May 30, 2026

In2Bones USA, LLC
Tina Mornak
Manager, Regulatory Affairs
7750a Trinity Road
Cordova, Tennessee 38018

Re: K261154
Trade/Device Name: CoLink® & CoLag® Non-Sterile Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 12, 2026
Received: May 13, 2026

Dear Tina Mornak:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K261154

Please provide the device trade name(s).

CoLink® & CoLag® Non-Sterile Screws

Please provide your Indications for Use below.

The In2Bones USA CoLink Non-Sterile screws when used in conjunction with compatible plating systems are indicated for:

CoLink T8 2.7mm Screws:
When used with the CoLink Afx Plating System: Stabilization and fixation of fractures and osteotomies in the ankle, including tibia and fibula in both pediatric and adult patients.

CoLink T15 3.0mm Screws:
When used with the CoLink Mfx System: Stabilization and fixation of fractures, revision procedures, joint fusion, osteotomies and reconstruction in the midfoot bones of the foot, including repair of Lis Franc injuries.

CoLink T15 3.5mm Screws:
When used with the CoLink Afx Plating System: Stabilization and fixation of fractures and osteotomies in the ankle, including tibia and fibula in both pediatric and adult patients in both pediatric and adult patients.

When used with the CoLink Mfx Plating System: Stabilization and fixation of fractures, revision procedures, joint fusion, osteotomies and reconstruction in the midfoot bones of the foot, including repair of Lis Franc injuries in both pediatric and adult patients.

The In2Bones USA CoLag Non-sterile screws, when used in conjunction with compatible plating systems or used independently in a lag screw technique are indicated for:

CoLag T8 3.0mm Screws:
When used with the Colag Fracture and Correction System: Internal bone fixation for bone fractures, fusions, osteotomies and non-unions of various bones, including humerus, radius, ulna, tibia, calcaneus, fibula, and small bones (metacarpals, metatarsals, and phalanges).

CoLag T15 4.0mm Screws:
When used with the Colag Fracture and Correction System: Internal bone fixation for bone fractures, fusions, osteotomies and non-unions of various bones, including humerus, radius, ulna, tibia, calcaneus, fibula, and small bones (metacarpals, metatarsals, and phalanges).

When used with the CoLink® Mfx System: Stabilization and fixation of fractures, revision procedures, joint fusion, osteotomies and reconstruction in the midfoot bones of the foot, including repair of Lis Franc injuries in both pediatric and adult patients.

Please select the types of uses (select one or both, as applicable).

☒ Prescription Use (21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☒ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

510(k) Summary

CoLink® & CoLag® Non-Sterile Screws

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Corporation is hereby submitting the 510(k) Summary of Safety and Effectiveness for this 510(k).

I. SUBMITTER

In2Bones USA
7750A Trinity Road
Cordova, TN 38018

Company Contact: Tina Mornak
Manager, Regulatory Affairs
724-518-3191
tinamornak@conmed.com

Date Prepared: May 29, 2026

II. DEVICE NAME

Proprietary Name:	CoLink® & CoLag® Non-Sterile Screws
Common Name:	Screw, Fixation, Bone
Panel:	87-Orthopedic
Product Code:	HWC
Device Class:	II
Regulation Number:	21 CFR 888.3040

III. PREDICATE/LEGALLY MARKETED DEVICE

Primary Device Name: CoLink® Afx
Company Name: In2Bones USA
510(k): K181113

Additional Predicate Device Name: CoLink® Mfx
Company Name: In2Bones USA
510(k): K210060

Additional Predicate Device Name: CoLag®2
Company Name: In2Bones USA
510(k): K180377

IV. DEVICE DESCRIPTION

The subject CoLink and CoLag Non-Sterile screws are titanium alloy (Ti6Al4V ELI) screws intended for internal bone fixation in adult patients. They are provided non-sterile and to be cleaned and steam sterilized at the healthcare facility prior to surgical implantation. These screws may be used independently or in

conjunction with previously cleared In2Bones plating systems, consistent with their cleared clinical applications.

V. INTENDED USE / INDICATIONS FOR USE

The In2Bones USA CoLink Non-Sterile screws when used in conjunction with compatible plating systems are indicated for:

CoLink T8 2.7mm Screws:

When used with the CoLink Afx Plating System: Stabilization and fixation of fractures and osteotomies in the ankle, including tibia and fibula in both pediatric and adult patients.

CoLink T15 3.0mm Screws:

When used with the CoLink Afx Plating System: Stabilization and fixation of fractures and osteotomies in the ankle, including tibia and fibula in both pediatric and adult patients.

When used with the CoLink Mfx System: Stabilization and fixation of fractures, revision procedures, joint fusion, osteotomies and reconstruction in the midfoot bones of the foot, including repair of Lis Franc injuries in both pediatric and adult patients.

CoLink T15 3.5mm Screws:

When used with the CoLink Afx Plating System: Stabilization and fixation of fractures and osteotomies in the ankle, including tibia and fibula in both pediatric and adult patients.

When used with the CoLink Mfx Plating System: Stabilization and fixation of fractures, revision procedures, joint fusion, osteotomies and reconstruction in the midfoot bones of the foot, including repair of Lis Franc injuries in both pediatric and adult patients.

The In2Bones USA CoLag Non-sterile screws, when used in conjunction with compatible plating systems or used independently in a lag screw technique are indicated for:

CoLag T8 3.0mm Screws:

When used with the Colag Fracture and Correction System: Internal bone fixation for bone fractures, fusions, osteotomies and non-unions of various bones, including humerus, radius, ulna, tibia, calcaneus, fibula, and small bones (metacarpals, metatarsals, and phalanges).

