



August 13, 2024

In2Bones USA
Christine Scifert
VP of Quality Assurance & Regulatory Affairs
6000 Poplar Ave, Suite 115
Memphis, Tennessee 38119

Re: K241387

Trade/Device Name: CoLink NeoFuse MIS 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: May 13, 2024
Received: May 15, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher Ferreira -S

Christopher Ferreira, M.S.
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

Indications for Use

510(k) Number (if known)
K241387

Device Name
CoLink® NeoFuse MIS Plating System

Indications for Use (Describe)

The CoLink® NeoFuse MIS Plating System is a fusion plate indicated for anterior fixation of ankle arthrodesis and fractures, including the distal tibia and talus.

The addition of a posterior compression screw and a fully threaded screw through the tibiotalar joint (example CoLag 6.7mm screw) are required for ankle fusion procedure.

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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K241387
510(k) Summary
CoLink® NeoFuse MIS Plating System
August 12, 2024

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

Primary Contact: Christine Scifert

Trade Name: CoLink® NeoFuse MIS 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 CoLink® NeoFuse MIS Plating System includes sterile fusion plates and screws for anterior fixation of ankle arthrodesis and fractures, including the distal tibia and talus. The addition of a medial-lateral compression screw through the tibiotalar joint is required. These subject devices are a line extension of the CoLink® NeoFuse Plating System.

Indications for Use:

The CoLink® NeoFuse MIS Plating System is a fusion plate indicated for anterior fixation of ankle arthrodesis and fractures, including the distal tibia and talus.

The addition of a posterior compression screw and a fully threaded screw through the tibiotalar joint (example CoLag 6.7mm screw) are required for ankle fusion procedure.

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

Primary Predicate

- K213069 – In2Bones CoLink® NeoFuse Plating System

Additional Predicate

- K173121 – In2Bones SAS NeoFuse Ankle Fusion Plating System

Reference Devices

- K181113 – In2Bones CoLink® Afx Plating System
- K170518 – In2Bones Fracture and Correction System
- K213698 – In2Bones CoLink® PCR Plating System

A comparison of the technological similarities and differences between the subject and predicate devices is shown below.

Device	CoLink® NeoFuse MIS Plating System (Subject Device)	CoLink® NeoFuse Plating System (K213069)	In2Bones SAS NeoFuse Ankle Fusion Plating System (K173121)
Intended Use	Fixation Plates and Screws	Fixation Plates and Screws	Fixation Plates and Screws
Indications for Use	<p>The CoLink® NeoFuse MIS Plating System is a fusion plate indicated for anterior fixation of ankle arthrodesis and fractures, including the distal tibia, talus, and calcaneus.</p> <p>The addition of a posterior compression screw and a fully threaded screw through the tibiotalar joint (example CoLag 6.7mm screw) is required.</p>	<p>The CoLink® NeoFuse Plating System is a fusion plate indicated for anterior fixation of ankle arthrodesis and fractures, including the distal tibia, talus, and calcaneus.</p> <p>The addition of a compression screw through the tibiotalar joint (example CoLag 6.7mm screw) is required.</p>	<p>The In2Bones NeoFuse Ankle Fusion plating system is indicated for anterior fixation of ankle arthrodesis and fractures, including the distal tibia, talus and calcaneus.</p> <p>The addition of a compression screw through the tibiotalar joint (example IBS 6.5mm screw) is required.</p>
Product Code	HRS, HWC	HRS, HWC	HRS, HWC
Material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)
Geometry and Dimensions	<p>Available in 2 configurations: Standard and Ø3.5mm Talar Holes</p> <p>Screws: Talar fixation: Either 4.5mm, or 3.5mm locking, non-locking or VAL screw; also 5.0mm non-locking cancellous for the standard plate Tibial fixation: 4.5mm locking, non-locking or VAL screw or 5.0mm non-locking cancellous screw</p>	<p>Available in 2 styles, 2 sizes each: Anterior and Anterolateral, 3 Hole and 5 Hole.</p> <p>Screws: Talar fixation: 3.5mm locking, non-locking or VAL screw; Tibial fixation: 4.5mm locking, non-locking or VAL screw; Transverse screw: 4.5mm non-locking screw.</p>	<p>Available in 1 size only</p> <p>Screws: Talar fixation: 3.5mm locking screw with washer; Tibial fixation: 4.5mm locking screw with washer; Transarticular screw: 4.5mm cortical screw.</p>
	<p>Plate Length:1.87in Plate Thickness: .098in - .140in Shaft width: .410in - .453in Talar width:.816in</p>	<p>Plate Length:3.10in– 4.28in Plate Thickness: .098in - .123in Shaft width: .460in - .492in Talar width: .953-1.020in</p>	<p>Plate Length: 3.7in (94mm) Plate Thickness: .138in (3.5mm) Shaft width: .497in (12.54mm) Talar width: 1.020in (25.9mm)</p>

Performance Testing: Testing was conducted per a modified ASTM F382 set up for the plates for the CoLink NeoFuse MIS Plating System and the plates were found to be substantially equivalent. The test setup was modified from ASTM F382 to more accurately simulate anticipated mechanical loading on the plate in vivo. No additional mechanical testing was required for the screws. The CoLink NeoFuse MIS Plating System was validated per ISO 10993-1 for biocompatibility, ISO 11137-2 for gamma sterilization and ISO 11607-1 for packaging. Endotoxin testing was completed per ANSI/AAMI ST72.

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.