July 29, 2019

Vilex in Tennessee, Inc
Victor Lavi
Executive Vice President
111 Moffitt Street
McMinnville, Tennessee 37110

Re: K191289
Trade/Device Name: Bone Screw Line Addition
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: May 8, 2019
Received: May 13, 2019

Dear Victor Lavi:

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,

Shumaya Ali, MPH
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191289

Device Name

Bone Screw Line Addition

Indications for Use *(Describe)*
The Bone Screw Line Addition is intended to be used for the following indications:

- Bone fractures
  - o Jones fractures
  - o Acute fractures
  - o Avulsion fractures
  - o Repetitive stress fractures
  - o Malleolar fractures
  - o Talus fractures
  - o Greater tuberosity fractures
- Fixation of malunions and non-unions
- Osteotomies
- 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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Bone Screw Line Addition

I. Submitter:

Vilex in Tennessee, Inc.
111 Moffitt Street
McMinnville, TN 37110

Contact Person:
Victor Lavi
Executive VP
Email: info@vilex.com
Phone: 931-474-7550

Date of Summary: July 2, 2019

II: Device

Proprietary Name:	Bone Screw Line Addition (BSLA)
Common Name:	Screw, Fixation, Bone
Regulatory Class:	Class II
Regulation:	21 CFR 888.3040 Smooth or Threaded Metallic Bone Fixation Fastener
Device Product Codes:	HWC, HTN
Panel:	Orthopedic

III. Predicate Devices

Device	Manufacturer	510(k) No.	Clearance Date
Primary predicate			
Vilex/Orthex/Duval Cannulated Bone Screw	Vilex, Inc.	K991197	04/26/1999
Predicates			
Charlotte Carolina Jones Fracture System Screw	Wright Medical Technology, Inc.	K140952	05/15/2014
Asnis JFX System	Stryker Trauma AG	K153154	12/28/2015

IV. Device Description

The Vilex ***Bone Screw Line Addition*** includes an implantable device system intended for fixation of bone fractures and osteotomies of the upper and lower extremities. The ***Bone***

Bone Screw Line Addition

Screw Line Addition (BSLA) system consists of cannulated and solid screws. The implants are offered fully or partially threaded and in 4.5, 5.5, and 6.0 mm thread diameters. The ***BSLA*** implants are fabricated from either titanium or stainless steel.

V. Intended Use

The Bone Screw Line Addition is intended to be used for the following indications:

- Bone fractures
    - Jones fractures
    - Acute fractures
    - Avulsion fractures
    - Repetitive stress fractures
    - Malleolar fractures
    - Talus fractures
    - Greater tuberosity fractures
- Fixation of malunions and non-unions
- Osteotomies
- Arthrodesis

VI. Comparison of Technological Characteristics with the Predicate Devices

The ***BSLA*** is technologically substantially equivalent to predicate devices in terms of intended use, material, design, mechanical performance and safety. The ***BSLA*** is manufactured from the same materials as the listed predicate devices. Screws have similar lengths and similar diameters. Washers have similar inner and outer diameters. The Vilex ***BSLA*** devices differ slightly in thread form and screw head geometry from the predicate devices. Analyses confirmed that the ***BSLA*** is substantially equivalent when compared to the predicate devices. The design characteristics of the subject system do not raise any new types of questions of safety or effectiveness.

VII. Performance Data

Engineering analyses demonstrated that the ***BSLA*** does not introduce an added risk when compared to the cleared predicate devices. Analysis was used to demonstrate substantially equivalent mechanical strength (i.e., torsional strength, shear strength, bending strength, and pull out strength).

Analyses and evaluation concluded that the subject ***BSLA*** is substantially equivalent to the predicate devices.

VIII. Conclusions

A review of the device indications, material composition, bone screw and washer design, and technological characteristics confirmed that the ***BSLA*** are substantially equivalent to the predicate devices. While the ***BSLA*** are not identical to the predicate devices, comparisons of the subject and predicate devices confirmed that any differences in technological characteristics do not raise different questions of safety and effectiveness than the predicate device. From the evidence submitted in this 510(k), the subject devices can be expected to perform at least as well as the predicate devices. Therefore, it is concluded that the ***Bone Screw Line Addition*** is substantially equivalent to the predicate devices.