DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 5, 2017

In2Bones USA, LLC
% Louise Focht
President
Enmed International, Inc
PO Box 249
Del Mar, California 92014

Re: K163293
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
Dated: April 1, 2017
Received: April 4, 2017

Dear Ms. Focht:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

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 below.

510(k) Number *(if known)*
K163293

Device Name

CoLink™ 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.

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.

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510(k) Summary of Safety and Effectiveness
K163293

Summary of 510 (k) safety and effectiveness information upon which the substantial equivalence determination is based:

I. Submitter

Date Prepared:	May 4, 2017
Device Submitter:	In2Bones USA, LLC 6060 Poplar Avenue, Suite 380 Memphis, TN 38119
Phone:	901-260-7931
Contact Person:	Louise Focht

II. Device

Proprietary Name:	Colink™ Plating System
Common Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener.
Regulatory Class:	21 CFR 888.3030, Class II 21 CFR 888.3040, Class II
Product Code:	87 HRS, HWC

III. Predicate Device

Predicate Device:	Stryker (Memometal) Anchorage Bone Plate System, K083447 Integra Total Foot System, K123000
Reference Device:	In2Bones SAS, I.B.S. Osteosynthesis screws, K131920 In2Bones USA, RTS System, K153609 In2Bones USA, NeoSpan, K161426

IV. 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.

V. Intended Use and 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.

VI. Comparison of technological characteristics with the predicate device

The In2Bones USA CoLink™ Plating System and the legally marketed predicate device have the same intended use and similar indications for use, similar dimensions, geometry and materials. The In2Bones device and the predicate are both available in multiple sizes and various shapes. The plates are attached to bone using various diameter and length screws. The In2Bones USA CoLink™ System is made from titanium alloy.

VII. Performance Data

Testing including bacterial endotoxin, static driving torque, static pullout, static torsion, screw/plate push through, static bending, fatigue bending and pullout fixation were performed. The results of the testing demonstrate that the device is substantially equivalent to the predicate device identified.

VIII. Conclusions

The In2Bones USA CoLink™ Plating System when compared to the predicate have similar intended use and indications for use, technological characteristics, and principals of operation as the predicate device. Thus, the In2Bones USA Colink™ Plating System design characteristics do not raise any new types of questions of safety or effectiveness and thus is substantially equivalent to the predicate device.