November 28, 2017

In2bones Sas
% Norman Estrin
Managing Partner
Estrin Consulting Group LLC
3100 N. Leisure World Blvd., Apt. 121
Silver Spring, Maryland 20906

Re: K170688
Trade/Device Name: PIT'Stop® implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 17, 2017
Received: October 23, 2017

Dear Norman Estrin:

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,

Vincent J. Devlin -S

for

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)*
K170688

Device Name

PIT'Stop® implant

Indications for Use *(Describe)*

The PIT'Stop implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

- Flat foot treatment in children and adolescents
- Congenital flat foot
- Non successful long term orthopaedic treatment (shoes, insoles…)
- Tarsal coalitions
- Painfully flat foot
- Supple deformity in posterior tibial tendon dysfunction
- Paralytic flat foot
- Subtalar instability

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
For In2Bones PIT'Stop® 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	October 13th, 2017
Contact person	Norman F. Estrin, Ph.D. Estrin Consulting Group LLC 3100 N. Leisure World Blvd. Silver Spring, MD 20906 Phone: 240-994-9999 Email: estrin@yourFDAconsultant.com
Authorized Agent in the United States	Norman F. Estrin, Ph.D. Estrin Consulting Group LLC 3100 N. Leisure World Blvd. Silver Spring, MD 20906 Phone: 240-994-9999 Email: estrin@yourFDAconsultant.com
Proprietary Name	PIT'Stop® implant
Common name	Subtalar implant
Device classification regulation	21 CFR 888. 3040: Smooth or threaded metallic bone fixation screw or fastener Class II
Device Product Code and Panel	HWC: screw, fixation, bone 87 orthopedics

Device Description	The PIT'Stop® implant is a cannulated implant composed of two symmetrical and flattened sides, and small blades. The PIT'Stop® implant is designed to adequately maintain the filling of the sinus tarsi, and is made of PEEK, a material recognized for its mechanical and radiolucent properties. The PIT'Stop® implant is introduced into the axis of sinus tarsi, and its fixation is performed by anti-return flanges. The PIT'Stop implant should be removed: • at the end of the growth when used in pediatric patients or • by 12 months when used in adult patients or • if pain occurs earlier Sizes: The PIT'Stop® implant is designed in 7 sizes, from 10mm to 17mm. Material: The PIT'Stop® implant is made of PEEK according to standard ASTM F2026 and include markers made of tantalum according to ASTM F560. Single use: The PIT'Stop® implant is designed for single use only. Sterilization: The PIT'Stop® implant is supplied sterile, using gamma irradiation.
Predicate Devices	Newdeal KALIX® II Flat foot implant (K061765) Solana Surgical, LLC, Gaitway Implant System (K122738) In2Bones OS2®-VP varisation staple (K153770)
Indications for use:	The PIT'Stop® implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela. - Flat foot treatment in children and adolescents - Congenital flat foot - Non successful long term orthopaedic treatment (shoes, insoles…) - Tarsal coalitions - Painfully flat foot - Supple deformity in posterior tibial tendon dysfunction - Paralytic flat foot - Subtalar instability

Comparison of the indications for use with the predicate device:	The indications for use for the PIT'Stop® implant are identical to the predicate devices Newdeal KALIX® II Flat foot implant (K061765), and Solana Surgical, LLC, Gaitway Implant System (K122738).
Comparison of Technological characteristics and Substantial Equivalence Summary:	The PIT'Stop® implant is similar to the predicate devices Newdeal KALIX® II Flat foot implant (K061765) and Solana Surgical, LLC, Gaitway Implant System (K122738) in intended use, design, sizes and principles of operation, and is similar to the predicate device OS2®-VP Varisation staple (K153770) in material.
Summary Performance Data	Performance testing of the PIT'Stop® implant 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 PIT'Stop® implant. The results of the testing performed by the independent test laboratory indicate that the PIT'Stop® implant met the acceptance criteria.
CONCLUSION	**Based on the comparison of indications for use and technological characteristics and the results of the testing performed, the PIT'Stop® implant is substantially equivalent to the predicate devices identified in the 510(k) submission.**