



June 15, 2018

In2Bones USA, LLC
% Christine Scifert
Exec VP
Mrc-x, LLC
6075 Poplar Avenue, Suite 500
Memphis, Tennessee 38119

Re: K181113

Trade/Device Name: 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: April 26, 2018
Received: April 27, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K181113

Device Name

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K181113

510(k) Summary
CoLink™ Afx Plating System
June 15, 2018

Company: In2Bones USA, LLC
6060 Poplar Ave, Suite 380
Memphis, TN 38119
901-260-7931

Primary Contact: Christine Scifert

Company Contact: Rebecca Wahl

Trade Name: CoLink™ Afx 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
888.3040 - Smooth or threaded metallic bone fixation fastener

Panel: 87-Orthopedic

Product Code(s): HRS, HWC

Device Description: The In2Bones CoLink™ Afx Plating System is a system of plates and screws and surgical instruments used to treat traumatic fractures and osteotomies of the ankle. These subject devices are part of the overarching CoLink™ Plating System and will be commonly referred to as the CoLink™ Afx Plating System.

Indications for Use: 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.

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™ Plating System
- K983495- Syntec-Taichung Plates
- K151886- Acumed Ankle Fracture System Gen III
- K011335 – Synthes One-Third Tubular DCL Plate

The subject CoLink™ Plating System made of Titanium Alloy and Commercially Pure Titanium and 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: Static and fatigue four-point bend testing was performed per ASTM F382 on the subject CoLink™ Afx Plates and the results show the subject plates to be substantially equivalent to the predicate plates. Torsional strength, including insertion/removal torque, and axial pullout testing was performed per ASTM F543 on the subject CoLink™ Afx Screws and the results show the subject screws to be substantially equivalent to the predicate screws. Bacterial endotoxin testing (LAL) was performed.

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.