DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 8, 2016

In2Bones USA, LLC
% Ms. Louise Focht
President
ENMED International, Inc.
P.O. Box 249
Del Mar, California 92014

Re: K153609
Trade/Device Name: RTS Flexible 1st MPJ Implant w/Grommets
Regulation Number: 21 CFR 888.3720
Regulation Name: Toe joint polymer constrained prosthesis
Regulatory Class: Class II
Product Code: KWH
Dated: August 8, 2016
Received: August 9, 2016

Dear Ms. Focht:

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 Parts 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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 below.

510(k) Number *(if known)*

Device Name

Device Name: RTS Flexible 1st MPJ Implant w/Grommets

Indications for Use *(Describe)*

The RTS Flexible 1st MPJ Implant w/Grommets is intended for use in the treatment of:

- Hallux limitus or hallux rigidus
- Painful rheumatoid arthritis
- Hallux abducto valgus associated with arthritis
- Unstable or painful joint from previous surgery

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary of Safety and Effectiveness

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

I. Submitter

Date Prepared: September 8, 2016
Device Submitter: In2Bones USA, LLC
6060 Poplar Avenue, Suite 380
Memphis, TN 38119
Phone: 901-260-7931

Contact Person: Louise Focht

II. Device

Proprietary Name: RTS Flexible 1st MPJ Implant w/Grommets
Common Name: Flexible Great Toe Implant
Classification Name: Prosthesis, Toe, Constrained Polymer
Regulatory Class: 21 CFR 888.3720, Class II
Product Code: 87 KWH

III. Predicate Device

Predicate Device: Futura Biomedical, Flexible Great Toe Implant
K981194

IV. Device Description

The RTS Flexible 1st MPJ Implant w/Grommets is a double-stemmed, constrained, silicone prosthesis, intended to be implanted to replace the first metatarsophalangeal joint. The implant is designed to act as a joint spacer between the resected head of the first metatarsal and base of the proximal phalanx.

V. Intended Use and Indications for Use

The RTS Flexible 1st MPJ Implant w/Grommets is intended for use in the treatment of: Hallux limitus or hallux rigidus, Painful rheumatoid arthritis, Hallux abducto valgus associated with arthritis, Unstable or painful joint from previous surgery

VI. Comparison of technological characteristics with the predicate device

The RTS Flexible 1st MPJ Implant w/Grommets and the legally marketed predicate device have the same intended use and indications for use, similar dimensions, geometry and materials. The In2Bones device and the predicate are both available in four sizes. The stems of the devices are

fit into the intramedullary canals of the first metatarsal phalangeal joint. The devices are constrained and made of silicone elastomer. The devices also have proximal and distal grommets that may be used with the silicone implant.

VII. Performance Data

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

VIII. Conclusions

The RTS Flexible 1st MPJ Implant w/Grommets when compared to the predicate have the same intended use and indications for use, technological characteristics, and principals of operation as the predicate device. Thus the RTS Flexible 1st MPJ Implant w/Grommets design characteristics do not raise any new types of questions of safety or effectiveness and thus is substantially equivalent to the predicate device.