April 23, 2020

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

Re: K200762
Trade/Device Name: CoLink Cfx 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: March 23, 2020
Received: March 24, 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) 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

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)*

K200762

Device Name

CoLink® Cfx Plating System

Indications for Use *(Describe)*

The In2Bones USA LLC, CoLink® Cfx System is indicated for stabilization and fixation of fractures, revision procedures, osteotomies and reconstruction of the small bones in the foot and ankle including the calcaneus 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.

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510(k) Summary

CoLink® Cfx Plating System

April 10, 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® Cfx Plating System

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

Classification: II

Regulation Number: 888.3030 - Single/multiple component metallic bone fixation appliances and accessories

Panel: 87-Orthopedic

Product Code(s): HRS, HWC

Device Description: The In2Bones CoLink® Cfx Plating System is a system of plates and screws and surgical instruments intended for stabilization and fixation of calcaneal fractures and osteotomies. These subject devices are part of the overarching CoLink® Plating System and will be commonly referred to as the CoLink® Cfx Plating System.

Indications for Use: The In2Bones USA LLC, CoLink® Cfx System is indicated for stabilization and fixation of fractures, revision procedures, osteotomies and reconstruction of the small bones in the foot and ankle including the calcaneus in both pediatric and adult patients.

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

- K182148 – Paragon 28 Silverback Gorilla Plating System
- K181113 – In2Bones CoLink® Afx Plating System

Similar to the primary predicate device (K163293), the subject CoLink® Cfx Plating System is made of Titanium Alloy and provided sterile. The CoLink® Cfx Plating System has similar indications to the CoLink® Plating System (K163293) and Silverback Gorilla Plating System (K182148). This submission is adding additional plates for the calcaneus that will be used with previously cleared screws. The 3.5mm and 4.0mm screws initially cleared in the CoLink® Afx Plating System (K181113) can be used with the CoLink® Cfx Plating System. The previously cleared CoLag® screws (K170518 and K180377) that are intended to be used as stand-alone screws can also be used during the procedure with the CoLink® Cfx Plating System, but would not be used in conjunction with the plates or screws. The subject plates and screws have 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® Cfx Plating System. The 3.5mm and 4.0mm screws are identical to previously cleared screws and no new worst-case plates were added. Engineering analysis was conducted related to the CoLink® Plating four-point bend testing performed per ASTM F382 to show the subject plates are substantially equivalent to the predicate plates. The CoLink® Cfx Plating System is not a worst case for sterilization, biocompatibility, shelf life and pyrogenicity and was adopted into the previous validations for the CoLink® Afx System (K181113). 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.