NOV 2 3 2010

Exhibit #2 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) Number: K100721

1. **Date of Prepared:12Nov 2010**

2. **Proposed Device Identification**
   Trade/ Proprietary Name: Locking Bone Screw
   Common Name: Smooth or threaded metallic bone fixation fastener
   Classification Name: Screw, fixation, bone
   Device Class:II
   Product Code:HWC
   Regulation Number: 21 CFR 888.3040
   Intended Use:
   Locking Bone Screw isindicated for bone reconstruction, osteotomy, arthrodesis, joint fusion,fracture repair, and fracture fixation of bones appropriate for the size of the device.

3. **Sponsor Information**
   Establishment Registration Number: 3005597716
   Changzhou Orthmed Medical Instrument Co.,Ltd
   No.177, Qinling Road, New Zone,
   Changzhou, Jiangsu, China, 213022
   Phone: +86-519-85123770-8055
   Fax:+86-519-85123776

   Submission Correspondent
   Ms. Diana Hong, Mr. Lee Fu
   Shanghai Mid-Link Business Consulting Co., Ltd
   Suite 5D, No.19, Lane 999, Zhongshan No.2 Road(S)
   Shanghai, 20030, China
   Tel: +86-21-64264467
   Fax: 240-238-7587
   Email: Diana.hong@mid-link.net

4. Predicate Device Identification

Merete 3.5mm Locking Screws as cleared under K081513.

5. Device Description

The proposed device, Locking Bone Screw, is made of Titanium Alloy (6Al-4V ELI) that meetsASTM F136 - 08e1 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) which is intended to be used with Orthmed Locking Compressing Bone Plate for bone reconstruction,osteotomy, arthrodesis, joint fusion,fracture repair, and fracture fixation of bones appropriate for the size of the device.

Table 1 Specifications

Model Name	HCQ04 (Normal Head)	HC5Q04 (Normal Head/ Flat Head)	HCQ04 (Normal Head)	HCZ04 (Tapered Head)
Diameter (mm)	3.5	5.0	6.5	5.0
Length(mm)	10~65 every 1mm	10~120 every 1mm	20~120 every 1mm	18~85 every 1mm

6. Substantially Equivalence

Both the proposed and predicate device has same classification, similar intended use. Both of them were made of Titanium Alloy (6Al-4V ELI) that meets ASTM F136 - 08e1. The performance test was performed on both, the result demonstrated that they have similar performance. Therefore, the proposed device, Locking Bone Screw, is determined to be Substantially Equivalent (SE) to the predicate device, Merete 3.5mm Locking Screws as cleared under K081513.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The tests were performed per the following standards: ASTM F543-07, Standard Specification and Test Methods for Metallic Medical BoneScrews.

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

Changzhou Orthmed Medical Instrument Co., Ltd.
% Shanghai Midlink Business Consulting Co., Ltd.
Ms. Diane Hong
Suite 5D, No. 19, Lane 999
Zhongshan No.2 Road (S)
Shanghai, China 20030

NOV 2 3 2010

Re: K100721
Trade/Device Name: Locking Bone Screw Model HCQ04, HCZ04
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 12, 2010
Received: November 15, 2010

Dear Ms. Hong:

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,

Barbara Buchman for

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

Enclosure

Indication for Use

510(k) Number: K100721

NOV 2 3 2010

Device Name: Locking Bone Screw

Indications for Use:

Locking Bone Screw is indicated for bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for nsm

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

510(k) Number K100721