3. 510(k) Summary of Safety and Effectiveness

DEC 0 4 2008

Submitter's Name: Microware Precision Co., Ltd.
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Contact Person: Harrison Du

Preparation date: April 7, 2008

Registration Number:

Device Name: Microware Bone Plates and Bone Screws & Microware DHS/DCS Plate System

Proprietary Name: Microware Bone Plates and Bone Screws & Microware DHS/DCS Plate System

Common Name: Bone Fixation Plate and Screw

Classification Name: Class II: Plate, Fixation, Bone
HRS-CFR 888.3030
Class II: Screw, Fixation, Bone
HWC-CFR 888.3040
Class II: Appliance, fixation, nail/blade/plate Combination, multiple component
KTT-CFR 888.3030

Product Code: HRS, HWC, KTT

Panel Code: Orthopedic/87

Predicate Device Information:

Syntec-Taichung Non-sterile Bone Plate and Screw Implants (K983495)

Syntec-Taichung Non-sterile DHS/DCS Plate System (K983873)

INTAI Bone Plate and Bone Screw System & INTAI DHS/DCS Plate System (K063020)

Materials:

The non-sterile bone plates and screws are manufactured from commercial medical use 316L stainless steel that meet ASTM F138 and ASTM F139, and titanium alloy (Ti-6Al-4V) that meet ASTM F136.

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 DHS/DCS Plate System is provided non-sterile. Microware DHS/DCS Plate System is intended for use in fixation of fractures to the proximal femur. The system is indicated for use in trochanteric, pertrochanteric, intertrochanteric, and basilar neck fracture.

Device Description:

The Bone Plates and Bone Screws system & DHS/DCS Plate System consist of non-sterile bone plate and bone screw implants. The plates are devices, which are fastened to bone for purpose of providing fixation. They are principally differentiated by their function. Thus there are five kinds of styles: dynamic compression plate (DCP), tubular, special, mini and dynamic hip screw/dynamic condylar screw (DHS/DCS). The shape of the plate is an adaptation of the plate to the local anatomy and doesn't denote any function. Thus the name depends on the biomechanical function the plate is performing. Every plate is divided various types as following:

Plate Name	Geometry Shape
DCP	Narrow, lengthening-narrow, broad, lengthening-broad, straight
Tubular	Semi-tubular, one-third, and quarter

Special	L-shaped, T-shaped, spoon, cobra, lateral tibia head, condylar buttress, head, and hook
Mini	Straight, L-shaped, T-shaped, condylar, special, and reconstruction
DHS/DCS	Dynamic Hip Screw, Dynamic Condylar Screw

The series in size of Microware bone screws and bone plates except DHS/DCS are divided into mini, small and large. The range of plates in thickness are from 1.0 to 6.0 mm, width from 3.8 to 17 mm, length from 17 to 359 mm, and hole number from 2 to 22 holes.

On the other hand, the screws used either to fasten plates or similar devices onto bone, or, as lag screws, to hold together fragments of bone. The screws are differentiated by the manner in which they are inserted into bone, their function, their size, and the type of bone they are intended for. Thus there are four kinds of style: cortex, cancellous, malleolar, and cannulated. All screws have a hexagonal recess; this feature has proven itself to be of great advantage at the time of the screw removal and insertion. The range of screws in thread is diameter from 1.5 to 7.3 mm, total length from 6 to 150 mm.

The DHS/DCS Plate System consists of DHS/DCS plate, DHS/DCS Screw, DHS/DCS Compression Screw, and 4.5mm Cortex Screw (self-tapping). The DHS Plates are available with short and standard barrel which length is 25mm and 38mm respectively. And the barrel angles are available in 95°, 135°, 140°, 145°, and 150°. The self-tapping 4.5mm Cortex Screw can be used to fix the DHS/DCS Plate to the femoral shaft.

The DHS/DCS Screw is available in total length from 50 to 145mm, thread length 22mm, shaft diameter 7.9mm, and outer diameter 12.5 to 14mm. The thread of DHS/DCS screw has a buttress type.

The DHS/DCS Compression Screw can be used to achieve fracture compression. Its dimension is available with thread length 26mm and outer diameter 4.0mm.

Substantial Equivalence:

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

Microware DHS/DCS Plate System" is substantially equivalent to Syntec-Taichung Non-sterile Bone Plate and Screw implants (K983495), Syntec-Taichung Non-sterile DHS/DCS Plate System (K983873), and INTAI Bone Plate and Bone Screw System & INTAI DHS/DCS Plate System (K063020).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

DEC 0 4 2008

Re: K072562
Trade/Device Name: Microware Bone Plates and Bone Screws & Microware DHS/DCS 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, KTT
Dated: October 22, 2008
Received: November 3, 2008

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

2. Indications for Use

510(k) Number (if known): K072562

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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 General, Restorative and Neurological Devices

510(k) Number

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K072562