



August 8, 2019

In2Bones USA, LLC
Christine Scifert
VP of Quality and Regulatory
6000 Poplar Ave, Suite 115
Memphis, Tennessee 38119

Re: K190385

Trade/Device Name: CoLink Plating System, Fracture and Correction System, RTS Implant System,
NeoSpan Compression Staple System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories

Regulatory Class: Class II

Product Code: HRS, HWC, KWH, JDR

Dated: July 9, 2019

Received: July 10, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

List of Cleared Devices in K190385

List of Cleared Devices in K190385

1. CoLink® Plating System / CoLink® View Plating System / CoLink® Afx Plating System
2. Fracture and Correction System (5MST™ and CoLag™)
3. NeoSpan® Compression Staple Implant with Instruments
4. RTS® Silicone Toe System

Indications for Use

510(k) Number (if known)

K190385

Device Name

CoLink® Plating System / CoLink® View Plating System / CoLink® Afx Plating System

Indications for Use (Describe)

The In2Bones USA LLC, CoLink™ Plating System is indicated for stabilization and fixation of fractures, revision procedures, joint fusion, osteotomies and reconstruction of the small bones in the hand, wrist, foot and ankle in both pediatric and adult patients.

The In2Bones USA LLC, CoLink™ Afx Plating System is indicated for stabilization and fixation of fractures and osteotomies in the ankle, including tibia and fibula, in both pediatric and adult patients.

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)

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Indications for Use

510(k) Number (if known)

K190385

Device Name

Fracture and Correction System (5MS™ and CoLag™)

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)

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Indications for Use

510(k) Number (if known)

K190385

Device Name

NeoSpan® Compression Staple Implant with Instruments

Indications for Use (Describe)

The In2Bones NeoSpan® Compression Staple Implant w/instruments is indicated for hand and foot bone fragments, osteotomy fixation and joint arthrodesis.

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)

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Indications for Use

510(k) Number (if known)

K190385

Device Name

RTS® Silicone Toe System

Indications for Use (Describe)

The RTS® Flexible 1ST MPJ Implant w/Grommets is intended for use in the treatment of:

- Hallux limitus or hallux rigidus
- Painful rheumatoid arthritis
- Hallux abducto valgus associated with arthritis
- Unstable or painful joint from previous surgery

The RTS® Lesser MTP Implant is intended for use in the treatment of:

- Partial or complete dislocation of the lesser metatarsophalangeal joint
- Pain associated with either rheumatoid or osteoarthritis
- Repair of unsuccessful arthroplasties of the lesser metatarsophalangeal joint
- Stiffness at the lesser metatarsophalangeal joint associated with joint disease
- Hammertoe deformity where the proximal phalanx is dorsally located on the metatarsal in a fixed contracture state.

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)

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510(k) Summary
In2Bones USA, LLC – MR Labeling
July 9, 2019

Company: In2Bones USA, LLC
6000 Poplar Ave, Suite 115
Memphis, TN 38119
901-260-7931

Company Contact: Christine Scifert

Trade Name: CoLink® Plating System
CoLink® View Plating System
CoLink® Afx Plating System
RTS® Silicone Toe System
NeoSpan® Compression Staple System with Instruments
Fracture and Correction System

Common Name: Plate, Fixation, Bone
Screw, Fixation, Bone
Prosthesis, Toe, Constrained, Polymer
Staple, Fixation, Bone

Classification: II

Regulation Number: 888.3030 - Single/multiple component metallic bone fixation appliances
and accessories
888.3040 - Smooth or threaded metallic bone fixation fastener
888.3720 – Toe joint polymer constrained prosthesis

Panel: 87-Orthopedic

Product Code(s): HRS, HWC, KWH, JDR

Device Description:

The In2Bones CoLink® Plating System / CoLink® View Plating System is a system of plates and screws and surgical instruments used to treat fracture and reconstruction of the bones of the extremities. The CoLink® Afx Plating System is a system of plates and screws and surgical instruments used to treat traumatic fractures and osteotomies of the ankle. The products are made of ASTM F 136 Titanium

6Aluminum 4Vanadium Alloy (Ti6Al4V) and the CoLink® View System has inserts made of ASTM F 2026 Poly Ether Ether Ketone (PEEK).

