DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 26, 2015

IN2Bones SAS
% Norman F. Estrin, Ph.D.
Estrin Consulting Group LLC
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K143323
Trade/Device Name: OS2®-V 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: January 18, 2015
Received: January 29, 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 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.

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

004_Indications for Use.pdf

Indications for Use

510(k) Number (if known): Not yet assigned

Device Name: OS2®-V Varisation Staple

Indications For Use: The OS2®-V Varisation Staples are indicated for Akin type osteotomies.

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

005_510(k) Summary.pdf

510(k) SUMMARY
For In2Bones OS2®-V 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	20th February 2015
Contact person	Norman F. Estrin, Ph.D. Estrin Consulting Group LLC 9109 Copenhaver Drive Potomac, MD 20854 Phone: (301) 279-2899 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 Email: estrin@yourFDAconsultant.com
Proprietary Name	OS2®-V Varisation Staple
Common name	Bone Varisation 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®-V Varisation Staple is a metallic staple with two self-drilling tips. The treatment with a varisation staple allows, after possible treatment of the second ray, to correct the valgus deformation of the first ray and to recreate a square or Greek foot. Two types of staples are available depending on the bone surface. Sizes: The OS2®-V Varisation Staple is available in various angles (90° and 26°) and interaxis (8mm and 10mm). Material: The OS2®-V Varisation Staple is manufactured from stainless steel 316LVM, according to ISO 5832-1 and ASTM F138. It does not have any coating. Single use: The OS2®-V Varisation Staple is designed for single use only. Sterilization: The OS2®-V Varisation Staple is supplied sterile, using gamma irradiation. Place of use: The OS2®-V Varisation Staple is indicated for use in a hospital, or outpatient surgery center where sterile field may be created and maintained.
Predicate Devices	Integra / Newdeal SOLUSTAPLE (K991566) Memometal Varisation staple (K070033)
Indications for use:	The OS2®-V Varisation Staples are indicated for Akin type osteotomies

COMPARISON OF THE INDICATIONS FOR USE WITH THE PREDICATE DEVICES:

As with the predicate devices, the OS2®-V Varisation Staple is indicated for surgical implantation longer than 30 days in the fixation of bone fractures or for bone reconstruction.

510k number		K991566	Substantial equivalence discussion
manufacturer	In2Bones	Integra / Newdeal	OS2®-V Varisation Staple has exactly the same indications for use as the SOLUSTAPLE: "Akin type osteotomy"
Name of device	OS2®-V Varisation Staple	SOLUSTAPLE	
Indications for use	The OS2®-V Varisation Staples are indicated for Akin type osteotomies.	The SOLUSTAPLE® is indicated for Akin type osteotomy	

510k number		K070033	Substantial equivalence discussion
manufacturer	In2Bones	Memometal Varisation staple	OS2®-V Varisation Staple has exactly the same

Name of device	OS2®-V Varisation Staple	Varisation staple	indications for use as the Memometal Varisation staple: “Akin type osteotomy”
Indications for use	The OS2®-V Varisation Staples are indicated for Akin type osteotomies.	The Memometal Varisation Staple is indicated for Akin type osteotomy	

Comparison of Technological characteristics	The technological characteristics of the OS2®-V Varisation Staple are the same as the characteristics of predicate devices in terms of intended use and design. All these implants have the following features: - Insertion into bone: The OS2®-V Varisation Staple and all predicate devices are intended for surgical implantation into bone for longer than 30 days. - Indications for use: The OS2®-V Varisation Staple has similar indications for use when compared to the Integra / Newdeal SOLUSTAPLE (K991566) and Memometal Varisation staple (K070033): all are indicated for Akin type osteotomies. - Design: The OS2®-V Varisation Staple has similar design, when compared to the Integra / Newdeal SOLUSTAPLE (K991566) and Memometal Varisation staple (K070033): all are staples with self-drilling tips, available in straight and angle designs, manufactured from 1mm diameter wire. - Equivalent size range: The OS2®-V Varisation Staple has similar size range, when compared to the Integra / Newdeal SOLUSTAPLE (K991566) and Memometal Varisation staple (K070033): all are staples available in 8mm and 10mm interaxis, 10mm leg length, 26° and 90° angulation options. - Material: OS2®-V Varisation Staple has similar raw material, when compared to the Integra / Newdeal SOLUSTAPLE (K991566) and Memometal Varisation staple (K070033): all are manufactured from stainless steel 316L, according to ISO 5832-1 and ASTM F138. - The OS2®-V Varisation Staple has similar intended use and mechanical properties when compared to the Integra / Newdeal SOLUSTAPLE (K991566) and Memometal Varisation staple (K070033). Indeed, they are all compliant with standard ISO 8827 “Implants for surgery – staples with parallel legs for orthopaedic use – general requirements”.
Substantial Equivalence Summary	The OS2®-V Varisation Staple has similar technological characteristics when compared to the predicate devices. Substantial equivalence discussion is provided here below:

Substantial Equivalence Comparison and Discussion

510k number		K991566	K070033
manufacturer	In2Bones	Integra / Newdeal	Memometal Varisation staple
Name of device	OS2®-V Varisation Staple	SOLUSTAPLE	Varisation staple
Use	Single use	Single use	Single use
Fixation	Bone	Bone	Bone
Indications for use	The OS2®-V Varisation Staples are indicated for Akin type osteotomies	The SOLUSTAPLE® is indicated for Akin type osteotomy	The Memometal Varisation Staple is indicated for Akin type osteotomy
Design	Staple with self-drilling tips, available in straight and angle designs, manufactured from 1mm diameter wire.	Staple with self-drilling tips, available in straight and angle designs, manufactured from 1mm diameter wire.	Staple with self-drilling tips, available in straight and angle designs, manufactured from 1mm diameter wire.
size	available in 8mm and 10mm interaxis, 10mm leg length 26° and 90° angulation options	available in 8mm and 10mm interaxis, 10mm leg length 26° and 90° angulation options	available in 8mm and 10mm interaxis, 10mm leg length 26° and 90° angulation options
Raw material	stainless steel 316L, according to ISO 5832-1 and ASTM F138	stainless steel 316L, according to ISO 5832-1 and ASTM F138	stainless steel 316L, according to ISO 5832-1 and ASTM F138

Summary Performance Data	Performance assessment for the OS2®-V Varisation Staple was made through mechanical comparison with predicate devices, animal and clinical testing being considered not applicable. Mechanical performance was assessed according to ASTM F564 Standard Specification and Test Methods for Metallic Bone Staples. This standard describes methods to assess the Varisation and fatigue bending properties, and the pull-out fixation strength. This specification standard also provides requirements for materials, finish, inspection practices, care and handling. In addition, standard ISO 8827 provides requirements for design (global design, tips design, legs design), tolerances, materials and their mechanical characteristics, finish, packaging and marking. An engineering / dimensional comparison to the predicates was performed to ascertain substantial equivalence. OS2®-V Varisation Staple is substantially equivalent to the predicate devices identified in the 510(k) submission. No new materials or processes are used in the development of this implant.

CONCLUSION	**Based on the evaluations performed, the design and**

	indications of the OS2®-V Varisation Staples are substantially equivalent to the predicate devices identified in the 510(k) submission. No new materials or processes are used in the development of this implant. **The OS2®-V Varisation Staples are acceptable for the application.**