distal Radius Plating System (K012114) Additional Predicates: Synthes (USA) 3.5ram LCP Hook Plate (K082072) 2.4mmn Variable Angle LCP Dorsal Distal Radius System (K102694) Arzzt 3.5 / 4.5 Small & Large Fragments System (K162507) Synthes Stainless Steel Modular Hand System (K030310) Reference Predicate: Ins Hilden Tibial Arzzt (K133166)
11.	Device Description:	The Arzzt Distal Radius and Ulna System consist in a

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variety of plates intended for dorsal and volar use, with orifices to receive either locking or non-locking screws. The screws are can be total or partially threaded, some are self-tapping and they can be with or without locking features. System is also available with locking pegs. All plates and screws may be manufactured in stainless steel (ASTM F138) and titanium (ASTM F136). The System is non-sterile and single use only.

12. Technological Characteristic comparison:

- **Similarities**: Single use devices. Same materials of manufacture. Similar compatible screw sizes, and plate types
- **Differences**: The specific geometries of the plates differ (e.g., tip point features, decreased cortical surface complexity/flat undersurface design)

13. Intended Use:

The Arzzt Distal Radius and Ulna System is intend to use for fixation of complex intra- and extra-articular fractures and osteotomies of the distal radius and other small bones.

14. Non-Clinical Testing:

We performed engineering analyses comparing the static bending and static torsional yield strengths of the Arzzt locking plates to the predicate devices proving to be as strong as the predicate devices. For the screws, we performed ASTM F543 testing and engineering analyses comparing the maximum shear stress and thread of the Arzzt locking and cortical screws to the predicate device.

15. Conclusion:

Based on the testing and technological properties of the subject device as compared to the predicate device, we believe that no new questions of safety and effectiveness have been raised, and that the subject device is substantially equivalent to the predicate devices.