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

October 6, 2016

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

Re: K160174
Trade/Device Name: I.B.S.™ 2.0 Osteosynthesis Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: August 30, 2016
Received: August 31, 2016

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,

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)*
K160174

Device Name
I.B.S.™ 2.0 Osteosynthesis screw

Indications for Use *(Describe)*
The I.B.S.™ 2.0 Osteosynthesis screws are intended for:
- The fixation of arthrodeses, osteotomies or fractures of small bones of the upper and lower limbs
- Osteosynthesis requiring 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**510(k) SUMMARY**
**For In2Bones I.B.S.™ 2.0 Osteosynthesis screw**

| | |
|---|---|
| Sponsor identification | In2Bones SAS<br>28 chemin du Petit Bois<br>69130 Ecully – France<br>Phone: +33.4.72.29.26.26<br>Fax: +33.4.72.29.26.29 |
| Establishment registration number | 3010470577 |
| 510(k) number | K160174 |
| Date of preparation | October 5, 2016 |
| Contact person | Norman F. Estrin, Ph.D.<br>Estrin Consulting Group LLC<br>9109 Copenhaver Drive<br>Potomac, MD 20854<br>Phone: (301) 279-2899<br>Cell: 240-994-9999<br>Email: estrin@yourFDAconsultant.com |
| **Authorized Agent in the United States I.B.S.™ 2.0 Osteosynthesis Screw** | Norman F. Estrin, Ph.D.<br>Estrin Consulting Group LLC<br>9109 Copenhaver Drive<br>Potomac, MD 20854<br>Phone: (301) 279-2899<br>Fax: (301) 294-0126<br>Cell: 240-994-9999<br>Email: estrin@yourFDAconsultant.com |
| **Proprietary Name** | I.B.S.™ 2.0 Osteosynthesis screw |
| **Common name** | Bone fixation screw |
| **Device classification regulation** | 21 CFR 888.3040: Smooth or threaded metallic bone fixation screw or fastener<br>Class II |
| **Device Product Code and Panel** | HWC: screw, fixation, bone<br>87 orthopedics |

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| **Device Description** | The I.B.S™ 2.0 Osteosynthesis screw is a line extension of the existing compression screw line cleared in K131920 I.B.S™ Osteosynthesis screw.<br><br>The I.B.S.™ 2.0 Osteosynthesis screws are cannulated screws available in a compression design.<br>The cannulation of the screws provides a helpful feature during surgery, as a wire is used to guide insertion of the screw.<br>The compression design has a non-threaded shaft, allowing optimal compression between the two bone fragments, which may enhance bone osteosynthesis.<br><br>The I.B.S.™ 2.0 Osteosynthesis screws are self-drilling and self-tapping screws, which enables introduction of the screw without any preparation of the hole (using a drill and /or a tap) in most cases.<br><br>Sizes: The I.B.S.™ 2.0 Osteosynthesis screws are available in 2.0mm diameter, in length ranging from 10mm to 30mm.<br><br>Material: The I.B.S.™ 2.0 Osteosynthesis screws are manufactured from titanium alloy Ti6Al4V as per ISO 5832-3 and ASTM F136. They do not have any coatings.<br><br>Single use: The I.B.S.™ 2.0 Osteosynthesis screws are designed for single use only.<br><br>Sterilization: The I.B.S.™ 2.0 Osteosynthesis screws are supplied sterile, using gamma irradiation.<br><br>Place of use: The I.B.S.™ 2.0 Osteosynthesis screws are indicated for use in a hospital, or outpatient surgery center where sterile field may be created and maintained. |
| **Predicate Devices** | Vilex Cannulated Bone Screw Double Thread (K014154)<br>I.B.S.™ osteosynthesis screw (K131920)<br>SBI AUTOFIX screw (K052576) |
| **Indications for use:** | The I.B.S.™ 2.0 Osteosynthesis screws are intended for:<br>- The fixation of arthrodeses, osteotomies or fractures of small bones of the upper and lower limbs<br>- Osteosynthesis requiring mono or bicortical compression<br>The size of the chosen screw should be adapted to the specific indications. |
| **Comparison of Technological** | The technological characteristics of the I.B.S.™ 2.0 Osteosynthesis screws are equivalent to the characteristics of predicate devices in |

**characteristics** terms of design, size range, raw material. All these implants have the following features:

- Insertion into bone: The I.B.S.™ 2.0 Osteosynthesis screws and all predicate devices are intended for surgical implantation into bone for longer than 30 days.

