April 14, 2020

Tinavi (Anhui) Medical Technologies Co., Ltd.
Jianhua Jiang
Quality Manager
Building 5,Robot Industrial Base of TusCity,
Jinxiu Avenue/Susong Road,
Hefei, 230601 Cn

Re: K191803
Trade/Device Name: Orthopedic Fixation Pin
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JDW
Dated: January 13, 2020
Received: January 13, 2020

Dear Jianhua Jiang:

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,

Colin O'Neill, M.B.E.
Acting Assistant Director
DHT6B: Division of Spinal 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)*
K191803

Device Name
Orthopedic Fixation Pin

Indications for Use *(Describe)*
Orthopedic Fixation Pin is indicated for fixation of bone fractures, bone reconstruction, and as guide pins for insertion of other implants.

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

I. SUBMITTER:

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Summary prepared：06/20/2019

II. DEVICE

Name of Device: Orthopedic Fixation Pin
Regulation Number: 21 CFR part 888.3040
Common Name: Smooth or threaded metallic bone fixation fastener
Classification Panel: Orthopedic
Regulatory Class: II
Product Code: JDW

III. PREDICATE DEVICE

Primary predicate device: In2Bones® Kirschner wire (K153204)

IV. DEVICE DESCRIPTION

The Orthopedic Fixation Pin is straight, partially threaded; and has trocar point on one end. The device is available in various diameters and lengths to accommodate the specific indication. The pins are made from stainless steel in accordance with ASTM F138-13.

V. INDICATIONS FOR USE

The Orthopedic Fixation Pin is indicated for fixation of bone fractures, bone reconstruction, and as guide pins for insertion of other implants.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Orthopedic Fixation Pin and the In2Bones® Kirschner wire are to be used as fixation implants for bone fractures, joint fusion, bone reconstruction, or as guide pins for insertion of other implantable devices. Additionally, the Orthopedic Fixation Pin is similar to the In2Bones® Kirschner in regard to insertion, design, size ranges, and material.

Item	**Proposed Device Orthopedic Fixation Pin**	**Predicate Device In2Bones® Kirschner wire**
K number	TBD	K153204
Classification	Class II	Class II
Product Code	JDW	HTY, JDW
Common name	Pin, Fixation, Threaded	Pin, Fixation, Smooth Pin, Fixation, Threaded
Intended use	The Orthopedic Fixation Pins are intended to be used as fixation implants for bone fractures, joint fusion, bone reconstruction, or as guide pins for insertion of other implantable devices	The In2Bones® Kirschner wires are intended to be used as fixation implants for bone fractures, joint fusion, bone reconstruction, or as guide pins for insertion of other implantable devices
Indications for use	The Orthopedic Fixation Pins are indicated for fixation of bone fractures, bone reconstruction, and as guide pins for insertion of other implants. The size of the Orthopedic Fixation Pins chosen should be adapted to the specific indication.	The In2Bones® Kirschner wires are indicated for fixation of bone fractures, bone reconstruction, and as guide pins for insertion of other implants. The size of the In2Bones® Kirschner wire chosen should be adapted to the specific indication.
Duration of Use	Longer than 30 days	Longer than 30 days

Place of use	The Orthopedic Fixation Pins are indicated for use in a hospital, or outpatient surgery center, where sterile field may be created and maintained.	The In2Bones® Kirschner wires are indicated for use in a hospital, or outpatient surgery center, where sterile field may be created and maintained.
Sizes	The Orthopedic Fixation Pins are available in various diameters (1.1 mm to 2.5mm) and lengths (70mm to 300mm).	The In2Bones® Kirschner wire is available in various diameters (0.8mm to 2.5mm) and lengths (70mm to 300mm).
Material	The Orthopedic Fixation Pins are manufactured from stainless steel (00Cr18Ni14Mo3) in accordance with ASTM F138-13. It does not have any coating.	The In2Bones® Kirschner wire is manufactured from stainless steel 316LVM, according to ISO 5832-1 and ASTM F138-13. It does not have any coating.
Design	Orthopedic Fixation Pin is a stainless steel pin. The Orthopedic Fixation Pin is straight, partially threaded; and has trocar point on one end. The pins are available in various diameters and lengths.	The In2Bones® Kirschner wire is a metallic wire available in four point styles: sharp, partially threaded, lanceolate, both ends sharp. One part is fixed on standard surgical power tool equipment for insertion.
Single Use	Single use	Single use
Biocompatibility	Biocompatible	Biocompatible
Sterilization	The Orthopedic Fixation Pins are supplied non-sterile. The non-sterile Orthopedic Fixation Pins must be steam sterilized before use.	The In2Bones® Kirschner wire is supplied sterile and non-sterile. The sterile In2Bones® Kirschner wire is sterilized using gamma radiation. The non-sterile In2Bones® Kirschner wire must be steam sterilized before use.

VII. PERFORMANCE DATA

Non-Clinical Performance Data

To verify that the Orthopedic Fixation Pin is substantially equivalent to the predicate device, representative samples of Orthopedic Fixation Pin were underwent a series of tests including bench testing (static pullout per ASTM F543, static torsion test per ASTM F1541, tensile testing), and biocompatibility testing (cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity, subchronic systemic toxicity pyrogenicity, genotoxicity, and carcinogenicity).

Clinical Performance Data

No data from human clinical studies have been included to support the substantial equivalence of the proposed device, Orthopedic Fixation Pin, as clinical studies are not required for this medical device.

VIII. CONCLUSION

The same intended use, the similarity in overall technological characteristics, and performance data result in that Orthopedic Fixation Pin are substantially equivalent to legally marketed device.