September 20, 2022

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

Re: K220359
Trade/Device Name: Tandry Compression Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 22, 2022
Received: August 22, 2022

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, 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)*
K220359

Device Name
Tandry Compression Screw System

Indications for Use *(Describe)*
Tandry Compression Screw System is intended for the treatment of fractures, osteotomies, and fusions of bone with the appropriate screw size.

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
K220359

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: September, 20, 2022

Registration Number: 3007738812

Trade Name: Tandry Compression Screw System

Common Name: Screw, Fixation, Bone

Classification Name: Smooth or threaded metallic bone fixation fastener

Classification: Class II

Classification Number: 21 CFR 888.3040

Product Code: HWC

Predicate Device Information:
Primary Predicate: APTUS® Cannulated Compression Screws (K133460)
Additional Predicates: Tandry Locking Plate System (K171904)

Device Description:
Tandry Compression Screw System consists of 2.8mm, 3.6mm, 4.1mm, 4.7mm, 5.5, and 7.5mm cannulated compression screw, 2.0mm compressions screw and 2.0mm compression pin. The 2.0mm compression pin features a beak-off groove between a shaft and compression screw body, the shaft can be separated from the compression screw body by bending it back and forth. The screw system has multiple lengths depending on the diameter of the screws. All screws and pins are fabricated from Ti-6Al-4V and anodized.

Indication for use:

Tandry Compression Screw System is intended for the treatment of fractures, osteotomies, and fusions of bone with the appropriate screw size.

Technological Characteristics:

The Tandry Compression Screw System is fabricated from titanium alloy per ASTM F136. The design feature for the Tandry Compression Screw System is 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

  Based on the testing results and assessment, results indicate the Tandry Compression Screw System meets the acceptance criteria defined in the FDA guidance document, Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway, to support substantial equivalence.
- Biocompatibility

  According to the evaluation of the FDA guideline "Use of International Standard ISO 10993-1, Biological evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management process", and the proposed device meets biocompatibility requirement.
- 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 as well.
- The Tandry Compression Screw 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 Compression Screw System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Summary of Substantial Equivalence:

The Tandry Compression Screw 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. Furthermore, the indications of the subject and primary predicate are equivalent.

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Standards utilized for non-clinical performance testing

- ASTM F-543-17, Standard Specification and Test Methods for Metallic Medical Bone Screws
- Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway
- ANSI/AAMI/ISO 10993-1: 2018, Biological evaluation of medical devices – Part1: 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 – Part1: 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.