November 28, 2017

In2Bones SAS
% Ms. Christine Scifert
Executive Vice President
MRC-X, LLC
6075 Poplar Ave, Suite 500
Memphis, Tennessee 38119

Re: K173121
Trade/Device Name: Ankle Fusion Plating System
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: September 27, 2017
Received: September 29, 2017

Dear Ms. 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. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173121

Device Name
Ankle Fusion Plating System

Indications for Use *(Describe)*
The In2Bones Ankle Fusion plating system is indicated for anterior fixation of ankle arthrodesis and fractures, including the distal tibia, talus and calcaneus.

The addition of a compression screw through the tibiotalar joint (example IBS™ 6.5mm screw) is required.

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.

510(k) SUMMARY
For In2Bones Ankle Fusion Plating System

Sponsor identification	In2Bones SAS 28 chemin du Petit Bois 69130 Ecully – France Phone: +33.4.72.29.26.26 Fax: +33.4.72.29.26.29
Establishment registration number	3010470577
Date of preparation	November 8, 2017
Contact person	Christine Scifert, MS, MEM MRC-X, LLC 6075 Poplar Avenue, suite 500 Memphis, TN 38119 Cell: 901-831-8053 Email: Christine.Scifert@mrc-x.com
Proprietary Name	Ankle Fusion Plating System
Common name	Ankle Fusion Plating System
Device classification regulation	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories Class II
Device Product Code and Panel	HRS: plate, fixation, bone HWC: screw, fixation, bone 87 orthopedics

Device Description	The Ankle Fusion Plating System is composed of an anatomically contoured plate, with a distal part adapted to the talar neck, and a proximal part adapted to the distal tibial epiphysis and diaphysis. Rigid fixation is achieved by screws. The Ankle Fusion Plating System implants (plate and screws) are manufactured from Ti6Al4V. A dedicated instrument set is available for the bone preparation, screw sizing and insertion of the Ankle Arthrodesis Plating System. A specific targeting device is available for the insertion of the additional I.B.S® 6.5mm screw. Sizes: The Ankle Fusion Plate is available in one size, with left and right versions. Fixation screws are available in 3.5 or 4.5mm diameter, with length ranging from 10 to 100mm. Material: The Ankle Fusion Plating System implants (plate and screws) are manufactured from Ti6Al4V, as per ISO 5832-1 and ASTM F136. Single use: The Ankle Fusion Plating System is designed for single use only. Sterilization: The Ankle Fusion Plating System is supplied sterile, using gamma irradiation. Place of use: The Ankle Fusion Plating System is indicated for use in a hospital, or outpatient surgery center where sterile field may be created and maintained.
Predicate Devices	Primary Predicate: Tibiaxys (K073375), Newdeal, Acquired by Integra LifeSciences Additional Predicates: Peri-Loc Ankle Fusion Plating System (K083032), Smith and Nephew Ankle Fusion Plating System (K141735), Arthrex ExtremiLock Ankle Fusion Plating System (K133691), Osteomed LCP Ankle Arthrodesis Plate (K022255), Synthes Ortholoc3Di Ankle Fusion Plating system (K121425), WMT

Indications for use:	The In2Bones Ankle Fusion plating system is indicated for anterior fixation of ankle arthrodesis and fractures, including the distal tibia, talus and calcaneus. The addition of a compression screw through the tibiotalar joint (example IBS™ 6.5mm screw) is required.
Comparison of the indications for use with the predicate devices:	The indications for use for the In2Bones Ankle Fusion Plating System are similar to the predicate devices Newdeal Tibiaxys (K073375), Smith and Nephew Peri-Loc Ankle Fusion Plating System (K083032), Arthrex Ankle Fusion Plating System (K141735), Osteomed ExtremiLock Ankle Fusion Plating System (K133691), Synthes LCP Ankle Arthrodesis Plate (K022255), and Wright Medical Ortholoc3Di Ankle Fusion Plating system (K121425)
Comparison of Technological characteristics and Substantial Equivalence Summary:	The In2Bones Ankle Fusion Plating System is similar to the predicate devices Newdeal Tibiaxys (K073375), Smith and Nephew Peri-Loc Ankle Fusion Plating System (K083032), Arthrex Ankle Fusion Plating System (K141735), Osteomed ExtremiLock Ankle Fusion Plating System (K133691), Synthes LCP Ankle Arthrodesis Plate (K022255), and Wright Medical Ortholoc3Di Ankle Fusion Plating system (K121425) in intended use, design, size ranges, principle of operation and materials.
Summary Performance Data	Performance testing of the Ankle Fusion Plating System was assessed through mechanical bench testing performed by an independent test laboratory, animal and clinical testing being considered not applicable. Testing performed included static and dynamic compression tests on Ankle Fusion Plating System. The results indicate that the Ankle Fusion Plating System met the acceptance criteria.
Pyrogen testing	The method used to make the determination that the device meets pyrogen limit specification is the Limulus Amebocyte Lysate (LAL) test in accordance with ANSI/AAMI ST72:2011: *Bacterial endotoxins – Test methods, routine monitoring and alternative to batch testing*.
CONCLUSION	**Based on the comparison of indications for use and technological characteristics and the results of the testing performed, the Ankle Fusion Plating System is substantially equivalent to the predicate devices identified in the 510(k) submission.**