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

February 1, 2016

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

Re: K153204
Trade/Device Name: In2Bones® Kirschner Wire
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY, JDW
Dated: November 1, 2015
Received: November 4, 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

005_Indications for Use.pdf

Indications for Use

510(k) Number (if known): ~~Not yet assigned~~ K153204

Device Name: In2Bones® Kirschner wire

Indications For Use: The In2Bones® Kirschner wires are indicated for fixation of bone fractures, bone reconstruction, and as guide pins for insertion of other implants. The size of the In2Bones® Kirschner wire chosen should be adapted to the specific indication.

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)

510(k) SUMMARY
For In2Bones® Kirschner wire

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 28, 2015
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
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Proprietary Name	In2Bones® Kirschner wire
Common name	Osteosynthesis wire
Device classification regulation	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener Class II
Device Product Code and Panel	HTY: Pin, Fixation, Smooth JDW: Pin, Fixation, Threaded 87 orthopedics

Device Description	The In2Bones® Kirschner wire is a metallic wire available in four point styles: sharp, partially threaded, lanceolate, both ends sharp. One part is fixed on standard surgical power tool equipment for insertion. Sizes: The In2Bones® Kirschner wire is available in various diameters (0.8mm to 2.5mm) and length (70mm to 300mm). Material: The In2Bones® Kirschner wire is manufactured from stainless steel 316LVM, according to ISO 5832-1 and ASTM F138-13. It does not have any coating. Single use: The In2Bones® Kirschner wire is designed for single use only. Sterilization: The In2Bones® Kirschner wire is supplied sterile and non-sterile. The sterile In2Bones® Kirschner wire is sterilized using gamma radiation. The non-sterile In2Bones® Kirschner wire must be steam sterilized before use. Place of use: The In2Bones® Kirschner wire 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) Syntec-Taichung Non-sterile Kirschner Wires and Steinmann Pins (K983121)
Indications for use:	The In2Bones® Kirschner wires are indicated for fixation of bone fractures, bone reconstruction, and as guide pins for insertion of other implants. The size of the In2Bones® Kirschner wire chosen should be adapted to the specific indication.

Comparison of the indications for use with the predicate devices:	The indications for use for the In2Bones® Kirschner wire are similar to the predicate devices Syntec Taichung Non-sterile Kirschner Wires and Steinmann Pins (K983121) and NEWDEAL K WIRE (K983121).
Comparison of Technological characteristics with the predicate devices:	The In2Bones® Kirschner wire is similar to the predicate devices in regards to insertion, design, size ranges, and materials: - They all are intended for surgical implantation into bone for longer than 30 days. - The In2Bones® Kirschner wire has identical design as the Syntec-Taichung Non-sterile Kirschner Wires and Steinmann Pins (K983121) predicate, except for the partially threaded self-drilling tip. The In2Bones® Kirschner wire has the identical design as the NEWDEAL K WIRE (K022599) predicate, except for the lanceolate self-drilling tip - The In2Bones® Kirschner has similar size range when compared to the predicate devices. - The In2Bones® Kirschner wire has similar raw material, when compared to the NEWDEAL K WIRE (K022599) and Syntec-Taichung Non-sterile Kirschner Wires and Steinmann Pins (K983121): all are manufactured from the same type of stainless steel and meet appropriate ASTM standards.
Substantial Equivalence Summary:	The In2Bones® Kirschner wire has similar technological characteristics when compared to the predicate devices The indications for use, design and sizes available are similar and any differences do not impact safety and effectiveness.
Summary Performance Data	The In2Bones® Kirschner wires are stainless steel wires with diameters and lengths comparable to those featured in the predicate device systems. The design and indications of the In2Bones® Kirschner wires 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. Moreover, the In2Bones® Kirschner wires conform to the international standard ISO 5838-1 (2013). Testing, therefore, is not needed to demonstrate that the subject devices are substantially equivalent to other legally marketed Kirschner wires.

CONCLUSION	Based on the evaluations performed, the design and indications of the In2Bones® Kirschner wires 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 In2Bones® Kirschner wires are acceptable for the applications requested.