The Fracture and Correction System consists of the 5MS® Plate and Screw System and the CoLag® cannulated lag screws used to treat fracture and reconstruction of the bones of the extremities. The products are made of ASTM F 136 Titanium 6Aluminum 4Vanadium Alloy (Ti6Al4V).

The RTS® Lesser MTP Implant System is a double stem silicone implant which is placed into the intramedullary canals of the first metatarsal and proximal phalangeal bones of the forefoot. The RTS® Flexible 1st MPJ Implant w/Grommets System is a flexible silicone great toe implant. Titanium grommets are also available for use in the first metatarsal (only) if the option is desired by the surgeon. The implant is used in the treatment of arthritis of the metatarsophalangeal joint. The implants are made from silicone elastomer NuSil Med 4755 from NuSil.

The In2Bones NeoSpan® Compression Staple Implant is a super elastic compression staple made of superelastic Nitinol (ASTM F2063). The devices are available in multiple sizes. The implant is designed to hold bones together until healing occurs.

Indications for Use:

CoLink® Plating System / CoLink® View Plating System / CoLink® Afx Plating System

The In2Bones USA LLC, CoLink™ Plating System is indicated for stabilization and fixation of fractures, revision procedures, joint fusion, osteotomies and reconstruction of the small bones in the hand, wrist, foot and ankle in both pediatric and adult patients.

The In2Bones USA LLC, CoLink™ Afx Plating System is indicated for stabilization and fixation of fractures and osteotomies in the ankle, including tibia and fibula, in both pediatric and adult patients.

RTS® Silicone Toe System

The RTS® Flexible 1ST MPJ Implant w/Grommets is intended for use in the treatment of:

- Hallux limitus or hallux rigidus
- Painful rheumatoid arthritis
- Hallux abducto valgus associated with arthritis
- Unstable or painful joint from previous surgery

The RTS® Lesser MTP Implant is intended for use in the treatment of:

- Partial or complete dislocation of the lesser metatarsophalangeal joint
- Pain associated with either rheumatoid or osteoarthritis
- Repair of unsuccessful arthroplasties of the lesser metatarsophalangeal joint
- Stiffness at the lesser metatarsophalangeal joint associated with joint disease
- Hammertoe deformity where the proximal phalanx is dorsally located on the metatarsal in a fixed contracture state.

NeoSpan® Compression Staple Implant with Instruments

The In2Bones NeoSpan® Compression Staple Implant w/instruments is indicated for hand and foot bone fragments, osteotomy fixation and joint arthrodesis.

Fracture and Correction System (5MS™ and CoLag™)

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:
 - K182402 – CoLink View Plating System
- Secondary Predicates:
 - K180377 – Fracture and Correction System
 - K181113 – CoLink Afx Plating System
 - K173491 – RTS Lesser MTP Implant System
 - K172300 – CoLink View Plating System
 - K170518 – In2Bones Fracture and Correction System
 - K163293 – CoLink Plating System
 - K161426 – NeoSpan Compression Staple Implant with Instruments
 - K153609 – RTS Flexible 1 MPJ Implant with Grommets
- Reference Predicates:
 - K160553 – DePuy Synthes MR Conditional Labeling
 - K172975 – DePuy Synthes MR Conditional Labeling
 - K152631 – MPO Total Knee Systems MR Labeling

The subject In2Bones USA, LLC product families have been demonstrated to be substantially equivalent to the previously cleared devices identified above as the products are identical in indications, materials and geometry. The only modification is the addition of MR labeling.

Performance Testing:

MR Testing per ASTM Standards (ASTM F2052, ASTM F2213, ASTM F2182 and ASTM F2119) was conducted on worst case products to cover all In2Bones product families.

Conclusion

Based on the test results and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.