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JUL 3 0 2014

510(k) SUMMARY
For In2Bones DUAFIT® interphalangeal 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	New company. Will register following FDA clearance (Owner/Operator Number: 10046803)
Date of preparation	July 23, 2014
Contact person	Norman Estrin Estrin Consulting Group LLC 9109 Copenhaver Drive Potomac, MD 20854 Phone: (301) 279-2899 Fax: (301) 294-0126 Email: estrin@yourFDAconsultant.com
Authorized Agent in the United States	Norman Estrin Estrin Consulting Group LLC 9109 Copenhaver Drive Potomac, MD 20854 Phone: (301) 279-2899 Fax: (301) 294-0126 Email: estrin@yourFDAconsultant.com
Proprietary Name	Duafit® interphalangeal implant
Common name	Intramedullary bone fastener
Device classification regulation	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener Class II
Device Product Code and Panel	HWC: screw, fixation, bone 87 orthopedics
Device Description	The DUAFIT® interphalangeal implant is an intramedullary implant, designed to act as a bone fastener for proximal interphalangeal arthrodesis of the lesser rays. Design is a combination of a proximal taper with barbs and a distal blade for enhanced stabilization.

	It is made available in multiple lengths and diameters, and in 3 different angles. The implant is manufactured from PEEK-OPTIMA®, polymer from Invibio®, and is designed for single use only. Sizes: The DUAFIT® interphalangeal implant is available in various angles (straight / 0° - 10° - 17°) and lengths (size 1 to 4, corresponding to 11 to 20mm). Material: The DUAFIT® interphalangeal implant is manufactured from Polyetheretherketone PEEK-OPTIMA®, polymer from Invibio®, as per ASTM 2026. It does not have any coating. Single use: The DUAFIT® interphalangeal implant is designed for single use only. Sterilization: The DUAFIT® interphalangeal implant is supplied sterile, using gamma irradiation. Place of use: The DUAFIT® interphalangeal implant is indicated for use in a hospital, or outpatient surgery center where sterile field may be created and maintained.
Predicate Devices	Newdeal K-wire (K022599) Metasurg DigiFuse (K111536) Parcus PEEK CF push-in suture anchor (K102326) WMT Pro-Toe (K120645) Arrowhead Arrow-Lok (K112675) Smith and Nephew Bioraptor 2.3 PK suture anchor (K071586) Merete MetaToe (K100414) Synchro Medical Toegrip (K143477)
Indications for use:	The DUAFIT® interphalangeal implant is intended for fixation of proximal interphalangeal joint arthrodesis of the lesser toes. Examples include: - rigid or semi-rigid deformity of the PIP joint - revision of failed arthroplasty or arthrodesis - 2nd toe shortening

Comparison of Technological characteristics	The technological characteristics of the DUAFIT® interphalangeal implant 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 DUAFIT® interphalangeal implant and all predicate devices are intended for surgical implantation into bone for longer than 30 days. - Tapered barded design in its proximal part - The DUAFIT® interphalangeal implant has similar tapered barded design in its proximal part, when compared to the Parcus PEEK CF push-in suture anchor (K102326), Smith and Nephew Bioraptor 2.3 PK suture anchor (K071586), Metasurg DigiFuse implant (K111536) , WMT Pro-Toe (K120645), Merete MetaToe (K100414) and Synchro Toegrip (K133477). - Blade design in its distal part - The DUAFIT® interphalangeal implant has similar blade design in its distal part, when compared to the Metasurg DigiFuse implant (K111536) and WMT Pro-Toe (K120645). Its shape is also similar to the distal part of the Synchro Toegrip (K133477). - Canulated design: The DUAFIT® interphalangeal implant is available with a similar canulated design, when compared to the Metasurg DigiFuse implant (K111536). - Straight / Angled design: The DUAFIT® interphalangeal implant has similar straight and angled design, when compared to the Metasurg DigiFuse implant (K111536), WMT Pro-Toe (K120645) , Arrowhead Arrow-Lok (K112675) and Synchro Toegrip (K133477) - Made from PEEK: The DUAFIT® interphalangeal implant has exactly the same raw material PEEK-OPTIMA®, polymer from Invibio®, when compared to the Smith and Nephew Bioraptor 2.3 PK suture anchor (K071586). It has similar raw material, when compared to the Parcus PEEK CF push-in suture anchor (K102326) and Synchro Toegrip (K133477) . The Newdeal / Integra K-wire (K022599), the WMT Pro-Toe (K120645) and Arrowhead Arrow-Lok (K112675) are manufactured from stainless steel 316L, and the Metasurg DigiFuse implant is manufactured from Titanium Alloy TA6V. The Merete MetaToe is manufactured from EndoSorb PLGA bioabsorbable material. - Equivalent size range: The DUAFIT® interphalangeal implant has similar size range, when compared to the Metasurg DigiFuse implant (K111536), WMT Pro-Toe (K120645) , Arrowhead Arrow-Lok (K112675), Merete MetaToe (K100414) and Synchro Toegrip (K133477). - The DUAFIT® interphalangeal implant has similar intended use and mechanical properties when compared to the Merete MetaToe EndoSorb (K100414). Results from testing confirmed that the DUAFIT® interphalangeal implant is at least equivalent to the predicate device.

Substantial Equivalence Summary	The DUAFIT® interphalangeal implant has similar indications for use and technological characteristics when compared to the predicate devices.
Summary Performance Data	The following tests were performed to demonstrate that the DUAFIT interphalangeal implant is substantially equivalent to other predicate devices: - Static four-point bending test - Cyclic four-point bending test. The results of these studies showed that the DUAFIT interphalangeal implant met the acceptance criteria.
CONCLUSION	**Based on the evaluations performed, the design and indications of the DUAFIT® interphalangeal implant 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.** **In addition, the results of the testing performed by the test lab indicated that the implants performed as expected for each test.** **The DUAFIT® interphalangeal implants are acceptable for the application.**

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

July 30, 2014

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

Re: K132912
Trade/Device Name: DUAFIT® Interphalangeal Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 3, 2014
Received: July 9, 2014

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,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132912

Device Name: DUAFIT® Interphalangeal Implant

Indications For Use:
The DUAFIT® Interphalangeal implant is intended for fixation of proximal interphalangeal joint arthrodesis of the lesser toes.
Examples include:
Rigid or semi-rigid deformity of the PIP joint
Revision of failed arthroplasty or arthrodesis
2nd toe shortening.

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)

Elizabeth L. Frank -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K132912