July 9, 2021

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

Re: K200575
Trade/Device Name: Truemed Hand, Foot and Ankle Plates 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: June 4, 2021
Received: July 8, 2021

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200575

Device Name
Truemed Hand Foot and Ankle Plates System

Indications for Use *(Describe)*
Intended use for fixation of complex intra and extra-articular fractures and osteotomies, selective trauma, reconstructive procedures, fusions osteotomies, non-unions, replantations, complex extra articular fractures and fusions of bones of the anatomical regions of the hand, foot and ankle, particularly for osteopenic bone in adults and adolescents.

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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Premarket Notification 510(k) Summary

1. Submitter's Name:	Truemed Group LLC
2. Contact Person:	Nina V. Galeana 2002 Timberloch Place Suite 200 The Woodlands, TX 77380 Telephone: 832 442 2310
3. Date Prepared:	July 8th, 2021
4. Device Name:	Truemed Hand, Foot and Ankle Plates System
5. Common Name:	plates and screws
6. Classification Name:	Primary: Plate, Fixation, Bone and accessories per 21 CFR section 888.3030 Secondary: 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 Devices:	**PRIMARY PREDICATE** **K150099 -**Depuy Synthes Variable Angle Locking Hand System (1.3 Y 2.0 Mm Plates and Screws). **SECONDARY PREDICATES** **K030310** -Synthes Stainless Steel Modular Hand System. **K050110-**Synthes (USA) LCP Modular Foot Plates. **K100776-**Synthes 2.4 Mm / 2.7 Mm Variable Angle (Va)- LCP Forefoot/Midfoot System. **K071264-**Synthes (USA) 2.4/2.7mm Locking Foot Module. **K020401-**Synthes Calcaneal Plate. **K120854-**Synthes Variable Angle LCP Ankle Trauma System. **K143191-**McGinley Innovations IntelliSense Drill. **K182650-** Arzzt Distal Radius And Ulna System.

11. Device Description:

The Truemed Hand, Foot and Ankle Plates System consist in a variety of plates designed for specific bone areas, with orifices to receive either locking or non- locking screws. The screws can be total or partially threaded, some are self-tapping and they can be with or without locking features. All plates and screws may be manufactured in either Stainless Steel **(ASTM 138 - 13a)** or Titanium **(ASTM F136-12a)**.

12. Indications for use:

Intended use for fixation of complex intra and extra- articular fractures and osteotomies, selective trauma, reconstructive procedures, fusions osteotomies, non- unions, replantations, complex extra articular fractures and fusions of bones of the anatomical regions of the hand, foot and ankle, particularly for osteopenic bone in adults and adolescents.

13. Technological Comparison

Truemed Hand, Foot and Ankle Plates System and predicate devices **Arzzt Radius and Ulna System (K182650)** are manufactured from the same metals (stainless steel 316LS and Ti 6AI-4V ELI). Both materials meet specifications and chemical and physical characteristics that are necessary for the development of medical implants according to ISO 5832 Implants for surgery metallic materials.

14. Test Performed:

We performed engineering analyses comparing the static bending and static torsional yield strengths of the locking plates to the predicate devices proving to be as strong as the predicate devices. Mechanical Testing **was also performed on the screws** in accordance to ASTM F543 ANNEX: A1, A2 and A3 (Torsional properties, Insertion and Removal Torque, Axial Pullout Strength).

Engineering Analysis was performed on the plates in comparison to the predicate device. We used sectional views to calculate the Area moment of inertia and distance from the neutral axis to the surface at the minimum cross section using SolidWorks.
According to the minimum yield stress for stainless steel (ASTM F138-13a) and Titanium alloy (ASTM F136-12a), subject device proves to be as functional as predicate device.
Biocompatibility risk assessment was also performed for all components included in the subject device.

- **ASTM F 983-86 (Reapproved 2009)** Standard Practice for Permanent Marking of Orthopedic Implant Components
- **ASTM F 543 – 13** Standard Specification and Test Methods for Metallic Medical Bone Screws
- **ASTM F 382-99** Standard Specification and Test Method for Metallic Bone Plates

15. Substantial Equivalence:

The Truemed Hand, Foot and Ankle Plates System has an intended use, target population, materials, performance properties equal to those featured in the predicates K150099, K030310, K050110, K100776, K071264, K020401, K120854, K143191 and K182650. In consideration of the technological and morphological characteristics of the devices, K150099, K030310, K050110, K100776, K071264, K020401, K120854, K143191 and K182650, a review of the product features and design lead us to find substantial equivalence. Engineering analysis and mechanical testing performed on the plates and screws that make up the Truemed Hand, Foot and Ankle Plates System indicate that they are substantially equivalent to the predicate devices in performance and functionality.

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.