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

May 10, 2017

In2Bones SAS
% Dr. Norman Estrin
Managing Partner
Estrin Consulting Group LLC
3100 N. Leisure World Blvd., Apt. 121
Silver Spring, Maryland 20906

Re: K170594
Trade/Device Name: I.B.S. ^{TM} osteosynthesis screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 18, 2017
Received: May 1, 2017

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" (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.

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,

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)*

K170594

Device Name
I.B.S.™ osteosynthesis screws

Indications for Use *(Describe)*

The I.B.S.™ compression and neutralization osteosynthesis screws are intended for:
- The fixation of arthrodesis, osteotomies or fractures of long or short bones of the upper and lower limbs
- Osteosynthesis requiring a mono or bicortical compression

The size of the chosen screw should be adapted to the specific indications.

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 I.B.S.™ osteosynthesis screws device modification

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	May 7, 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 I.B.S.™ 2.0 Osteosynthesis Screw	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
Initial 510(k) number	K131920
Proprietary Name	I.B.S.™ osteosynthesis screws
Common name	Bone fixation screw
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 modified I.B.S™ osteosynthesis screws are a range extension of the existing screw line cleared in K131920 I.B.S™ osteosynthesis screw. The modification made on the I.B.S.™ osteosynthesis screw are: • I.B.S.™ Osteosynthesis Compression Screw, diameter 6.5mm: - Range extension of the total screw length, with addition of lengths from 85mm to 120mm, and creation of dedicated references; - Modification of the distal thread to a long distal thread for screws, with total length comprised between 60mm and 120mm, and creation of dedicated references. • I.B.S.™ Osteosynthesis Neutralization Screw, diameter 6.5mm: - Range extension of the total screw length, with addition of lengths from 85mm to 120mm, and creation of dedicated references. • I.B.S.™ Osteosynthesis Compression and Neutralization screw, diameter 2.5mm: - Range extension of the total screw length, with addition of length 30mm, and creation of dedicated references.
Predicate Devices	Compression design: • SBI, Autofix (K052576) • Biomet Trauma, BioDrive Cannulated screw system (K082874) • In2Bones, I.B.S.™ 2.0 Osteosynthesis screw (K160174) • In2Bones, I.B.S.™ Osteosynthesis screw (K131920) Neutralization design: • Acumed, Acutrak screws (K944330) • Biomet Trauma, BioDrive Cannulated screw system (K082874) • In2Bones, I.B.S.™ 2.0 Osteosynthesis screw (K160174) • In2Bones, I.B.S.™ Osteosynthesis screw (K131920)

Indications for use:	The I.B.S.™ compression and neutralization osteosynthesis screws are intended for: - The fixation of arthrodesis, osteotomies or fractures of long or short bones of the upper and lower limbs - Osteosynthesis requiring a mono or bicortical compression The size of the chosen screw should be adapted to the specific indications.
Comparison of Technological characteristics	The technological characteristics of the modified I.B.S.™ osteosynthesis screws are equivalent to the characteristics of predicate devices in terms of design, size range, raw material. All these implants have the following features: - Insertion into bone: The modified I.B.S.™ osteosynthesis screws and all predicate devices are intended for surgical implantation into bone for longer than 30 days. - Design: Predicate devices have similar design as the modified I.B.S.™ osteosynthesis screws. They all are cannulated, self-tapping and self-drilling screws with either a compression or a neutralization design. - Indications for use: Predicate devices have equivalent indications for use as the modified I.B.S.™ Osteosynthesis screws in terms of fixation of arthrodesis, osteotomies or fractures of long or short bones of the upper and lower limbs. These non-identical indications are equivalent and do not impact the safety and effectiveness of the modified I.B.S.™ Osteosynthesis screws. - Equivalent size range: Predicate devices have comparable size range of as the modified I.B.S.™ Osteosynthesis screws. The slightly difference of the predicates does not impact the safety and effectiveness of the modified I.B.S.™ Osteosynthesis screws. The length discrepancies of the I.B.S.™ osteosynthesis screw predicate (K131920) in comparison to the modified I.B.S.™ Osteosynthesis screws 6.5mm diameter are the reason of this Special 510(k) submission and do not impact the safety and effectiveness of the modified I.B.S.™ Osteosynthesis screws 6.5mm diameter, as it is explained in the “Performance Testing” section. - Material: The modified I.B.S.™ osteosynthesis screws have identical raw material, when compared to the predicate: all are manufactured from Titanium alloy Ti6Al4V, according to ISO 5832-3 and ASTM F136 standards.

Substantial Equivalence Summary	As described above, the modified I.B.S.™ osteosynthesis screws have similar technological characteristics when compared to the predicate devices.
Summary Performance Data	The dimensional modifications between the unmodified I.B.S.™ osteosynthesis Screws, K131920, and the modified I.B.S.™ osteosynthesis Screws have been evaluated through dimensional comparison with predicate devices and analysis of the impact on mechanical behavior based on standard ASTM F543. This standard describes methods to assess the torque to failure, insertion torque, axial pullout strength, and self-tapping performance of screws. No new bench testing was deemed required to assess the torsional properties, driving torque and axial pullout of the modified I.B.S.™ osteosynthesis screws. Therefore, the subject device was demonstrated to be as safe and effective as the above predicates
Pyrogen testing	The method used to make the determination that the device meets pyrogen limit specification is the Limulus Amebocyte Lysate (LAL) test in accordance with ANSI/AAMI ST72:2011: *Bacterial endotoxins – Test methods, routine monitoring and alternative to batch testing*.
CONCLUSION	**Based on the evaluations and the results of the dimensional comparison performed, the design and indications of the modified I.B.S.™ osteosynthesis screws 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 modified I.B.S.™ osteosynthesis screws are acceptable for the application.**