January 17, 2020

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

Re: K193543
Trade/Device Name: CoLink Plating System, Fracture and Correction System, CoLink Mini Plating System, CoLink View Plating System, CoLink Afx Plating 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
Dated: December 16, 2019
Received: December 20, 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 devices cleared in K193543

List of devices cleared in K193543

1. CoLink® Plating System / CoLink® View Plating System / CoLink® Afx Plating System / CoLink® Mini Plating System
2. Fracture and Correction System (5MS™ and CoLag™)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193543

Device Name

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

Indications for Use *(Describe)*

The In2Bones USA LLC, CoLink® Plating System / CoLink® View Plating System / CoLink® Mini 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193543

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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510(k) Summary

In2Bones USA, LLC – MR Labeling

January 17, 2020

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
CoLink® Mini Plating System
Fracture and Correction System

Common Name: Plate, Fixation, Bone
Screw, 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

Panel: 87-Orthopedic

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

Device Description:

The In2Bones CoLink® Plating System / CoLink® View Plating System / CoLink® Mini Plating System and Fracture and Correction System are previously cleared plate and screws systems. The scope of this submission is to add a new packaging system for the previously cleared screws. The screws are all made of ASTM F 136 Titanium 6Aluminum 4Vanadium Alloy (Ti6Al4V). The implants are MR conditional.

Indications for Use:

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

The In2Bones USA LLC, CoLink® Plating System / CoLink® View Plating System / CoLink® Mini 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.

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:
  - K191535 – CoLink Mini Plating System
- Secondary Predicates:
  - K182402 / K172300 – CoLink View Plating System
  - K180377 – Fracture and Correction System
  - K181113 – CoLink Afx Plating System
  - K170518 – In2Bones Fracture and Correction System
  - K163293 – CoLink Plating System

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 adding a new packaging system for the previously cleared screws.

Performance Testing:

Sterilization (ISO 11137), packaging (ISO 11607), shelf life (ASTM F1980) and biocompatibility (ISO 10993-1) validations and rationales were conducted and provided to demonstrate substantial equivalence. LAL endotoxin testing was confirmed to be conducted on each implant batch.

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.