



October 24, 2016

In2BonesUSA, LLC
% Ms. Louise Focht
President
ENMED International, Inc.
P.O. Box 249
Del Mar, California 92014

Re: K161426

Trade/Device Name: NeoSpan™ Compression Staple Implant w/instruments
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR
Dated: September 15, 2016
Received: September 19, 2016

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 Parts 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" (21CFR 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,

Vincent J. Devlin -S

for
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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known) K161426

Device Name

NeoSpan™ Compression Staple Implant w/instruments

Indications for Use (Describe)

The In2Bones USA NeoSpan™ Compression Staple Implant w/instruments is indicated for hand and foot bone fragments, osteotomy fixation and joint arthrodesis.

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 K161426

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

I. Submitter

Date Prepared: October 18, 2016
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: NeoSpan™ Compression Staple Implant w/instruments
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Common Name: Bone Staple
Classification Name: Staple, Fixation, Bone
Regulatory Class: 21 CFR 880.3030, Class II
Product Code: 87 JDR

III. Predicate Device

Predicate Device: Vilex eZ-Staple Superelastic Bone Fixation Staple K112837
Stryker EasyClip K122113

IV. Device Description

The In2Bones NeoSpan™ Compression Staple Implant w/instruments is a super elastic compression staple made of superelastic Nitinol. The devices are available in multiple sizes. The implant is designed to hold bones together until healing occurs.

V. Intended Use and Indications for Use

The In2Bones USA NeoSpan™ Compression Staple Implant w/instruments is indicated for hand and foot bone fragments, osteotomy fixation and joint arthrodesis.

VI. Comparison of technological characteristics with the predicate device

The In2Bones USA NeoSpan™ Compression Staple Implant and the legally marketed predicate device have the same intended use and indications for use, same dimensions, geometry and

materials. The In2Bones device and the predicate are both available in multiple sizes. The staples are fit into two holes drilled into various bones to provide fixation for bone fracture, osteotomy and fusion. The In2Bones USA NeoSpan™ Compression Staple Implant is made from superelastic nitinol.

VII. Performance Data

Testing including pyrogenicity, corrosion, static bending, fatigue bending and pullout fixation was performed. The results of the testing demonstrate that the device is substantially equivalent to the predicate device identified

VIII. Conclusions

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