February 3, 2020

Jiangsu Trauhui Medical Instrument Co., Ltd.
% Mike Gu
Regulatory Affairs Manager
Guangzhou Osmunda Medical Device Consulting Co., Ltd
8-9th Floor, R&D Building, No.26 Qinglan Street
Panyu District
Guangzhou, Guangdong 510006
China

Re: K190842
Trade/Device Name: Comus Locking Plate systems
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: March 28, 2019
Received: April 1, 2019

Dear Mike 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190842

Device Name
Comus Locking Plate systems

Indications for Use *(Describe)*
Comus Locking Plate systems can be used for adult patients with age above 21 as indicated for fixation of Bone fracture in ulna, radius, humerus, femur and tibia.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) Summary

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

1. SUBMITTER

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Secondary Person:	Contact	ZhouYu Quality Manager Jiangsu Trauhui Medical Instrument Co., Ltd Tel: (+86) 519-88769966 Fax: (+86) 519-88738899
Date prepared		Feb 03, 2020

2. DEVICE

Device Name:	Comus Locking Plate systems
Common/Usual Name:	Comus Locking Plate systems
Regulation number	21 CFR 888.3030 and 888.3040
Regulation Name	Single/multiple component metallic bone fixation appliances and accessories
Regulation Class:	II
Product Code:	HRS, HWC
Classification Name	Single/multiple component metallic bone fixation appliances and accessories

3. PREDICATE DEVICES

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Primary predicate device: K143002, Changzhou Dingjian Medical Appliance Company, Ltd

Reference device: K142943, Canwell Medical Co., Ltd.

These predicates have not been subject to a design-related recall.

4. DEVICE DESCRIPTION

The proposed device Comus Locking Plate systems are a combination of plates and screws, which can be used for adult patients with age above 21 as indicated for fixation of fractures.

The plate is made of Titanium, which meet ASTM F67, and the screw is made of titanium alloy (Ti-6A-l4V ELI) which conforms to ASTM F136, which both are widely used for surgical implants with well-known biocompatibility and mechanical properties.

5. INDICATIONS FOR USE

Comus Locking Plate systems can be used for adult patients with age above 21 as indicated for fixation of Bone fracture in ulna, radius, humerus, femur and tibia.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comus Locking Plate systems are substantially equivalent to the cleared predicate device (K143002) and the reference device (K142943).

Comus Locking Plate systems have same indications for use, patient population, material and sterilization with the predicates.

In design specification aspect, the plate of the subject device and the predicates all have the same clinical using bone position: cortical bone and cancellous bone, and they have the same plate geometric shape. The subject plate has a similar but a smaller size dimension range than the predicates. In addition, the subject plates have the similar number of holes in the plate design.

The screw of the subject device has the same design structure with the predicates, and has a similar dimension range than the predicates.

The subject device has a similar mechanical performance with the predicates. Section 7 shows that the testing comparison results of the subject and predicate device is comparable.

7. NON-CLINICAL DATA

The following non-clinical data were provided in support of the substantial equivalence determination.

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Performance testing

Comparative performance tests were conducted between Comus Locking Plate systems and the predicate device, according to ASTM F382-14 and ASTM F543-17. The specific conducted tests are listed below.

- Static four-point bending test of the plate
- Dynamic four-point bending test of the plate
- Torsional properties of the screw
- Driving torque of the screw
- Pull-out test of the screw

The test result shows that the subject device is substantial equivalent with the predicate device.

Biocompatibility

The plate is made of Titanium, which meet ASTM F67, and the screw is made of titanium alloy (Ti-6A-l4V ELI) which conforms to ASTM F136, which both are widely used for surgical implants with well-known good biocompatibility. After conducting risk analysis and validation, the production process does not affect the raw material's biological performance.

Animal Study

The subject of this premarket submission, Comus Locking Plate systems do not require animal studies to support substantial equivalence.

8. CLINICAL DATA

The subject of this premarket submission, Comus Locking Plate systems did not require clinical studies to support substantial equivalence.

9. CONCLUSION

The non-clinical data support the safety of the device and the performance testing report demonstrate that the Comus Locking Plate system should perform as intended in the specified use conditions.

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From the comparison analysis and the results of comparative performance testing described, Jiangsu Trauhui Medical Instrument Co., Ltd concludes that the Comus Locking Plate systems are substantial equivalent to the predicate devices.