May 24, 2024

In2Bones USA, LLC
Christine Scifert
VP, Quality and Regulatory
6000 Poplar Ave, Suite 115
Memphis, Tennessee 38002

Re: K233089
Trade/Device Name: NeoSpan® Compression Implant 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, JDR
Dated: April 25, 2024
Received: April 25, 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,

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

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)*
K233089

Device Name
NeoSpan® Compression Implant System

Indications for Use *(Describe)*
The NeoSpan® Compression Implant System is a nitinol implant intended to provide fixation of fractures, fusions, or osteotomies of the hand and foot.

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

NeoSpan® Compression Implant System

May 24, 2024

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

Primary Contact: Christine Scifert

Trade Name: NeoSpan® Compression Implant System

Common Name: Plate, Fixation, Bone; Staple, Fixation, Bone; Screw, Fixation, Bone

Classification: II

Regulation Number: 888.3030 - Single/multiple component metallic bone fixation appliances and accessories (primary)
888.3040 – Smooth or threaded metallic bone fixation fastener

Panel: 87-Orthopedic

Product Code(s): HRS (primary), JDR
HWC

Device Description: In2Bones NeoSpan® Compression Implant System (CIS) is a product expansion of the existing NeoSpan Compression Staple Implant w/ Instruments (K161426). The NeoSpan® Compression Implant System consists of implants offered in various configurations from 2 and 3 legs with no hole or 1-to-3 holes intended for bone screw assembly for additional fixation. The fixed-leg implants are comprised of Nitinol per ASTM F2063. The devices are sterile implants intended to provide fixation of fractures, fusions, or osteotomies of the hand and foot.

Bone screw options for the NeoSpan® Compression Implant System are previously cleared 3.0mm and 3.5mm locking and non-locking screws in lengths 10-30mm made from titanium alloy.

Indications for Use: The NeoSpan® Compression Implant System is a nitinol implant intended to provide fixation of fractures, fusions, or osteotomies of the hand and foot.

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

Primary Predicate

- K161426 –NeoSpan Compression Staple Implant w/ Instruments

Additional Predicate

- K160300 - CrossRoads Extremity Systems MotoBAND Implant System
- K222645 - Treace Medical Compression Implant System
- K112837 – Vilex eZ-Staple Superelastic Bone Fixation Staple

Reference Device

- K201149 – CoLink Plating System
- K181113 – CoLink Afx Plating System

The subject NeoSpan® Compression Implant System is similar geometry to the previously cleared CrossRoads Extremity Systems MotoBAND Implant System and Treace Medical Compression Implant System. The NeoSpan® Compression Implant System has 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: The NeoSpan® Compression Implant System was evaluated against the predicates per ASTM F564 (Static Bending, Fatigue Bending, Pull-Out) and was shown to be substantially equivalent to the predicate implants. Corrosion testing per ASTM F2129 & ASTM F3044 was conducted for the subject device. The NeoSpan® Compression Implant 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.