

APR 13 2011

Chapter 1 510(k) Summary

510(K) SUMMARY

This summary regarding 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21CFR 807.92.

Sponsor : ORTHOPAEDIC DEVICE RESEARCH CENTER

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Contact Person: Cheng-Kung Cheng
Direct, Orthopaedic Device Research Center

Device Name: ODRC-Dynamic Hip Screw System

Classification:

- 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

Predicate Devices : SYNTHES DHS System (K981757)

Material :

The ODRC-Dynamic Hip Screw System components are manufactured from medical grade 316L stainless steel that meets ASTM F138 & ASTM F139/ISO 5832-1.

Device Description :

The ODRC-Dynamic Hip Screw System consists of non-sterile ODRC-DHS Plate, ODRC-DHS Screw, ODRC-DHS Blades, compression screw, and 4.5 mm cortex screw. The ODRC-DHS Plate is a straight with an angled barrel portion that accepts ODRC-DHS Screw and ODRC-DHS Blades. The barrel angle is 135° and length of 36 mm. The plates are available in multiple lengths (lengths ranging from 46 mm to 206 mm) to accommodate differing patient anatomy. The plate accepts DHS Helix Screw (lengths ranging from 75 mm to 130 mm) and 4.5 mm cortex screws.

Indication for Use :

The ODRC-Dynamic Hip Screw System is provided non-sterile. The device may be used for fixation of fractures of the proximal femur, such as femoral neck, trochanteric, pertrochanteric, or Intertrochanteric zones.

Performance Data :

Mechanical testing (static and dynamic four point bending test (ASTM F382), and static and dynamic axial compression bending test (ASTM F384)) was conducted to demonstrate substantial equivalence to the predicate system. The results demonstrate that the ODRC-Dynamic Hip Screw System performs as well as or better than the predicate device.

Basis of Substantial Equivalence :

The ODRC-Dynamic Hip Screw System has been demonstrated to be substantially equivalent to predicate system with respect to technical characteristics, performance, and intended use. The information provided within this premarket notification supports substantial equivalence of the subject device to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Orthopaedic Device Research Center
% Cheng-Kung Cheng
No. 155, Sec 2, Li-Nung Street
Taipei
China (Taiwan) 112

APR 13 2011

Re: K103015

Trade/Device Name: ODRC – Dynamic Hip Screw System
Regulation Number: 888.3040
Regulation Name:
Regulatory Class: Class II
Product Code: KTT, HRS, HWC
Dated: March 31, 2011
Received: April 8, 2011

Dear Mr.Cheng:

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

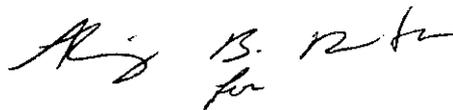
Page 2 – Mr. Cheng – Kung Cheng

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" (21 CFR 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,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson" with a stylized flourish at the end.

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

Indications for Use

510(k) Number (K103015):

Device Name: ODRC-DHS System

Indications for Use:

The ODRC-DHS 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 fractures.

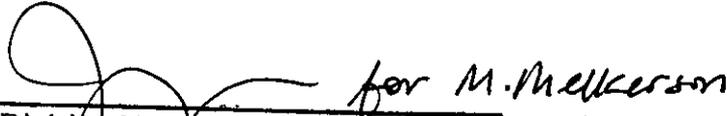
Prescription Use x AND/OR Over-The-Counter Use

(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

510(k) Number K103015