August 24, 2020

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

Re: K202054
Trade/Device Name: Dynex Ring Fixation System, Diametrix Ring Fixation System
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 24, 2020
Received: July 24, 2020

Dear Joyce Thacker:

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.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202054

Device Name
Dynex® Ring Fixation System
Diametrix® Ring Fixation System

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.

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510(k) Summary

I. Submitter

Vilex, LLC
111 Moffitt Street
McMinnville, TN 37110

Contact Person: Joyce Thacker, Operations Manager
Phone: 931-474-7550
Date Prepared: August 21, 2020

II. Device

Device Proprietary Name:	Dynex® Ring Fixation System and Diametrix® Ring Fixation System
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.
- X-Fix Line Additions, K151881, Vilex in Tennessee, Incorporated
- Vilex Ultima External Fixation System with HA Coated Pins and Wires, K132820, Vilex, Inc.
- Ultima HA Coated Half Pins and Wire, K163487, Vilex In Tennessee, Inc.

IV. Device Description

The Dynex® Ring Fixation System and Diametrix® Ring Fixation System fall within the Vilex External Fixation System product line. The systems consist of the following components:

- Dynex dynamic external fixation components (rings, footplates, and arches) or Diametrix static external fixation components (rings, footplates, and arches);
- Half pins and wires (regular and HA coated);
- Ball Markers for X-Ray;

- External fixation assembly hardware (e.g. wire fixation bolts, half pin bolts, struts, plates and posts, hinges, washers, support rods, and linear distractors); and
- Instruments (e.g. drills, drivers, tensioners, cutters, and benders),

The Dynex® Ring Fixation System components can be used as an external fixation and hexapod system, when configured with two or more rings and telescoping struts. The P&C CORA software (K151881) may be used in conjunction with the Dynex® Ring Fixation System to assist in pre-operative planning.

The Diametrix® Ring Fixation System components are traditional ring fixation components with frames that utilize tensioned wires and half pins.

Both systems utilize the same external fixation assembly hardware and instruments.

The Dynex rings, manufactured from aluminum, are offered in Full, 5/8, half and 3/8 sizes with footplates. The rings are circular with concentric inner and outer holes which provides versatility for hardware fixation points.

The Diametrix rings, manufactured from aluminum, are offered in in Full, 5/8, Half, and 3/8 sizes with footplates. The rings are tabbed which allows for multiple connection points and minimizes hardware interference.

The half pins and wires are constructed from stainless steel (ASTM F138 LVM). The coated half pins and wires are coated with Hydroxyapatite (HA). The half pins (Ø 3.0, 4.0, 4.5, 5.0, 6.0 mm) are provided in multiple lengths (60 – 200 mm) and are provided in sterile and non-sterile packaging. The wires are available in multiple designs (wire sharp bayonet, pear wire sharp bayonet, and wire bayonet olive) and are provided in 1.2, 1.5, and 1.8 mm diameters and range in length from 250 – 400 mm. The HA coated wires are provided sterile.

The external fixation rings, footplates, arches, struts, and assembly accessories are manufactured from stainless steel and anodized aluminum and are provided in various sizes to accommodate variations in patient size.

These components can be combined to create various frame assemblies.

The instruments and ball markers for X-Ray are manufactured from stainless steel.

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® Ring Fixation System and Diametrix® Ring Fixation System are identical to the predicate devices with respect to indications for use, offered variants, design, materials, sterilization, and manufacturing methods.

VII. Performance Data

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

VIII. Conclusion

As the only differences between the subject and predicate devices are the product trade names, the Dynex® Ring Fixation System and Diametrix® Ring Fixation System are substantially equivalent to the predicate devices.