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

October 23, 2017

Tianjin ZhengTian Medical Instrument Co., Ltd
Wang Qi
Regulatory Affairs Specialist
No.318, Jingyi Road, Airport Economic Zone
Tianjin, CN 100082
P.R. China

Re: K170056
Trade/Device Name: IRENE Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 26, 2017
Received: 09/26/2017

Dear Wang Qi:

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" (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 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,

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 below.

510(k) Number *(if known)*

K170056

Device Name
IRENE Cannulated Screw System

Indications for Use *(Describe)*

IRENE Cannulated Screw System is intended for fracture fixation, fusion and osteotomies of bones appropriate for the size of the device. For specific screw indications please see below.

Acutec Headless Compression Screw:

Used for fusion, fractures, or osteotomies of the clavicle, humerus, radius, ulna, ilium, femur, patella, fibula, tibia, talus, malleolus, calcaneus and other small bones.

Cannulated Screw:

Intended for bone fracture fixation and bone fragment fixation. Washers may be used with the Cannulated Screw in cases where the patient has poor bone quality.

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.

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 and the Safe Medical Devices Act of 1990, the following information is provided for IRENE Cannulated Screw System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, "Format for Traditional and Abbreviated 510(k)", issued on August 12, 2005.

1. 510(k) Submitter and Owner

Tianjin ZhengTian Medical Instrument Co., Ltd
Address: No.318, Jingyi Road, Airport Economic Zone, Tianjin, P.R. China
Official Correspondent: Xiang, Zhaojun
Position: Regulatory Affairs Manager
Tel: +86 10 82292929
Fax: +86 10 82290740
E-mail: xiangzhaojun@naton.cn
Date of preparation of the Summary: Oct 17, 2017

2. Submission Contact

Wang, Qi
Position: Regulatory Affairs Specialist
Tel: +86 10 82292929
E-mail: wangqi@naton.cn

3. Proposed Device

Trade Name: IRENE Cannulated Screw System
Common Name: Screw, Fixation, Bone
Class: Class 2
Regulation: 21 CFR 888.3040
Product Code: HWC (Bone Fixation Screw)
Review Panel: Orthopedic

Device description:

IRENE Cannulated Screw System includes two kinds of screws, Acutec Headless Compression Screw and Cannulated Screw. Acutec Headless Compression Screw has six different diameters in various lengths and is

manufactured from Titanium Alloy (ASTM F 136 and ISO 5832-3). Cannulated Screw has four different diameters in various lengths and contains two optional washers. Cannulated Screw and washers are manufactured from Titanium Alloy (ISO 5832-3).

Indication for use:

IRENE Cannulated Screw System is intended for fracture fixation, fusion and osteotomies of bones appropriate for the size of the device. For specific screw indications please see below.

Acutec Headless Compression Screw:

Used for fusion, fractures, or osteotomies of the clavicle, humerus, radius, ulna, ilium, femur, patella, fibula, tibia, talus, malleolus, calcaneus and other small bones.

Cannulated Screw:

Intended for bone fracture fixation and bone fragment fixation. Washers may be used with the Cannulated Screw in cases where the patient has poor bone quality.

4. Predicate Device and Reference Device

	Predicate Device 1	Predicate Device 2	Reference Device
510(k) Number	k063298	k100359	k151508
Predicate Device Name	OsteoMed Headless Cannulated Screw System	DARCO® Headed Cannulated Screws	IRENE Locking Compression Plate System
Manufacture	OsteoMed	Wright	Zhengtian
Classification	888.3040(HWC)	888.3040(HWC)	888.3040(HWC) 888.3030(HRS)

5. Preclinical Data

Mechanical testing is conducted to demonstrate that differences in technological characteristics of the proposed device to predicate device do not raise new questions regarding safety and effectiveness, and Substantially Equivalent to the predicate device is thus concluded. The testing including torsional properties, driving torque test and axial pullout test incorporates the following standard as test method to evaluate the performance of both proposed and predicate device: ASTM F543-13, Standard

Specification and Test Methods for Metallic Medical Bone Screws.

6. Clinical Data

No clinical data is presented in this submission.

7. Substantial Equivalence Comparison

Table 1: comparison between Acutec Headless Compression Screw and predicate devices 1

Element	Proposed Device Acutec Headless Compression Screw	Predicate Device 1 OsteoMed Headless Cannulated Screw System
Class	2	2
Regulation number	21 CFR 888.3040	21 CFR 888.3040
Indication for use	Used for fusion, fractures, or osteotomies of the clavicle, humerus, radius, ulna, ilium, femur, patella, fibula, tibia, talus, malleolus, calcaneus and other small bones.	The OsteoMed Headless Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bone appropriate for the size of the device. Screws are intended for single use only.
Material	Ti6Al4V	Ti6Al4V
Design	Fully threaded, headless, cannulated	Headless, cannulated
Diameter	2.5~7.5mm	2.0~6.5mm
Length	8~120mm	10~120mm
Supplied	Non-sterile	Non-sterile
Single-use only	Yes	Yes
Sterilization	Steam sterilization	Steam sterilization

Table 2: comparison between Cannulated Screw and predicate devices 2

Element	Proposed Device Cannulated Screw	Predicate Device 2 Wright DARCO® Headed Cannulated Screws
Class	2	2
Regulation number	21 CFR 888.3040	21 CFR 888.3040

Indication for use	Intended for bone fracture fixation and bone fragment fixation. Washers may be used with the Cannulated Screw in cases where the patient has poor bone quality.	Intended for use over a guide pin or wire for bone fracture fixation and bone fragment fixation. Washers may be used with the screws in cases where the patients has poor bone quality.
Material	Ti6Al4V	Ti6Al4V
Design	self-tapping, cannulated	self-tapping/self-drilling, cannulated
Diameter	3.5~7.3mm	2.7~7.5mm
Length	20~110mm	8~120mm
Supplied	Non-sterile	Non-sterile
Single-use only	Yes	Yes
Sterilization	Steam sterilization	Steam sterilization

8. Substantial Equivalence Conclusion

The proposed device is found to possess similar technological characteristics on design under the premises of sharing same intended use. Device performance is compared through the testing of mechanical properties of the proposed and predicate device by methods stipulated in published standards in order to evaluate whether differences existing in the design raise safety issue by compromising performance. Results of testing indicates no difference between the level of performance of proposed device and the predicate device, through which the differences are deemed not relevant to device performance and has been justified, and the conclusion of Substantial Equivalence is reached.