CoLag T15 4.0mm Screws:

When used with the Colag Fracture and Correction System: Internal bone fixation for bone fractures, fusions, osteotomies and non-unions of various bones, including humerus, radius, ulna, tibia, calcaneus, fibula, and small bones (metacarpals, metatarsals, and phalanges).

When used with the CoLink Mfx System: Stabilization and fixation of fractures, revision procedures, joint fusion, osteotomies and reconstruction in the midfoot bones of the foot, including repair of Lis Franc injuries in both pediatric and adult patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The CoLink & CoLag Non-Sterile Screws are similar to the predicate device in that the design of both include threaded titanium alloy bone screws with similar materials, geometry, drive interfaces, and mechanical fixation principles. The main difference in the subject device from the predicate device is the change from sterile to nonsterile configuration, as all other design and functional characteristics remain the same. CoLink & CoLag Non-Sterile Screws are safe, effective and substantially equivalent to the predicate as demonstrated by non-clinical performance testing.

	Subject Device	**Predicate Devices**
Device Name	CoLink & CoLag Non-Sterile Screws	CoLink AFX Plating System CoLink Mfx Plating System CoLag Fracture and Correction System
Manufacturer	In2Bones USA	In2Bones USA
Regulation Number	21 CFR 888.3040	21 CFR 888.3040, 21 CFR 888.3030
Product Code	HWC	HWC, HRS
Device Class/Name	Class II	Class II
Fundamental Scientific Technology	metallic bone fixation screws	metallic bone fixation screws
Indications for Use	The In2Bones USA CoLink and CoLink Afx Non-Sterile screws when used in conjunction with compatible plating systems are indicated for: <u>CoLink T8 2.7mm Screws:</u> • When used with the CoLink Afx Plating System: Stabilization and fixation of fractures and osteotomies in the ankle, including tibia and fibula in both pediatric and adult patients. <u>CoLink T15 3.0mm Screws:</u> • When used with the CoLink Mfx System: Stabilization and fixation of fractures, revision procedures, joint fusion, osteotomies and reconstruction in the midfoot bones of the foot, including repair of Lis Franc injuries in both pediatric and adult patients. <u>CoLink T15 3.5mm Screws:</u> • When used with the CoLink Afx Plating System: Stabilization and fixation of fractures and osteotomies in the ankle, including tibia and fibula in both pediatric and adult patients. • When used with the CoLink Mfx Plating System: Stabilization and fixation of fractures, revision procedures, joint fusion, osteotomies and reconstruction in the midfoot bones of the foot,	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. The In2Bones USA LLC CoLink Mfx Plating System is indicated for stabilization and fixation of fractures, revision procedures, joint fusion, osteotomies and reconstruction in the midfoot bones of the foot, including repair of Lis Franc injuries. The In2Bones USA LLC Fracture and Correction System lag screws are intended to be used as stand-alone bone screws, or in a plate-screw system for internal bone fixation for bone fractures, fusions, osteotomies and non-unions of various bones, including humerus, radius, ulna, tibia, calcaneus, fibula, and small bones (metacarpals, metatarsals, and phalanges).

	including repair of Lis Franc injuries in both pediatric and adult patients. The In2Bones USA CoLag Non-sterile screws, when used in conjunction with compatible plating systems or used independently in a lag screw technique are indicated for: <u>CoLag T8 3.0mm Screws:</u> • When used with the Colag Fracture and Correction System: Internal bone fixation for bone fractures, fusions, osteotomies and non-unions of various bones, including humerus, radius, ulna, tibia, calcaneus, fibula, and small bones (metacarpals, metatarsals, and phalanges). <u>CoLag T15 4.0mm Screws:</u> • When used with the Colag Fracture and Correction System: Internal bone fixation for bone fractures, fusions, osteotomies and non-unions of various bones, including humerus, radius, ulna, tibia, calcaneus, fibula, and small bones (metacarpals, metatarsals, and phalanges). • When used with the CoLink Mfx System: Stabilization and fixation of fractures, revision procedures, joint fusion, osteotomies and reconstruction in the midfoot bones of the foot, including repair of Lis Franc injuries in both pediatric and adult patients.	
Material	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)
Geometry and Dimensions	8mm-60mm length (CoLink Afx) 8mm – 60mm length (CoLink Mfx) 12mm-60mm length (CoLag)	8mm-60mm length (CoLink Afx) 8mm – 60mm length (CoLink Mfx) 8mm-115mm length (CoLag)

VII. PERFORMANCE DATA/RATIONALES

The implants subject of this submission were determined not to be worse case and were adopted into previous validations conducted:

- Biocompatibility per ISO 10993-1
- Steam Sterilization validation per ISO 17665
- Cleaning validation
- Mechanical performance

VIII. CONCLUSION

The subject CoLink, CoLink Afx & CoLag Non-Sterile Screws are substantially equivalent in design, materials, indications for use, principles of operation and technological characteristics to the predicate devices. Based upon the findings of non-clinical testing, the differences present no issues of safety and efficacy, and the subject CoLink & CoLag Non-Sterile Screws are substantially equivalent to the predicates: CoLink Afx Plating System screws (K181113), CoLink Mfx Plating System screws (K210060) and CoLag2 screws (K180377).