DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 3, 2015

Canwell Medical Company, Ltd
% Mr. Mike Gu
Osmunda Medical Device Consulting Company, Ltd.
7th Floor Jingui Business Building
982 Cogyuan Road, Baiyun District
510420 Guangzhou
China

Re: K142943
Trade/Device Name: Metallic Locking Bone Plate and Screw
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
Dated: July 3, 2015
Received: July 6, 2015

Dear Mr. Gu,

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K142943

Device Name
Metallic Locking Bone Plate and Screw

Indications for Use *(Describe)*

The metallic locking bone plate and screw are intended for adult patients with age above 21 as indicated fixation of fractures, including ulna, radius, humerus, femur, tibia, clavicle, and fibula for the following indications:
- ostcotomies, mal-unions, and non-unions;
- single, segmental, and comminuted fractures;
- normal bone density and osteopenic bone.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

Canwell Medical Co., Ltd.

No. 466 South Xianhua Street, High-tech Industrail Zone, Jinhua, Zhejiang, 321016 P. R. of China

Primary Contact Person:	Mike Gu
	Regulatory Affairs Manager
	OSMUNDA Medical Device Consulting Co., Ltd
	Tel: (+86) 20-6232 1333
	Fax: (+86) 20-8633 0253
Secondary Contact Person:	Chen Hui
	Regulatory Affairs Manager
	Canwell Medical Co., Ltd.
	Tel: +86-(0)579-8911-9235
	Fax: +86-(0)579-8223-9558

Date Prepared: September 30, 2014

II. DEVICE

Name of Device:	Metallic Locking Bone Plate and Screw
Common/Usual Name:	Bone Fixation Plate and Bone Fixation Screw
Classification Names:	Plate, Fixation, Bone (21 CFR 888.3030)
	Screw, Fixation, Bone (21 CFR 888.3040)
Regulation Class:	II
Product Code:	HRS and HWC

III. PREDICATE DEVICE

Locking Bone Plates and Screws' predicate devices: K073159, K073432, K130108 and K130009;

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The proposed device, metallic Locking Bone Plate and Screw consists of bone plate and screw. The bone plates are used for internal fixation of bone fracture, including ulna, radius, humerus, femur and tibia. Implant is manufactured with Ti6Al4V Eli and titanium which conforms to ASTM F 136 and ASTM F67.

The proposed devices are provided un-sterilized. They shall be sterilized prior to use by healthcare provider. The proposed devices shall never be reused.

V. INDICATIONS FOR USE

The metallic locking bone plate and screw are intended for adult patients with age above 21 as indicated fixation of fractures, including ulna, radius, humerus, femur, tibia, clavicle, and fibula for the following indications:

- osteotomies, mal-unions, and non-unions
- single, segmental, and comminuted fractures
- normal bone density and osteopenic bone

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Metallic Locking Bone Plate and screw employ the same plate and screw technology as its predicate devices K073159, K073432, K130108 and K130009.

Metallic Locking Bone Plate and Screw is a structure formed by locking plate (which has at least one taper-thread hole) and locking screw (which has a head of taper-thread). Wherein the metal locking plate is a fracture fixation device with threaded holes, When the screw is revolved tightened in the plate, the plate system becomes an angle-fixed device. Locking plate can have both locking and non-locking screw holes fitting with various types of screws (also known as locking compression plate). In practice, positioning a plurality of screws in the locking plate maintains fracture anatomical reduction, which restores physiological function after bone healing.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- ASTM F382 - 99(2008) Standard Specification and Test Method for Metallic Bone Plates , bend testing;
- ASTM F543 – 13 Standard Specification and Test Methods for Metallic Medical Bone Screws metallic Bone Plates.

Biocompatibility testing:

Metallic Locking Bone Plate and Screw is made of pure titanium and Ti-6Al-4V, complying with the ASTM F1472 and ASTM F67; the materials have been employed successfully in human implant applications in contact with soft tissue and bone for over a decade. Due to the well-characterized level of biological response exhibited by this alloy, it has been used as a control material in Practice F 981

There is no Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices

Animal and clinical study

The subject of this premarket submission, metallic Locking Bone Plate and Screw, does not require clinical studies to support substantial equivalence.

VIII. CONCLUSIONS

The non-clinical data support the safety of the device and the performance testing report demonstrate that the metallic Locking Bone Plate and Screw should perform as intended in the specified use conditions. Canwell Medical Co., Ltd. considers the metallic locking bone plate and screw do not raise any new issues of safety or effectiveness.