In2Bones USA, LLC
Christine Scifert
Senior Director of Regulatory Affairs
6060 Poplar Ave, Suite 380
Memphis, Tennessee 38119

September 27, 2018

Re: K182402
Trade/Device Name: CoLink View 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 31, 2018
Received: September 4, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Jesse Muir -S
2018.09.27 18:49:41 -04'00'

For
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*

K182402

Device Name
CoLink(r) View Plating System

Indications for Use *(Describe)*

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

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

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"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."

510(k) Summary

CoLink® View Plating System

Special 510(k)

September 25, 2018

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

Primary Contact: Christine Scifert

Trade Name: CoLink® View 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® Plating System is a system of plates and screws and surgical instruments used to treat fracture and reconstruction of the bones of the extremities. Previous clearances include plates made from ASTM F 136 Titanium 6Aluminum 4Vanadium Alloy (Ti6Al4V ELI) material (K163293) and plates that include inserts made of ASTM F 2026 Poly Ether Ether Ketone (PEEK) or ASTM F 136 Titanium 6Aluminum 4Vanadium Alloy (Ti6Al4V ELI) materials (K172300). The PEEK material cleared previously was from the supplier, Evonik Industries. The scope of this submission is to modify the supplier of the PEEK material from Evonik Industries to Invibio Biomaterial Solutions. There is no design change to the implants and the instruments used with the system are identical. The Invibio PEEK material meets ASTM F 2026.

Indications for Use: The In2Bones USA LLC, CoLink® Plating System/CoLink® View 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

- K172300 – InBones USA CoLink™ View Plating System

Additional Predicates

- K163293 – In2Bones USA CoLink™ Plating System

Reference Predicates

- K181113 – In2Bones USA CoLink™ Afx Plating System
- K173616 – In2Bones SAS DIP Arthrodesis System

The subject PEEK components from CoLink® View Plating System have been shown to be substantially equivalent to the previously cleared devices cleared under K163293 and K172300 as the products are identical in indications, materials and geometry.

Performance Testing: No additional mechanical testing or validations were required to establish substantial equivalence.

Conclusion

Based on the material information provided for Invibio and the comparison to the predicate devices, the subject device is determined to be substantially equivalent to the predicate devices.