January 4, 2024

Zimed Medikal
℅ Barry Sands
President and Founder
RQMIS, Inc.
110 Haverhill Road Suite 524
Amesbury, Massachusetts 01913

Re: K230507
Trade/Device Name: Zimed Distal Medial Tibial Plate and Screw 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: December 5, 2023
Received: December 6, 2023

Dear Barry Sands:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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)*
K230507

Device Name
Zimed Distal Medial Tibial Plate and Screw System

Indications for Use *(Describe)*
The Zimed Distal Medial Tibial Plate and Screw System is indicated for fixation of complex extra-articular and intra-articular distal medial tibial fractures and osteotomies.

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.

510(K) SUMMARY

Submitter information

Date Prepared	January 2, 2024
Applicant/Manufacturer	**Zimed Medikal Sanayi ve Ticaret Limited Sirketi** Aydinlar Mah.03070 Cad.No:04 Sehitkamil Gaziantep Turkiye Gaziantep, Sehitkamil, 27580, Turkiye
Primary Contact	Barry Sands President and Founder, RQMIS Phone: (978) 358-7307 Email: regulatorysubmissions@rqmis.com

Device information

Trade Name of Subject Device	Zimed Distal Medial Tibial Plate and Screw System
Common Name	Plate, Fixation, Bone; Screw, Fixation, Bone
Device class	Class II
Product Code	HWC, HRS (primary)
Regulation Number	888.3030 Single/multiple component metallic bone Fixation appliances and accessories (Primary) 888.3040 Smooth or threaded metallic bone fixation fastener
Predicate Devices:	**Primary predicate**: Synthes (USA) LCP Distal Tibia Plate (K013248) **Reference predicate**: HEMC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, HEMC BRAND of DHS Plating system (K222282)

Device Description

Zimed Distal Medial Tibial Plate and Screw System is used for complex extra-articular and intra-articular distal tibial fractures, and osteotomies surgeries specifically designed for the anatomical alignment of the broken bones and to provide splinting with the ability to ensure the early mobility of the patient. Zimed plate and screw system is implantable device in long term contact with bones.

Zimed Distal Medial Tibial Plate and Screw System will be supplied non-sterile.

Indications for Use

The Zimed Distal Medial Tibial Plate and Screw System is indicated for fixation of complex extra-articular and intra-articular distal medial tibial fractures and osteotomies.

Intended Use – Comparison of the subject device with Primary & Reference Predicate Devices

The subject device, Zimed Distal Medial Tibial Plate and Screw System, has similar intended use and indication for use to the primary predicate Synthes (USA) LCP Distal Tibia Plate (K013248), and reference predicate, HEMC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, HEMC BRAND of DHS Plating system (K222282)

Technological Characteristics – Comparison with the primary predicate, Synthes (USA) LCP Distal Tibia Plate (K013248) and reference predicate, HEMC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, HEMC BRAND of DHS Plating system (K222282)

The technological characteristics comparison demonstrated that the subject device, the Plate and Screw System are substantially equivalent in intended uses, designs, materials, and operational principles to the previously cleared predicate devices, respectively.

Basis of Substantial Equivalence

The substantial equivalence of the subject device was determined per the FDA guidance document, “The 510(k) program: evaluating substantial equivalence in premarket Notification [510(k)].” The analysis of the technological characteristics, which include design, material composition and other device features, as defined in section 513(i)(1)(B) of the FD&C Act and 21 CFR 807.100(b)(2) (ii)(A), demonstrated that the Plate and Screw System are substantially equivalent to the identified predicate devices, respectively.

Zimed Distal Medial Tibial Plate and Screw System are substantially equivalent to the respective predicates. Comparison to the predicates does not raise different questions of safety and effectiveness. The performance testing, device comparisons, designs, and feature analysis

demonstrate that the subject device is substantially equivalent to the identified predicate devices, respectively.

Performance Testing

The performance tests on the subject device were conducted in accordance with ASTM F382, ASTM F136 and ASTM F543 standards. Performance test reports confirmed that the subject device, Zimed Distal Medial Tibial Plate and Screw System, and the reference predicate, HEMC BRAND Locking Bone Plates and Screws Osteosynthesis Plating System, HEMC BRAND of DHS Plating system (K222282) meet ASTM F136 and ASTM F543 and used the same test methodology as the required specifications. We utilized the FDA guidance "Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway" for the screw testing, and the FDA guidance, "Orthopedic Fracture Fixation Plates - Performance Criteria for Safety and Performance Based Pathway" for the plate testing. Therefore, the subject device is substantially equivalent to the respective predicates' devices identified throughout this submission.

Substantial Equivalence Conclusion

Zimed Distal Medial Tibial Plate and Screw System has similar intended use, material comparison, design, operational principle, and equivalent technological characteristics to the respective predicate devices. The non-clinical performance test reports support the safety, effectiveness and performance of the subject device and demonstrate that any difference in technological characteristics and material composition do not raise any new questions of safety and effectiveness. Therefore, the subject device is substantially equivalent to the respective predicate devices.