In2Bones USA, LLC
% Christine Scifert
Executive Vice President
MRC-X, LLC
6075 Poplar Avenue, Suite 500
Memphis, Tennessee 38119

June 20, 2018

Re: K180377
Trade/Device Name: Fracture and Correction System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HRS
Dated: May 14, 2018
Received: May 16, 2018

Dear Christine Scifert:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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 on last page.*

510(k) Number *(if known)*

K180377

Device Name

In2Bones Fracture and Correction System

Indications for Use *(Describe)*

The In2Bones USA LLC, Fracture and Correction System plates and screws are intended to treat fractures, fusions, osteotomies and non-unions of the 5th metatarsal.

The Fracture and Correction System lag screws 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 of various bones, including humerus, radius, ulna, tibia, calcaneus, fibula, and small bones (metacarpals, metatarsals, and phalanges).

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

# 510(k) Summary

*In2Bones Fracture and Correction System*

*June 18, 2018*

**Company:** In2Bones USA, LLC
6060 Poplar Ave, Suite 380
Memphis, TN 38119
901-260-7931

**Primary Contact:** Christine Scifert

**Company Contact:** Rebecca Wahl

**Trade Name:** Fracture and Correction System

**Common Name:** Screw, Fixation, Bone
Plate, Fixation, Bone

**Classification:** II

**Regulation Number:** 888.3040 - Smooth or threaded metallic bone fixation fastener
888.3030 - Single/multiple component metallic bone fixation appliances and accessories

**Panel:** 87-Orthopedic

**Product Code(s):** HWC, HRS

**Device Description:** The In2Bones Fracture and Correction System is a system of plates and screws and surgical instruments used to treat fracture and reconstruction of the bones of the extremities. The scope of this submission is to add smaller diameter CoLag™ Screws as well as a version of all lag screws within the system that has a modified tip design. All screws are manufactured from Titanium Alloy conforming to ASTM F136.

**Indications for Use**: The In2Bones USA LLC, Fracture and Correction System plates and screws are intended to treat fractures, fusions, osteotomies and non-unions of the 5th metatarsal.

The Fracture and Correction System lag screws 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 of various bones, including humerus, radius, ulna, tibia, calcaneus, fibula, and small bones (metacarpals, metatarsals, and phalanges).

**Substantial Equivalence:** The subject components were demonstrated to be substantially equivalent to the following systems previously cleared by the FDA:

Primary Predicate

- K170518 – In2Bones Fracture and Correction System

Additional Predicates

- K052576 – AutoFix Screws
- K160174 – IBS 2.0mm Screws
- K143460 – Wright Medical Cannulated Screw System

See below for a comparison table of the subject and predicate devices.

| Device | **In2Bones Fracture and Correction System CoLag™ Screws (Subject Device)** | **In2Bones Fracture and Correction System (K170518)** | **AutoFix Screws (K052576)** | **IBS 2.0mm Screws (K160174)** | **Wright Medical Cannulated Screw System (K143460)** |
|---|---|---|---|---|---|
| **Intended Use** | Fixation Screws | Fixation Plates and Screws | Fixation Screws | Fixation Screws | Fixation Screws |
| **Indications for Use** | The In2Bones USA LLC, Fracture and Correction System plates and screws are intended to treat fractures, fusions, osteotomies and non-unions of the 5th metatarsal.<br><br>The Fracture and Correction System lag screws 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 of various bones, including humerus, radius, ulna, tibia, calcaneus, fibula, and small bones (metacarpals, metatarsals, and phalanges). | The In2Bones USA LLC, Fracture and Correction System plates and screws are intended to treat fractures, fusions, osteotomies and non-unions of the 5th metatarsal.<br><br>The Fracture and Correction System lag screws 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 of various bones, including humerus, radius, ulna, tibia, calcaneus, fibula, and small bones (metacarpals, metatarsals, and phalanges). | The SBi AutoFIX Twin Pitch Cannulated Compression Screw System implants are indicated in the treatment of fractures, non-unions, pseudoarthrosis and degenerative changes as well as corrective osteotomies geared towards a functionally stable osteosynthesis in small bones. | The IBS 2.0 Osteosynthesis screws are intended for:<br>- The fixation of arthrodesis, 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. | The CSS cannulated bone screw is indicated for bone fractures, osteotomies, arthodeses, osteochronditis and tendon reattachment. These screws are not intended for attachment or fixation to the posterior elements (pedicles) of cervical, thoracic, or lumbar spine. |
| **Product Code** | HRS, HWC | HRS, HWC | HWC | HWC | HWC |
| **Material** | Titanium Alloy (ASTM F136) | Titanium Alloy (ASTM F136) | Stainless Steel | Titanium Alloy (ASTM F136) | Titanium Alloy |
| **Geometry and Dimensions** | **2.0mm, 8-55mm Length**<br>**2.5mm, 8-10mm Length**<br>**2.5mm, 8-55mm Length**<br>**3.0mm, 12-40mm Length**<br>**4.0mm, 20-60mm Length**<br>**5.0mm, 30-70mm Length**<br>**6.7mm, 30-115mm Length** | **2.5mm, 12-30mm Length**<br>**3.0mm, 12-40mm Length**<br>**4.0mm, 20-60mm Length**<br>**5.0mm, 30-70mm Length**<br>**6.7mm, 30-115mm Length** | **2.0mm, 10-30mm Length**<br>**2.5mm 10-30mm Length**<br>**3.0mm 12-40mm Length**<br>**4.0mm 20-50mm Length**<br>**6.5mm 45-100mm Length** | **2.0mm, 10-30mm Length** | **2.0mm, 7-50mm Length**<br>**2.5mm, 10-50mm Length**<br>**3.0mm, 12-50mm Length**<br>**3.5mm, 12-50mm Length**<br>**4.0mm, 14-50mm Length** |

The subject Fracture and Correction System components have been demonstrated to be substantially equivalent to the previously cleared devices cleared under K170518, K052576, K160174, and K143460 as the products are similar in indications, materials and geometry.

**Performance Testing / Rationales:** Insertion/Removal Testing, Static Pull-out Testing, and Torque Capacity Testing per ASTM F543 demonstrated that the subject device is substantially equivalent to the predicate. The implants and instruments that are the subject of this submission were determined not to be worst case and were adopted into previous validations conducted for biocompatibility, cleaning, sterilization and packaging. LAL endotoxin testing was confirmed to be conducted on each implant batch.

**Conclusion**

Based on the test results, nonclinical tests and rationales and the comparison to the predicate devices, the subject device is as safe and as effective and performs as well as or better than the legally marketed predicates and therefore is determined to be substantially equivalent to the predicate devices.