November 14, 2024

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

Re: K242814
Trade/Device Name: Tandry Q-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
Dated: September 13, 2024
Received: September 18, 2024

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Thomas Mcnamara -S

For: Christopher Ferreira, MS
Assistant Director
DHT6C: Bone-Soft Tissue Interface and Fracture Fixation 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242814

Device Name

Tandry Q-Locking Plate System

Indications for Use *(Describe)*

The Tandry Q-Locking Plate System is intended to provide fixation during fractures, fusions, and osteotomies. The Tandry Q-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.

Each plate is indicated for the following anatomic regions:
- 1.5mm and 2.0mm Q-locking plates: Metacarpals, metatarsals, tarsals, and phalanges
- 2.4mm Q-locking plates: Radius, wrist, and ulna
- 3.5 mm Q-locking plates: Clavicle, scapula, humerus, olecranon, pelvis, fibula, calcaneus, and tibia
- 5.0 mm Q-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) #: K242814

510(k) Summary

Prepared on: 2024-11-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Microware Precision Co., Ltd.
Applicant Address	No. 12, Keyuan 2nd Rd., Situn District, Taichung City 40763 Taiwan
Applicant Contact Telephone	886424636275
Applicant Contact	Mr. Harrison Du
Applicant Contact Email	harrisondu@microware.com.tw

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Tandry Q-Locking Plate System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K230690	Tandry Locking Plate System	HRS
K171904	Tandry Locking Plate System	HRS
K141527	DEPUY SYNTHES VARIABLE ANGLE LOCKING HAND SYSTE	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The Tandry Q-Locking Plate System consists of various sized plates, screws and instruments. The plates are designed to distribute for local anatomies and can accept, cortex, shaft and cancellous, locking, Q-Locking (variable angle) screws. The screws are designed with self-tapping to promote the operation efficiency to insert the bones. Both plate and screw feature variable angle locking design.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Tandry Q-Locking Plate System is intended to provide fixation during fractures, fusions, and osteotomies. The Tandry Q-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.

Each plate is indicated for the following anatomic regions:
- 1.5mm and 2.0mm Q-locking plates: Metacarpals, metatarsals, tarsals, and phalanges
- 2.4mm Q-locking plates: Radius, wrist, and ulna
- 3.5 mm Q-locking plates: Clavicle, scapula, humerus, olecranon, pelvis, fibula, calcaneus, and tibia
- 5.0 mm Q-locking plates: Femur and tibia

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the Tandry Q-Locking Plate System is the same as the primary predicate device and identical to the relevant sections of the additional predicate indications.

Technological Comparison 21 CFR 807.92(a)(6)

The Tandry Q-Locking Plate System shares the same fundamental technological characteristic as the predicate devices (K230690, K171904, and K 141527) including materials, shapes, operation, and package. The only difference is that the screw holes of the Tandry Q-locking plate feature variable angle function.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The biomechanical tests were practiced according to ASTM F543-17 for the screw and F382-17 for the plate. This test method is intended to compare the strengths of different products. The Tandry Locking Plate system is chosen to be predicate device to compare with Tandry Q-Locking Plate System.

Mechanical performance testing of constructs has been performed to compare the subject Tandry Q-Locking Plate System to the predicate Tandry Locking Plate System. This data supports that the mechanical performance of the subject devices is substantially equivalent to that of the predicate devices.