28, chemin du Petit Bois
69130 Ecully - FRANCE
Tel. +33(0)4 72 29 26 26
Fax +33 (0)4 72 29 26 29
contact@in2bones.com
www.in2bones.com

APR 0 4 2014

004_Revised 510(k) Summary for I.B.S. Snap-off Screw (K132911) Response to September 17, 2013 RTA Checklist, Section A4a.pdf

510(k) SUMMARY
In2Bones I.B.S.® Snap-off screw

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
Date of preparation	August 1st, 2013
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	I.B.S.® Snap-off screw
Common name	Bone fixation screw
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 I.B.S.® Snap-off screw is a one-piece device made of Titanium Alloy intended to be used as a screw for bone reconstruction, osteotomy and fracture fixation of bones appropriate for the size of the device. The implant is a self-drilling and self-tapping snap-off screw. It is machined on the end of a drill shank which inserts into a driver. After insertion of the screw into the bone, the drill shank twists off and breaks cleanly from the screw head. The implant is supplied sterile and is available in various sizes diameters and lengths. Sizes: The I.B.S.® Snap-off screws are available in various diameters and lengths. Material: The I.B.S.® Snap-off screws are manufactured from titanium alloy TA6V as per ISO 5832-3 and ASTM F136. They do not have any coating. Single use: The I.B.S.® Snap-off screws are designed for single use only. Sterilization: The I.B.S.® Snap-off screws are supplied sterile, using gamma irradiation. Place of use: The I.B.S.® Snap-off screws are indicated for use in a hospital, or outpatient surgery center where sterile field may be created and maintained.
Predicate Devices	Integra / Newdeal Spin screw (K991477) Arthrex Low Profile Screws (K103705) Nexa Orthopedics / Nexa Bone screw (K053394)
Indications for use	The I.B.S.® Snap-off screws are indicated for bone reconstruction, osteotomy and fracture fixation of bones appropriate for the size of the device. Examples include: Mono-cortical fixation of small bone fragments Weil osteotomy Osteotomies and fractures fixation in the foot and hand.

COMPARISON OF THE INDICATIONS FOR USE WITH THE PREDICATE DEVICES:

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

510k number	K132911	K991477	K103705	K053394
manufacturer	In2Bones	Newdeal – an Integra Lifesciences company	Arthrex	Nexa Orthopedics / Tornier
Name of device	**I.B.S.® Snap-off screw**	SPIN® screw	Low Profile Screw - QuickFix	Nexa Bone screw system / NexFix
Use	Single use	Single use	Single use	Single use
Fixation	Bone	Bone	Bone	Bone
Indications for use	The I.B.S.® Snap-off screws are indicated for bone reconstruction, osteotomy and fracture fixation of bones appropriate for the size of the device. Examples include: Mono-cortical fixation of small bone fragments Weil osteotomy Osteotomies and fractures fixation in the foot and hand.	The SPIN® Snap-off screw is indicated for fixing the elective osteotomies of the mid-foot bones and the metatarsal and phalanges of the foot only. Examples include: Weil osteotomy Unicortical small bone fixation	The Arthrex Low Profile Screws (2.0-3.0mm solid) are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions in the ankle, foot, hand, and wrist.	The Nexa bone screw system provides fixation of fractures, fusions, or osteotomies of the hand and foot.

Comparison of Technological characteristics	The technological characteristics of the I.B.S.® Snap-off screw are the same as the characteristics of predicates devices in terms of intended use and design. All the screws have the following features: - Solid / non-cannulated – the I.B.S.® Snap-off screws and all predicate devices are solid / non-cannulated screws - Self-tapping and self-drilling, with a snap-off design - the I.B.S® Snap-off screws and all predicate devices are self-tapping and self-drilling screws with a snap-off mechanism - Material: made from Titanium alloys, with no new materials being introduced in the product - the I.B.S.® Snap-off screws and all predicate devices are manufactured from Titanium Alloy TA6V - Equivalent size range: the diameters and lengths covered by the predicate devices enable to cover diameters and lengths of the I.B.S.® Snap-off screws - Indicated for surgical implantation longer than 30 days - the I.B.S.® Snap-off screws and all predicate devices are indicated for surgical implantation longer than 30 days
Substantial Equivalence Summary	The **I.B.S.® Snap-off screw** has similar technological characteristics when compared to the predicate devices.
Summary Performance Data	Mechanical testing was performed according to ASTM F543-07. This standard describes methods to assess the torque to failure, insertion torque, axial pullout strength, and self-tapping performance of screws. The specification standard provides requirements for materials, finish, marking, care and handling, and the acceptable dimensions and tolerances for metallic bone screws implanted into bone tissue. As the specification standard states, the dimensions and tolerances are applicable only to metallic bone screws described in the specification itself. Additional information must be provided to document that the design of the product will provide adequate mechanical properties for the particular application. In addition, an engineering / dimensional comparison to the predicates was performed to ascertain substantial equivalence. The results of the testing performed by the test lab indicated that the **I.B.S.® Snap-off screw** performed as expected for each test.
CONCLUSION	**Based on the evaluations performed, the design and indications of the I.B.S.® Snap-off screw are substantially equivalent to the predicates 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 screws performed as expected for each test.** **The I.B.S.® Snap-off screws 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

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

April 4, 2014

Re: K132911
Trade/Device Name: I.B.S.® Snap-off 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 8, 2014
Received: March 11, 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

Indications for Use

510(k) Number (if known): K132911

Device Name: I.B.S® snap-off screw

Indications For Use:
The I.B.S® snap-off screws are intended for bone reconstruction, osteotomy and fracture fixation of bones appropriate for the size of the device.
Examples include :
Mono-cortical fixation of small bone fragments
Weil osteotomy
Osteotomies and fractures fixation in the foot and hand.

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 D. Frank -S

Division of Orthopedic Devices