In2Bones USA, LLC
% Christine Scifert
Exec VP
MRC-X, LLC
6075 Poplar Avenue, Suite 500
Memphis, Tennessee 38119

February 23, 2018

Re: K173491
Trade/Device Name: RTS Lesser MTP Implant System
Regulation Number: 21 CFR 888.3720
Regulation Name: Toe joint polymer constrained prosthesis
Regulatory Class: Class II
Product Code: KWH
Dated: January 24, 2018
Received: January 26, 2018

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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K173491

Device Name

RTS® Lesser MTP Implant System

Indications for Use *(Describe)*

The RTS® Lesser MTP Implant is intended for use in the treatment of:

- Partial or complete dislocation of the lesser metatarsophalangeal joint
- Pain associated with either rheumatoid or osteoarthritis
- Repair of unsuccessful arthroplasties of the lesser metatarsophalangeal joint
- Stiffness at the lesser metatarsophalangeal joint associated with joint disease
- Hammertoe deformity where the proximal phalanx is dorsally located on the metatarsal in a fixed contracture state.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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510(k) Summary

RTS® Lesser MTP Implant System

January 24, 2018

Company: In2Bones USA, LLC
6060 Poplar Ave, Suite 380
Memphis, TN 38119
901-260-7931

Primary Contact: Christine Scifert

Company Contact: Rebecca Wahl

Trade Name: RTS® Lesser MTP Implant System

Common Name: Polymer toe Prosthesis

Classification: II

Regulation Number: 888.3720 – Toe Joint Polymer Constrained Prosthesis

Panel: 87-Orthopedic

Product Code(s): KWH

Device Description: The In2Bones USA RTS® Lesser MTP Implant is a one-piece device manufactured from Medical Grade Silicone Elastomer. The implant is available in three sizes. The associated sterile instruments are made of medical grades of stainless steel and polymer materials

Indications for Use: The RTS® Lesser MTP Implant is intended for use in the treatment of:

- Partial or complete dislocation of the lesser metatarsophalangeal joint
- Pain associated with either rheumatoid or osteoarthritis
- Repair of unsuccessful arthroplasties of the lesser metatarsophalangeal joint
- Stiffness at the lesser metatarsophalangeal joint associated with joint disease
- Hammertoe deformity where the proximal phalanx is dorsally located on the metatarsal in a fixed contracture state.

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

Primary Predicate

- K022886 – OsteoMed Metatarsophalangeal Flexible Stabilizing Rod System

Additional Predicate

- K023531 – Integra Lesser Metatarsal Phalangeal Implant

Reference Device

- K153609 – In2Bones RTS® Flexible 1st MPJ Implant w/Grommets System

The subject RTS® Lesser MTP Implant made of Silicone Elastomer has demonstrated to be substantially equivalent to the previously cleared OsteoMed Metatarsophalangeal Flexible Stabilizing Rod System and the Integra Lesser Metatarsal Phalangeal Implant as the products are similar in indications, materials and geometry.

Performance Testing: Validations were performed on the cleaning, packaging and sterilization of the implants and associated surgical instruments. Engineering analysis including Finite Element Analysis was also performed. The results of the testing demonstrate that the device is substantially equivalent to the predicate device identified

Conclusion

The RTS® Lesser MTP Implant when compared to the predicate have the same intended use and indications for use, technological characteristics, and principals of operation. Thus the RTS® Lesser MTP Implant design characteristics do not raise any new types of questions of safety or effectiveness and thus is substantially equivalent to the predicate device.