November 18, 2021

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

Re: K212487
Trade/Device Name: CoLink Vallux 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: August 6, 2021
Received: August 9, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212487

Device Name
CoLink Vallux Plating System

Indications for Use *(Describe)*
The In2Bones USA, CoLink Vallux Plating System is indicated for fixation of translational osteotomies and corrective procedures of the hallux and associated disorders such as hallux valgus.

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 Vallux Plating System

November 18, 2021

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

Primary Contact: Christine Scifert

Trade Name: CoLink Vallux Plating System

Common Name: Plate, Fixation, Bone (Primary)
Screw, Fixation, Bone

Classification: II

Regulation Number: 888.3030 (Primary) - 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 Vallux Plating System includes a plate and screws and surgical instruments used to treat Hallux Valgus and reconstruction of bone for bunion corrections. These subject devices are part of the overarching CoLink® Plating System and will be commonly referred to as the CoLink Vallux Plating System.

Indications for Use: The In2Bones USA, CoLink Vallux Plating System is indicated for fixation of translational osteotomies and corrective procedures of the hallux and associated disorders such as hallux valgus.

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

- K181872 – CrossRoads MiniBunion®
- K153204 – In2Bones Kirschner Wire
- K191535 – In2Bones CoLink® Mini Plating System
- K181113 – In2Bones CoLink® Afx Plating System

The subject CoLink Vallux 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 Vallux Plating System. The 2.4mm and 2.7mm screws are identical to previously cleared screws and no new worst-case plate or screws were added. A rationale was conducted related to the CoLink Plating System, CoLink Mini Plating System and the In2Bones Kirschner Wire related to four-point bend testing per ASTM F382 to show the subject plate is substantially equivalent to the predicate plates. The CoLink Vallux Plating System was adopted into previously provided sterilization, packaging and endotoxin validations.

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.