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

In2Bones SAS
% Norman Estrin, Ph.D.
Managing Partner
Estrin Consulting Group LLC
9109 Copenhaver Drive
Potomac, Maryland 20854

March 21, 2016

Re: K153770
Trade/Device Name: OS2®-VP Varisation Staple
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: December 30, 2015
Received: December 30, 2015

Dear Dr. 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 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 yours,

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)*
K153770

Device Name
OS2®-VP Varisation Staple

Indications for Use *(Describe)*
The OS2®-VP Varisation Staples are indicated for Akin type osteotomies.

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.

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510(k) SUMMARY
For In2Bones OS2®-VP Varisation Staple

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	March 9th, 2016
Contact person	Norman F. Estrin, Ph.D. Estrin Consulting Group LLC 9109 Copenhaver Drive Potomac, MD 20854 Phone: (301) 279-2899 Cell: 240-994-9999 Email: estrin@yourFDAconsultant.com
Authorized Agent in the United States	Norman F. Estrin, Ph.D. Estrin Consulting Group LLC 9109 Copenhaver Drive Potomac, MD 20854 Phone: (301) 279-2899 Fax: (301) 294-0126 Cell: 240-994-9999 Email: estrin@yourFDAconsultant.com
Proprietary Name	OS2®-VP Varisation Staple
Common name	Bone staple
Device classification regulation	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories Class II
Device Product Code and Panel	JDR: staple, fixation, bone 87 orthopedics

Device Description	The OS2®-VP Varisation Staple is an osteosynthesis staple manufactured from PEEK, a material recognized for its mechanical and radiolucent properties. Sizes: The OS2®-VP Varisation Staple is available in various angles. Material: The OS2®-VP Varisation Staple is manufactured from PEEK according to standard ASTM F2026. Single use: The OS2®-VP Varisation Staple is designed for single use only. Sterilization: The OS2®-VP Varisation Staple is supplied sterile, using gamma irradiation. Place of use: The OS2®-VP Varisation Staple is indicated for use in a hospital, or outpatient surgery center where sterile field may be created and maintained.
Predicate Devices	Primary predicate device: In2Bones OS2®-V Varisation Staple (K143323) Additional predicate device: Memometal Easyclip (K070031) Newdeal K Wire (K022599) Reference predicate devices: In2Bones DUAFIT® Interphalangeal Implant (K132912)
Indications for use:	The OS2®-VP Varisation Staples are indicated for Akin type osteotomies.
Comparison of the indications for use with the predicate devices:	OS2®-VP Varisation Staple has indications for use identical to those of OS2®-V Varisation Staple (K143323) primary predicate device. As with the other predicate devices, the OS2®-VP Varisation Staple is indicated for surgical implantation longer than 30 days and for the fixation of bone in foot.
Comparison of Technological characteristics and Substantial Equivalence Summary	The OS2®-VP Varisation Staple is similar to the primary predicate device OS2®-V Varisation Staple (K143323) in intended use, design, sizes and principles of operation, and is similar to the reference predicate device In2Bones DUAFIT® Interphalangeal Implant (K132912) in material.

Summary Performance Data	Performance testing has been evaluated for OS2®-VP Varisation Staple through mechanical comparison with predicate devices, animal and clinical testing being considered not applicable. Mechanical testing was performed according to dedicated protocols based on standard ASTM F564. The results of the testing performed by the test laboratories indicate that the OS2®-VP Varisation Staple performed as expected for each test.
CONCLUSION	**Based on the comparison of indications for use and technological characteristics and the results of the testing performed, the OS2®-VP Varisation Staples are substantially equivalent to the predicate devices identified in the 510(k) submission.**