August 11, 2023

Vilex, LLC
Brock Johnson
President
111 Moffitt Street
McMinnville, Tennessee 37110

Re: K231493
Trade/Device Name: NITINEX Memory Compression Staple
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: August 9, 2023
Received: August 10, 2023

Dear Brock Johnson:

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,

Limin Sun -S

Limin Sun, Ph.D.
Assistant Director
DHT6A: Division of Joint
Arthroplasty 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.

Submission Number *(if known)*

K231493

Device Name

NITINEX Memory Compression Staple

Indications for Use *(Describe)*

The NITINEX Memory Compression Staple is intended 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.

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510(k) SUMMARY

Device Trade Name	NITINEX Memory Compression Staple
Date	August 9, 2023
Sponsor	Vilex, LLC 111 Moffitt Street McMinnville, TN 37110
Contact Person	Brock Johnson President (801)916-4157 brock.johnson@vilex.com
Device Common Name	NITINEX Memory Compression Staple
Regulatory Class	Class II
Product Code	JDR
Classification Name	Staple, Fixation, Bone
Regulation	21 CFR 888.3030
Regulation Name	Single/multiple component metallic bone fixation appliances and accessories
Device Regulation Panel	Orthopedic
Predicate Device	K112837, Vilex eZ-Staple Superelastic Bone Fixation Staple

Device Description:
The NITINEX Memory Compression Staple is a single-use bone fixation appliance intended to be permanently implanted. The implantation of the NITINEX Memory Compression Staple facilitates hand and foot bone fragment osteotomy fixation and joint arthrodesis. NITINEX Staples are compression staples made of shape memory nickel titanium alloy, nitinol. Vilex LLC will offer NITINEX Staples ranging in width from 8-mm to 30-mm with leg lengths ranging from 8-mm to 30-mm.

Indications for Use:
The NITINEX Memory Compression Staple is intended for hand and foot bone fragments osteotomy fixation and joint arthrodesis.

The indications for use of the NITINEX Memory Compression Staple are identical to those of the predicate device (K112837).

Technological Characteristics:
The NITINEX Memory Compression Staple is substantially equivalent to the predicate devices cleared under K112837. The NITINEX Memory Compression Staple has identical indications for use, basic designs, fundamental scientific principles, principles of operation, and implant materials as the predicate device.

The NITINEX Memory Compression Staple has a thicker staple bridge and different teeth size and spacing than the predicate device.

The NITINEX Memory Compression Staple System contains a sizer instrument to aid the surgeon in determining the appropriate size implant to use on the patient. The NITINEX Memory Compression Staple System also contains long drills and short drills to form snowman-shaped holes to aid in insertion. The predicate devices do not contain a sizer or long drills.

The NITINEX Memory Compression Staple System uses instruments that are composed of a nylon material and stainless steel. The predicate devices use instruments composed of stainless steel.

The NITINEX Memory Compression Staple is provided sterile to the end user and is intended for single use only. The predicate devices require end user sterilization prior to use and are intended for single use only.

The differences between the NITINEX Memory Compression Staple and the predicate devices are considered minor and raise no questions of safety or effectiveness. Therefore, the NITINEX Memory Compression Staple is substantially equivalent to the predicate device.

Assessment of performance data:
The following nonclinical tests were performed to demonstrate the substantial equivalence of the subject device to the predicate device:

- Static Pullout Testing per ASTM F564-17
- Bend Testing per ASTM F564-17
- Cyclic Polarization Corrosion Testing per ASTM F2129-19a

The mechanical tests evaluated samples from the NITINEX Memory Compression Staple against the predicate device. All tests demonstrated that the subject device performs equivalently to the predicate device. Therefore, the NITINEX Memory Compression Staple is substantially equivalent to the predicate device with respect mechanical strength and performance.

The corrosion testing demonstrated the corrosion resistance of the subject device. The NITINEX Memory Compression Staple was shown to meet equivalent corrosion resistance criteria as the predicate device.

Conclusion:
Based upon the similarities between the subject and the predicate devices, the NITINEX Memory Compression Staple is substantially equivalent to the predicate device. The technological differences between the subject and predicate devices are considered minor. The similarities in technological characteristics and the performance data demonstrate substantial equivalence.