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

January 19, 2018

Re: K173616
Trade/Device Name: DIP Arthrodesis System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY
Dated: November 21, 2017
Received: November 22, 2017

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. 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)*
K173616

Device Name
DIPArthrodesis System

Indications for Use *(Describe)*
The DIP implants are indicated for distal interphalangeal joint fusion of the long fingers. Treatment may include complementary immobilization of the finger (e.g. splint) if considered preferable by the surgeon.

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.

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510(k) SUMMARY
For In2Bones Distal InterPhalangeal Implant

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 21, 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	DIP Arthrodesis System
Common name	Distal InterPhalangeal Arthrodesis System
Device classification regulation	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener Class II
Device Product Code and Panel	HTY: pin, fixation, smooth 87 orthopedics

Device Description	The Distal InterPhalangeal (DIP) Arthrodesis System, is composed of intramedullary implant, designed to act as a bone fastener for distal interphalangeal arthrodesis of the long fingers. The implant is composed of 2 parts implanted in the proximal and distal phalanx and locked together in a rigid arthrodesis system. Sizes: The DIP Arthrodesis System is composed of implants available in different lengths and angles. The proximal implant is available in two sizes. The distal implant is available in 2 sizes combined with two angles of plantar flexion: 0 degree or 15 degrees to accommodate the size variation of the phalanges across the patient population and interphalangeal angles. Material: The DIP Arthrodesis System is manufactured from PEEK-OPTIMA® (PolyEtherEtherKetone) polymer from Invibio® as per ASTM F2026, a radiolucent material. Single use: The DIP Arthrodesis System is designed for single use only. Sterilization: The DIP Arthrodesis System is supplied sterile, using gamma irradiation.
Predicate Devices	Primary predicate: StayFuse (K990804), Pioneer, acquired by Tornier Additional predicates: X-Fuse (K070598), MemoMetal Implants, acquired by Stryker ToeGrip (K133477), Synchro Medical Reunite Resorbable bone pins (K011522), Biomet
Indications for use:	The DIP Arthrodesis System is indicated for distal interphalangeal joint fusion of the long fingers. Treatment may include complementary immobilization of the finger (e.g. splint) if considered preferable by the surgeon.
Comparison of the indications for use with the predicate devices:	The indications for use for the In2Bones DIP Arthrodesis System are similar to the predicate devices Tornier StayFuse (K990804), Stryker X-Fuse (K070598), Synchro Medical ToeGrip (K133477) and Biomet Reunite Resorbable bone pins (K011522).

Comparison of Technological characteristics and Substantial Equivalence Summary:	The In2Bones DIP Arthrodesis System is similar to the predicate devices Stryker X-Fuse (K070598), MemoMetal Implants, Tornier StayFuse (K990804), Synchro Medical ToeGrip (K133477), Biomet Reunite Resorbable bone pins (K011522), in intended use, design, size ranges, principle of operation and materials.
Summary Performance Data	Performance testing of the DIP Arthrodesis System was assessed through mechanical bench testing performed by an independent test laboratory. Testing performed included static and dynamic bending tests on DIP Arthrodesis System compared to predicate device. The results indicate that the DIP Arthrodesis 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 DIP Arthrodesis System is substantially equivalent to the predicate devices identified in the 510(k) submission.**