March 31, 2022

In2Bones USA, LLC
Christine Scifert
VP of Quality Assurance and Regulatory Affairs
6000 Poplar Ave, Suite 115
Memphis, Tennessee 38119

Re: K220260
Trade/Device Name: Hercules® Syndesmosis Implant System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: January 27, 2022
Received: January 31, 2022

Dear Christine Scifert:

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,

for

Limin Sun, Ph.D.
Acting Assistant Director
DHT6A: Division of Joint
Arthroplasty 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220260

Device Name
Hercules® Syndesmosis Implant System

Indications for Use *(Describe)*
The Hercules® Syndesmosis Implant System is intended to provide fixation during the healing process following a syndesmotic trauma such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures and as an adjunct in external and intramedullary fixation systems. The Hercules® Syndesmosis Implant System is also intended to provide fixation during healing process after joint reconstruction in the midfoot and forefoot including correction of hallux valgus deformity.

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

Hercules® Syndesmosis Implant System

March 30, 2022

Company: In2Bones USA, LLC
6000 Poplar Ave, Suite 115
Memphis, TN 38119
901-260-7931

Company Contact: Christine Scifert

Trade Name: Hercules® Syndesmosis Implant System

Common Name: Fixation button and suture

Classification: II

Regulation Number: 21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories

Panel: 87-Orthopedic

Product Code(s): HTN – Washer, bolt nut

Device Description: The In2Bones Hercules® Syndesmosis Implant System is a sterile, single-use, device intended to stabilize syndesmotic trauma of the ankle. The subject system consists of UHMWPE suture tensioned between two low profile titanium alloy buttons, designed to complement plate fixation or to allow use as a stand-alone device. This device is also packaged with various ancillary instruments to aid in insertion.

Indications for Use:

The Hercules® Syndesmosis Implant System is intended to provide fixation during the healing process following a syndesmotic trauma such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures and as an adjunct in external and intramedullary fixation systems. The Hercules® Syndesmosis Implant System is also intended to provide fixation during healing process after joint reconstruction in the midfoot and forefoot including correction of hallux valgus deformity.

Substantial Equivalence: The subject components were demonstrated to be substantially equivalent to the following systems previously cleared by the FDA:

Primary Predicate:

- K043248– Arthrex Tightrope

Additional Predicates:

- K170249 – Wright Medical Gravity Syndesmosis LP
- K170440 – Arthrosurface KISSLoc Suture System

The subject Hercules® Syndesmosis Implant System is made of UHMWPE sutures and titanium alloy and has been demonstrated to be substantially equivalent to the previously cleared devices identified above as the products are similar in indications, materials and geometry.

Reference Devices:

- K063778 and K181774 - Teleflex Force Fiber
- K083070 and K130033 - BioMet ZipTight – ToggleLoc

Performance Testing:

Cyclic displacement and load to failure bench testing (mechanical testing) was performed to demonstrate substantial equivalence to the predicate devices. The Hercules® Syndesmosis Implant System was validated per ISO 10993-1 for biocompatibility, ISO 11137-2 for gamma sterilization, ISO 11135 for ETO sterilization and ISO 11607-1 for packaging. Endotoxin testing was completed per ANSI/AAMI ST72.

Conclusion

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.