September 11, 2020

Vilex, LLC
Joyce Thacker
Operations Manager
111 Moffitt Street
McMinnville, Tennessee 37110

Re: K202143
Trade/Device Name: Dynex Micro®
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: KTT, JDW
Dated: July 30, 2020
Received: July 31, 2020

Dear Joyce Thacker:

(NOTE: Reprocessed SUD device types require a separate attachment of the list of all models cleared in the submission. A corrected SE letter will be required if the attachment is omitted.)

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,

Ting Song, Ph.D., R.A.C.
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.

510(k) Number *(if known)*
K202143

Device Name

Dynex Micro®

Indications for Use *(Describe)*

The Vilex External Fixation System is intended for external fixation with the following indications:

- Stabilization of Fractures & Osteotomy
- Rear and Mid-foot Arthrodesis
- Adult and Pediatric Leg Lengthening
- Correction of Bone Deformity in Upper & Lower Extremities

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

K202143

I. Submitter

Vilex, LLC
111 Moffitt Street
McMinnville, TN 37110

Contact Person: Joyce Thacker, Operations Manager
Phone: 931-474-7550
Email: joycet@vilex.com

Date Prepared: September 8, 2020

II. Device

Device Proprietary Name:	Dynex Micro®
Common or Usual Name:	External Fixation System
Classification Name:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulation Number:	21 CFR 888.3030
Product Code:	KTT (primary), JDW (secondary)
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- X-Fix, K052196, Vilex Inc.

IV. Device Description

The Dynex Micro® falls within the Vilex External Fixation System product line. The system consists of the following components:

- Half pins and pins;
- Guidewires;
- External fixation rails; and
- Instruments.

The half pins are constructed from stainless steel (ASTM F138 LVM) and are provided in multiple diameters (2.0, 2.5, 3.0, 4.0, 5.0, and 6.0 mm) and lengths (60 – 175 mm). The transfixation pins, also constructed from stainless steel, and are provided in three diameters (2.5, 3.0, and 5.0 mm) and two lengths (250 mm and 350 mm).

Guidewires are available in 1.1 mm and 1.6 mm diameter configurations and range in length from 60 – 150 mm.
The mini- and mono- rails are manufactured from stainless steel and aluminum and are provided in various sizes (100 – 300 mm) to accommodate variations in patient size.

The Dynex Micro® components are used with general and dedicated surgical instruments such as drill guides, drills, drill sleeves, wrenches, pin extenders, pin inserters, guide wire holders, and removal tools.

V. Indications for Use

The Vilex External Fixation System is intended for external fixation with the following indications:

- Stabilization of Fractures & Osteotomy
- Rear and Mid-foot Arthrodesis
- Adult and Pediatric Leg Lengthening
- Correction of Bone Deformity in Upper & Lower Extremities

VI. Comparison of Technological Characteristics

The Dynex Micro® is identical to the predicate device with respect to the indications for use, offered variants, design, materials, sterilization, and manufacturing methods.

VII. Performance Data

As the only difference between the subject and predicate devices is the product trade name, no additional performance data was submitted to demonstrate the substantial equivalence of the subject device to the predicate device.

VIII. Conclusion

As the only difference between the subject and predicate devices is the product trade name, the Dynex Micro® is substantially equivalent to the predicate device.