Microware Precision Co., Ltd.
Harrison Du
General Manager
No. 12, Keyuan 2nd Rd.,
Situn District
Taichung City 407630
Taiwan

September 18, 2018

Re: K171904
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: June 19, 2017
Received: June 26, 2017

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171904

Device Name
Tandry Locking Plate System

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

In addition, Tandry Locking Hip Plate System is intended for use in 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 to be used in 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Microware

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: Sep, 18, 2018

Registration Number: 3007738812

Device Name: Tandry Locking Plate System

Common Name: Bone Plate and Bone Screw

Classification Name: Class II, 21 CFR 888.3030 and 21 CFR 888.3040

Product Code: HWC and HRS

Predicate Device Information:
Microware Bone Plates and Bone Screws & Microware DHS/DCS Plate System (K072562)
Synthes LCP Distal Femur Plates (K062564)
Synthes 4.5mm Titanium LCP Proximal Tibia Plating System (K023802)
Synthes LCP Proximal Tibia Plate (K011978)
Synthes LCP Distal Tibia Plates (K013248)
Synthes (USA) Modular Mini Fragment LCP System (K063049)
Synthes (USA) 1.5mm Mini Fragment LCP System (K090047)

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:

Microware

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

In addition, Tandry Locking Hip Plate System is intended for use in 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 to be used in 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 Tandry Locking Plate System is fabricated from stainless steel 316L per ASTM F138 and F139, titanium alloy per ASTM F136 and unalloyed titanium per ASTM F67. The design feature for the Tandry Locking Plate System are similar to the predicate devices including dimensions, shape and sizes.

Summary of Performance Data (Nonclinical and/or Clinical)

Clinical Test

Clinical studies are not required to support substantially equivalent.

Non-Clinical Test

- Biomechanical Test

  The biomechanical tests ASTM F543 and F382 were performed to determine substantial equivalence for the Tandry Locking Plate System including the performance of plate and screw. Results indicate that the subject plate and screw are substantially equivalent to legally marketed devices offering a reasonable assurance of safety and effectiveness.
- The Tandry Locking Plate System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Tandry Locking Plate System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Microware

Summary of Substantial Equivalence:

The Tandry Locking Plate System is substantially equivalent to the predicated devices. Result of non-clinical tests and the similarities with the legally marketed predicate device indicate the device will perform within the intended use and no new issues of safety or efficacy have been raised.