In2Bones USA, LLC
Ms. Christine Scifert
VP, QA & RA
6000 Poplar Ave, Suite 115
Memphis, Tennessee 38119

May 4, 2021

Re: K203698
Trade/Device Name: CoLink® Sfx Implant System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HTY
Dated: April 6, 2021
Received: April 7, 2021

Dear Ms. 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,

for

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*
K203698

Device Name
CoLink® Sfx Implant System

Indications for Use *(Describe)*
The In2Bones USA CoLink® Sfx Implant System is a system of implantable K-wires and caps indicated for temporary fixation and stabilization of bone fractures and reconstructions. In addition, the K-wires can be used as guide pins for insertion of other implants. The caps are indicated for use in the protection of protruding ends of wires.

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® Sfx Implant System

April 2, 2021

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

Primary Contact: Christine Scifert

Trade Name: CoLink® Sfx Implant System

Common Name: Pin, Fixation, Smooth

Classification: II

Regulation Number: 888.3040 – Smooth or threaded metallic bone fixation fastener

Panel: 87-Orthopedic

Product Code(s): HTY

Device Description: The CoLink® Sfx Implant system is a system of implantable k-wires with tip protectors (caps) used to provide temporary fixation and stabilization of fractured bones of the extremities. The k-wire is made from stainless steel (ASTM F138) and the tip protectors are made from polyethylene. The tip protectors are not implantable and are for protection for protruding ends of wires. These subject devices are part of the overarching CoLink® Plating System.

Indications for Use: The In2Bones USA CoLink® Sfx Implant System is a system of implantable K-wires and caps indicated for temporary fixation and stabilization of bone fractures and reconstructions. In addition, the K-wires can be used as guide pins for insertion of other implants. The caps are indicated for use in the protection of protruding ends of wires.

Substantial Equivalence: The subject components were demonstrated to be substantially equivalent to the following systems previously cleared by the FDA:

Primary Predicate

- K153204 – In2Bones Kirschner Wire

Additional Predicates

- K022599 & K022597 – New Deal K Wire and K-Fix®
- K132895 – Wright Medical WMT Implantable K-wires

Reference Device

- K163293 – CoLink® Plating System

Similar to the primary predicate device (K153204), the subject CoLink® Sfx Implant System is made of Stainless and provided sterile. The CoLink® Sfx Implant System has similar indications to the New Deal K Wire and K-Fix® (K022599 & K022597) and Wright Medical WMT Implantable K-wires (K132895). This submission is adding k-wires and protective caps to the CoLink® family. The subject k-wires and caps 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® Sfx Implant System as the subject wires are not considered a worst case based on engineering analysis comparing the subject implants to legally marketed predicates. The protector caps do not require mechanical testing as they will not see any mechanical loading. Validations and risk assessments were conducted for the CoLink® Sfx Implant System for sterilization (ISO 11137-2), biocompatibility (ISO 10993-1), packaging and shelf life (ISO 111607-1) and pyrogenicity (ANSI-AAMI ST72). 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.