- Compression design: This design corresponds to a non-threaded part allowing compression between two bone fragments. The I.B.S.™ 2.0 Osteosynthesis screws and all predicate devices have a non-threaded part allowing compression between two bone fragments.

- Design: The Vilex Cannulated Bone Screw Double Thread (K014154), the I.B.S.™ osteosynthesis screw (K131920) and the SBI AUTOFIX screw (K052576) predicates have similar design as the I.B.S.™ 2.0 Osteosynthesis screw. They all are cannulated, self-tapping and self-drilling screws with a compression design.

- Indications for use: The Vilex Cannulated Bone Screw Double Thread (K014154), the SBI AUTOFIX screw (K052576) and the I.B.S.™ osteosynthesis screw (K131920) predicates have equivalent indications for use as the I.B.S.™ 2.0 Osteosynthesis screw.

- Equivalent size range: The Vilex Cannulated Bone Screw Double Thread predicate (K014154) has similar size range of 2.0mm diameter and length from 10mm to 24mm as the I.B.S.™ 2.0 Osteosynthesis screw.
  The I.B.S.™ osteosynthesis screw predicate (K131920) has similar lengths from 12mm to 28mm as the I.B.S.™ 2.0 Osteosynthesis screw. The I.B.S.™ osteosynthesis screw predicate (K131920) has a comparable diameter of 2.5mm instead of 2.0mm for the I.B.S.™ 2.0 Osteosynthesis screw.
  The SBI AUTOFIX predicate (K050681) has identical size range of 2.0mm diameter and length from 10mm to 30mm as the I.B.S.™ 2.0 Osteosynthesis screw.

- Material: The I.B.S.™ 2.0 Osteosynthesis screw has identical raw material, when compared to the Vilex Cannulated Bone Screw Double Thread (K014154), the I.B.S.™ osteosynthesis screw (K131920) and the SBI AUTOFIX screw (K052576): all are manufactured from Titanium alloy Ti6Al4V, according to ISO 5832-3 and ASTM F136 standards.

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| **Substantial Equivalence Summary** | As described above, the I.B.S.™ 2.0 Osteosynthesis screws have similar technological characteristics when compared to the predicate devices. |

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| **Summary Performance Data** | Performance testing has been evaluated for I.B.S.™ 2.0 Osteosynthesis screws through mechanical comparison with predicate devices, animal and clinical testing being considered not applicable.<br><br>First, an engineering / dimensional comparison to the predicate SBI AUTOFIX screw diameter 2.0 (K052576) was performed to ascertain substantial equivalence. This dimensional comparison enabled to demonstrate substantial equivalence of the I.B.S.™ 2.0 Osteosynthesis screw and the predicate device SBI AUTOFIX screw diameter 2.0 (K052576) as far as the Torsional properties are concerned.<br><br>In addition, mechanical testing for I.B.S.™ 2.0 Osteosynthesis screws and Vilex Cannulated Bone Screw Double Thread (K014154) predicate device was performed according to ASTM F543-13. This standard describes methods to assess the torque to failure, insertion torque, axial pullout strength, and self-tapping performance of screws. Bench tests were performed to assess the torsional properties, driving torque and axial pullout of the I.B.S.™ 2.0 Osteosynthesis screws.<br><br>The results of the testing performed by the test laboratory indicate that the I.B.S.™ 2.0 Osteosynthesis screw met all acceptance criteria and/or showed similar results as the predicate device Vilex Cannulated Bone Screw Double Thread (K014154).<br>Therefore, the subject device was demonstrated to be as safe and effective as the above predicates |
| **CONCLUSION** | **Based on the evaluations and the results of the testing performed, the design and indications of the I.B.S.™ 2.0 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.** |