



July 15, 2020

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

Re: K201149

Trade/Device Name: CoLink 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, HTN

Dated: July 2, 2020

Received: July 6, 2020

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali, M.P.H.  
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

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)

K201149

Device Name

CoLink® Plating System

Indications for Use (Describe)

CoLink® 2 Plating System -

The In2Bones USA, 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.

CoLink® Afx Plating System -

The In2Bones USA, 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.

The In2Bones USA CoLink® Afx Plating System screws are intended to be used as stand-alone bone screws, or in a plate-screw system for fracture fixation.

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.

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**510(k) Summary**  
*CoLink® Plating System*  
*July 2, 2020*

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

**Primary Contact:** Christine Scifert

**Company Contact:** Rebecca Wahl

**Trade Name:** CoLink® Plating System

**Common Name:** Plate, Fixation, Bone  
Screw, Fixation, Bone  
Washer, Bolt Nut

**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, HWC, HTN

**Device Description:** The In2Bones CoLink® 2 Plating System is a system of plates and screws and surgical instruments used to treat fractures and reconstruction of the bones of the extremities. These subject devices are part of the overarching CoLink® Plating System and will be commonly referred to as the CoLink® 2 Plating System. In addition, a washer is being added to the CoLink® Afx Plating System.

**Indications for Use:**

CoLink® 2 Plating System

The In2Bones USA, 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.

### CoLink® Afx Plating System

The In2Bones USA, 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.

The In2Bones USA CoLink® Afx Plating System screws are intended to be used as stand-alone bone screws, or in a plate-screw system for fracture fixation.

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

#### Primary Predicate

- K163293 – In2Bones CoLink® Plating System

#### Additional Predicates

- K172300 – In2Bones CoLink® View Plating System
- K181113 – In2Bones CoLink® Afx Plating System
- K170518 – In2Bones Fracture and Correction System
- K200762 – In2Bones CoLink® Cfx Plating System

The subject CoLink® Plating System is made of Titanium Alloy and has been demonstrated to be substantially equivalent to the previously cleared devices identified above as the products are similar in indications, materials and geometry.

**Performance Testing:** No additional mechanical testing was required for the CoLink® 2 Plating System. The 3.0mm screws are nearly identical to previously cleared screws and no new worst-case plates or screws were added. A rationale was conducted related to the CoLink® Plating four-point bend testing per ASTM F382 to show the subject plates are substantially equivalent to the predicate plates. A rationale was conducted related to the plate screws of the predicate CoLink® system for axial pullout, torque capacity and insertion torque characteristics per ASTM F543. The CoLink® 2 Plating System components and CoLink® Afx washers are not considered a worst case for sterilization, biocompatibility, shelf life and pyrogenicity and were adopted into the previous validations for the CoLink® Afx System (K181113). An assessment was conducted regarding MR environment and labeling, including RF induced heating simulation, and it was determined that the CoLink® 2 components are not considered a worst case compared to K163293. Bacterial endotoxin testing (LAL) is performed on each lot.

### **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.