August 17, 2023

Microware Precision Co., Ltd.
Harrison Du
General Manager
No. 12, Keyuan 2nd Rd., Situn District
Taichung, 40763
Taiwan

Re: K230690/S001
Trade/Device Name: Tandry Locking Plate 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 10, 2023
Received: March 13, 2023

Dear Harrison Du:

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 -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)*
K230690

Device Name
Tandry Locking Plate System

Indications for Use *(Describe)*
The Tandry Locking Plate System is intended to provide fixation during fractures, fusions, and osteotomies. The Tandry Locking Plate System is indicated for the clavicle, pelvis, scapula and calcaneus, small bones including the metacarpals, wrist, metatarsals, tarsals and phalanges, and long bones including the radius, ulna, humerus, olecranon, fibula, femur, and tibia.

In addition, the Tandry Locking Hip Plate System is indicated for fixation of fractures to the proximal femur. The plates are indicated for use in trochanteric, pertrochanteric, intertrochanteric, and basilar neck fracture.

Each plate is indicated for the following anatomic regions:
• 1.5mm and 2.0mm locking plates – Metacarpals, metatarsals, tarsals, and phalanges
• 2.4mm locking plates – Radius, wrist, and ulna
• 3.5 mm locking plates – Clavicle, scapula, humerus, olecranon, pelvis, fibula, calcaneal, and tibia
• 5.0 mm locking plates – 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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510(k) Summary

Submitter's Name: Microware Precision Co., Ltd.
Address: No. 12, Keyuan 2nd Rd., Situn District, Taichung City 40763, Taiwan
Tel: +886-4-24636275 # 100 Fax: +886-4-24636276

Contact Name: Harrison Du

Preparation Date: August 02, 2023

Registration Number: 3007738812

Device Name: Tandry Locking Plate System

Common Name:

- Plate, Fixation, Bone (Primary)
- Screw, Fixation, Bone

Classification Name:

- Single/multiple component metallic bone fixation appliances and accessories (Primary)
- Smooth or threaded metallic bone fixation fastener

Code of Federal Regulations (CFR)

- 21 CFR 888.3030 (Primary)
- 21 CFR 888.3040

Product Code:

- HRS (Primary)
- HWC

Device Class

- Class II

Predicate Device Information:

Primary device: Tandry Locking Plate System (K171904)

Reference device: VariAx Distal Radius Plating System, VariAx 2 System (K162841)

Device Description:

The Tandry Locking Plate System consists of various sized plates, screws and instruments. The plates are designed to distribute for local anatomies and can accept locking, cortex, shaft and cancellous screws. The screws are designed with self-tapping to promote the operation efficiency to insert the bones. The instruments are used for completing the surgery.

Indication for use:

The Tandry Locking Plate System is intended to provide fixation during fractures, fusions, and osteotomies. The Tandry Locking Plate System is indicated for the clavicle, pelvis, scapula and calcaneus, small bones including the metacarpals, wrist, metatarsals, tarsals and phalanges, and long bones including the radius, ulna, humerus, olecranon, fibula, femur, and tibia.

In addition, the Tandry Locking Hip Plate System is indicated for fixation of fractures to the proximal femur. The plates are indicated for use in trochanteric, pertrochanteric, intertrochanteric, and basilar neck fracture.

Each plate is indicated for the following anatomic regions:

- 1.5mm and 2.0mm locking plates – Metacarpals, metatarsals, tarsals, and phalanges
- 2.4mm locking plates – Radius, wrist, and ulna
- 3.5 mm locking plates – Clavicle, scapula, humerus, olecranon, pelvis, fibula, calcaneal, and tibia
- 5.0 mm locking plates – Femur and tibia

Technological Characteristics:

The design, features, materials, and Indications for use of the proposed device remain unchanged compared to the previously cleared device K171904 (predicate device). The modifications in this submission extend all plates to two specifications: pure titanium and titanium alloy; extend the type 2-anodized for screws and plates and some length specifications for the plates. These modifications do not change the intended use, fundamental scientific technology, or the biocompatibility requirement of the device system. The comparison table for the modification of Tandry Locking Plate System and the predicate devices are following Table 1.

Summary of Performance Data (Nonclinical and/or Clinical)

Clinical Test

Clinical studies are not required to support substantially equivalent.

Non-Clinical Test

- Biomechanical Test

  Since the proposed device is substantial equivalence to Tandry Locking Plate System K171904, the performance and testing result of the predicate can be utilized in the proposed device.
- Biocompatibility

  Representative samples of subject devices was subjected to the following: "Biocompatibility sample preparation was made according to ISO 10993-12. Biological Safety Assessment guided by ISO 10993-1. Cytotoxicity testing was performed per ISO 10993-5.
- Reprocessing and sterilization

  Since the proposed device is substantial equivalence to Tandry Locking Plate System K171904, the performance and testing result of the predicate can be utilized in the proposed device. The testing results support the proposed device to meet the validation requirement.

  The steam sterilization instructions are validated to a sterility assurance level (SAL) of 10^{-6} using the biological indicator overkill method. The sterilization validation test is performed in accordance with ANSI/AAMI/ISO 17665-1 and ANSI/AAMI/ISO 14937. The subject device is a single-use device.
- The Tandry Locking Plate System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the Tandry Locking Plate System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

Summary of Substantial Equivalence:

Based on the information contained within this submission, it is concluded that the Tandry Locking Plate System is substantially equivalent to the identified predicate device.

Standards utilized for non-clinical performance testing:

- ASTM F-543-17, Standard Specification and Test Methods for Metallic Medical Bone Screws
- ANSI/AAMI/ISO 10993-1: 2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- AAMI TIR30: 2011(R2016), A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices.
- ANSI/AAMI/ISO 17665-1: 2006/(R)2013, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.
- ANSI/AAMI/ISO 14937: 2009(R)2013, Sterilization of healthcare products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.