11/10/22

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

Re: K220360
Trade/Device Name: Tandry CMF Plate System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZL
Dated: October 11, 2022
Received: October 12, 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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K220360

Device Name
Tandry CMF Plate System

Indications for Use *(Describe)*
The Tandry CMF System is a Maxillofacial plate and screw system intended for osteotomy, stabilization and rigid fixation of maxillofacial/midface fractures and reconstruction including infraorbital area, zygomatic area and maxillofacial, and mandibular and maxillary correction surgery.

Each plate is indicated to be used in the following anatomic regions:
• 1.2mm upper-face plates – Orbital floor region, zygomatic region, and dento-alveolar region
• 1.5mm mid-face plates – Zygomatic region, orbital floor region, and maxilla
• 2.0 mm mini plates – Orthognathics midface/mandible
• 2.0/2.3mm mandible plates – Mandibular

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.

K220360

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: Nov, 10, 2022

Registration Number: 3007738812

Device Name: Tandry CMF Plate System

Common Name: Bone Plate and Bone Screw

Classification Name: Class II, 21 CFR 872.4760

Product Code: JEY and DZL

Predicate Device Information:
Primary device: Stryker Leibinger Universal CMF System (K022185)
Reference device: MCI - CMF System (K182758)
Tandry Locking Plate System (K171904)
Synthes Midfacial System (K953806)

Device Description:
The Tandry CMF Plate System consists of various sized plates and screws. The plates and screws are fabricated from pure titanium and Ti-6Al-4V. The plates are designed to distribute for respective anatomical and indicated areas, besides, they can be used with self-tapping, self-drilling, emergency self-tapping and locking screws.

Indication for use:
The Tandry CMF System is a Maxillofacial plate and screw system intended for osteotomy, stabilization and rigid fixation of maxillofacial/midface fractures and reconstruction including infraorbital area, zygomatic area and maxillofacial, and mandibular and maxillary correction surgery.

Each plate is indicated to be used in the following anatomic regions:

- 1.2mm upper-face plates – Orbital floor region, zygomatic region, and dento-alveolar region

- 1.5mm mid-face plates – Zygomatic region, orbital floor region, and maxilla
- 2.0 mm mini plates – Orthognathics midface/mandible
- 2.0/2.3mm mandible plates – Mandibular

Technological Characteristics:

The Tandry CMF Plate System is fabricated from titanium alloy per ASTM F136 and unalloyed titanium per ASTM F67. The screws are made of titanium alloy conforming to ASTM F136 and its surfaces are colored-anodized. The plates are manufactured in commercially pure titanium conforming to ASTM F67 and its surfaces are colored-anodized and type 2-anodized. The design feature for the Tandry CMF Plate System is similar to the predicate devices including dimensions, shape and sizes as 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

  The biomechanical tests ASTM F543 and F382 were performed to determine substantial equivalence for the Tandry CMF Plate System including the performance of plate and screw.

- Biocompatibility

  Representative samples of each of the 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 material, manufacturing process, geometry & physico-chemical, body/ fluid contact and sterilization process of the proposed device is the same as 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 CMF 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 CMF Plate 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 CMF Plate System is substantially equivalent to the predicated devices. Result of non-clinical tests and the similarities with the legally marketed predicate device have demonstrated substantial equivalence.

Table 1

Item \ Device	Proposed device	Primary predicate device	Reference device 1	Reference device 2	Reference device 3	SE ?
Device Name	Tandry CMF Plate System	Stryker Leibinger Universal CMF System	MCI - CMF System	Synthes Midfacial System	Tandry Locking Plate System	NA
510K Number	K220360	K022185	K182758	K953806	K171904	NA
Trade Name	Tandry	Stryker	MCI	Synthes	Tandry	NA
Indication for Use	The Tandry CMF System is a Maxillofacial plate and screw system intended for osteotomy, stabilization and rigid fixation of maxillofacial/midface fractures and reconstruction including infraorbital area, zygomatic area and maxillofacial, and mandibular and maxillary correction surgery. Each plate is indicated to be used in the following anatomic regions: • 1.2mm upper-face plates – Orbital floor region, zygomatic region, and dento-alveolar region • 1.5mm mid-face plates – Zygomatic region,	The Stryker Leibinger Universal CMF System is a Cranio-maxillofacial (CMF) plate and screw system intended for osteotomy, stabilization and rigid fixation of CMF fractures and reconstruction.	MCI - CMF System is intended for use in selective trauma of the midface, maxillofacial surgery, reconstructive procedures, and selective orthognathic surgery of the maxilla, mandible and chin.	The Synthes Midfacial System is a plate and screw system, manufactured from commercially pure (CP) titanium, and is intended for use in selective trauma of the midface and craniofacial skeleton; craniofacial surgery; reconstructive procedures; and selective orthognathic surgery of the maxilla and chin. The plates are available in a variety of configurations to accommodate various fracture sites, and attach to bone via 1.3mm or 1.7mm self-tapping screws, with a low plate/screw profile.	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.	No substantial differences between subject and reference device. Reference device 3 is only for evaluation of biocompatibility, reprocessing and sterilization.

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	orbital floor region, and maxilla • 2.0 mm mini plates – Orthognathics midface/mandible • 2.0/2.3mm mandible plates – Mandibular					
Materials	Pure titanium: ASTM F67 Titanium Alloy: ASTM F136	Pure titanium: ASTM F67 Titanium Alloy: ASTM F136	Pure titanium: ASTM F67 Titanium Alloy: ASTM F136	Pure titanium: ASTM F67	Pure Titanium: ASTM F67 Titanium Alloy: ASTM F136 Stainless steel: ASTM F138 and F139	No substantial differences between subject and reference device.
Dimensions	Screw Diameter: 1.2 to 2.7mm Length: 3 to 20mm Plate Thickness: 0.4 to 2.8mm Holes: 4 to 39 Holes	Screw Diameter: 1.2 to 2.7mm Length: 3 to 42mm Plate Thickness: 0.1 to 2.8mm Holes: 4 to 29 Holes	Screw Diameter: 1.5 to 2.3mm Length: 4 to 20mm Plate Thickness: 0.6 to 1.0mm Holes: 4 to 20 Holes	Screw Diameter: 1.3 to 1.7mm Length: 3 to 18mm Plate Thickness: 0.2 to 0.8mm Holes: 4 to 39 Holes	Screw Diameter: 1.5 to 4.5mm Length: 6 to 160mm Plate Thickness: 1.1 to 6.25mm Holes: 2 to 22 holes	No substantial differences between subject and reference device.
Surface	Colored-anodized and type2-anodized	Colored-anodized	Colored-anodized	Colored-anodized	Colored-anodized for titanium Electrolytic polishing for Stainless steel	No substantial differences between subject and reference device.
Sterilization	Non-sterilize. Steam sterilization before use.	Non-sterilize. Steam sterilization before use.	Non-sterilize. Steam sterilization before use.	Non-sterilize. Steam sterilization before use.	Non-sterilize. Steam sterilization before use.	No substantial differences between subject and reference device.