

MAY 01 2014

510(k) SUMMARY
In2Bones I.B.S.™ osteosynthesis screws

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Establishment registration number:	New Company. Will register following FDA clearance.
Date of preparation:	April 29, 2014
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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: 87 orthopedics

Device Description**Design and features:**

The I.B.S.[™] osteosynthesis screws are cannulated screws, available in a compression and a neutralization design. The cannulation of the screws provides a helpful feature during surgery, as a wire is used to guide insertion of the screw. The compression design has a non-threaded shaft, allowing optimal compression between the two bone fragments, which may enhance bone osteosynthesis.

The neutralization design is fully threaded and may be preferred when stabilization of the bone fragments without strong compression is required, as for example in some fractures in multiple fragments, or osteoporotic bone. Both designs 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.

Sizes:

The I.B.S.[™] osteosynthesis screws are available in 2.5mm, 3.0mm, 3.5mm, 4.5mm, 6.0mm, 6.5mm, and 8.0mm diameters, in length ranging from 20mm to 160mm.

Material:

The I.B.S.[™] osteosynthesis screws are manufactured from titanium alloy Ti6Al4V as per ISO 5832-3 and ASTM F136. They do not have any coatings.

Single use:

The I.B.S.[™] osteosynthesis screws are designed for single use only.

Sterilization:

The I.B.S.[™] osteosynthesis screws are supplied sterile, using gamma irradiation.

Place of use:

The I.B.S.[™] osteosynthesis screws are indicated for use in a hospital, or outpatient surgery center where sterile fields may be created and maintained. They are prescription devices.

**Predicate
Devices:****Compression design:**

Newdeal Stabilization screw (K050346)

SBI Autofix (K052576)

Synthes 7.0/7.3 cannulated screw (K962011)

Neutralization design:

Newdeal QWIX positioning screw (K071639)

Acumed Acutrak screws (K944330)

Synthes 7.0/7.3 cannulated screw (K962011)

Indications for use:	<p>The I.B.S.™ osteosynthesis screws are intended for:</p> <ul style="list-style-type: none"> - The fixation of arthrodeses, osteotomies or fractures of long or short bones of the upper and lower limbs - Osteosyntheses requiring a mono or bicortical compression <p>The size of the chosen screw should be adapted to the specific indication.</p>
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Comparison of the indications for use with the predicate devices:

As with the predicate devices, the I.B.S.™ osteosynthesis screws are indicated for surgical implantation longer than 30 days in the fixation of bone fractures or for bone reconstruction.

Comparison of Technological characteristics	<p>The technological characteristics of the I.B.S.™ osteosynthesis screws are the same as the characteristics of predicate devices in terms of indications for use and design. All the screws have the following features:</p> <ul style="list-style-type: none"> - Cannulated – the I.B.S.™ osteosynthesis screws and all the predicate devices are cannulated. - Made from Titanium alloys, with no new materials being introduced in the product – the IBS.™ osteosynthesis screws and all predicate devices are manufactured in Titanium alloy TA6V, except the SBI® AutoFix, which is manufactured in Stainless Steel 316L. - Compression design: non-threaded part allowing compression between two bone fragments – The I.B.S.™ Compression screw and all predicate devices have a non-threaded part allowing compression between two bone fragments - Neutralization design: fully threaded – The I.B.S.™ Neutralization screw and all predicate devices are fully threaded - Equivalent size range: The diameters and lengths covered by the predicate devices enable to cover all diameters and lengths of the I.B.S.™ osteosynthesis range.
Conclusions	<p>The I.B.S.™ osteosynthesis screw has a similar intended use, materials, dimensions, and designs when compared to the predicate devices. An engineering / dimensional comparison to the predicates was performed to demonstrate substantial equivalence. Based on these similarities, the I.B.S.™ osteosynthesis screws are substantially equivalent to the predicates identified in the 510(k) Summary.</p>



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

May 1, 2014

In2Bone SAS
% Norman F. Estrin, Ph.D.
Managing Partner
Estrin Consulting Group LLC
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K131920
Trade/Device Name: In2Bone I.B.SM 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: March 18, 2014
Received: March 19, 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

Page 2 – Dr. Norman F. Estrin

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 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: K131920

Device Name: I.B.S.™ osteosynthesis screw

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- The fixation of arthrodeses, osteotomies or fractures of long or short bones of the upper and lower limbs
- Osteosyntheses requiring a mono or bicortical compression

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

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

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OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K131920