3. Special 510(k) Summary of Safety and Effectiveness

Submitter's Name: Microware Precision Co., Ltd.

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Phone No: +886-4-24636275

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Contact Person: Harrison Du

Preparation date: October/02/2011

Registration Number: 3007738812

Device Name: Microware Bone Plates and Bone Screws

Proprietary Name: Microware Bone Plates and Bone Screws

Classification Name: Class II

CFR 888.3040: screw, fixation, bone- HWC

CFR 888.3030: washer, bolt, non-spinal, metallic- NDG

CFR 888.3030: plate, fixation, bone-HRS

CFR 888.3030: appliance, fixation, nail/blade/plate combination, multiple component-KTT

Predicate Device Information:

Microware Bone Plates and Bone Screws (K072562)

Kens Internal Fixation System (K090786)

Synthes 2.4mm Cannulated Screw (K012945)

Synthes Metallic Spiked Washers (K013806)

Synthes Spherical Washers (K052483)

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Materials:

The added devices are manufactured from stainless steel and titanium alloy that are the same as Microware Bone Plates and Bone Screw (K072562).

Indication for use:

Microware Bone Plates and Bone Screws are provided non-sterile. Microware Bone Plates and Bone Screws are intended to treat fractures of various bones, including the clavicle, pelvis, scapula, long bone (humerus, ulna, radius, femur, tibia and fibula), and small bone (metacarpals, metatarsals and phalanges).

Microware Bone Plates and Bone Screws Accessories:

1. The round washer is used to increase bone contact area for distributing the forces/load and prevent the screw head from sinking into the bone.
2. The spherical washer is used to increase bone contact area for distributing the forces/load, and prevent the screw head from sinking into the bone. In addition, it can be applicable on the insertion at acute angles.
3. The spiked washer is used for ligament reattachment or fixation.
4. The support screw is anchored in cancellous bone by its thread. It supports the countersink head of a cannulated screw in cancellous bone.

Device Description:

The added devices do not change the original intended use, material, label, and package. The added devices with changes are described as follows:

1. Added cortex, cancellous, and shaft screws are designed with self-tapping flutes and are easier to insert into the bone than non-self-tapping screws.
2. Added cortex screws 1.5 and 2.0mm are designed with a cruciform recess and can be applied with a cruciform tool.
3. Added screws of all sizes are designed with a hexalobular socket and they can improve torque transmission to facilitate easy insertion and removal.
4. Added cannulaed screws extend diameter specification with 6.5, 4.5, 4.0, 3.0 and 2.4mm.
5. Added implants include the round washer, spherical washer, spiked washer, and support screw which can be used with or without other implants.
6. Added screws extend length specifications.

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In addition, a new set of recommended sterilization parameters are added to the "Instruction for use".

Substantial Equivalence:

Performance testing included axial pullout, self-tapping performance, driving torque, torsional properties and the results demonstrated substantial equivalence to the predicate devices.

A comparison has shown that the proposed device is very similar or identical in terms of indication for use, material, followed performance and standard, and sterilization to the predicate devices, and no significant difference between the proposed and predicate devices has been found. Thus, the "Microware Bone Plates and Bone Screws" is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Microware Precision Co., Ltd.
% Mr. Harrison Du
No. 12, Keyuan 2nd Road
Situn District
Taichung City, Taiwan 40763

MAY - 2 2012

Re: K111008
Trade/Device Name: Microware Bone Plates and Bone Screws
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, KTT, NDG
Dated: April 02, 2012
Received: April 2, 2012

Dear Mr. 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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. Indications for Use

510(k) Number (if known): K111008

Device Name: Microware Bone Plates and Bone Screws

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Prescription Use X **AND/OR** **Over-The-Counter Use** ____

(Part 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices