October 12, 2021

Vilex LLC
% Roshana Ahmed
Sr. Regulatory Affairs Specialist
TELOS Partners LLC
571 Christina Lake Drive
Lakeland, Florida 33813

Re: K212552
Trade/Device Name: Correx Software
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, OSN
Dated: August 13, 2021
Received: August 13, 2021

Dear Roshana Ahmed:

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)*

K212552

Device Name

Correx Software

Indications for Use *(Describe)*

The Correx Software is intended to be used as a component of multilateral external fixation system for the Vilex External Fixation System with the indications listed below:

- 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.

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510(k) Summary

I. Submitter

Vilex, LLC
111 Moffitt Street
McMinnville, TN 37110

Contact Person: Brock Johnson, Vice President
Phone: (435)-659-1880
Date Prepared: October 12, 2021

II. Device

Device Proprietary Name:	Correx Software
Common or Usual Name:	Software for Diagnosis/Treatment External Fixation System
Classification Name:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Regulation Number:	21 CFR 888.3030
Product Code:	KTT/JDW/OSN
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following device:

- X-Fix Line Additions, K151881, Vilex in Tennessee, Incorporated

IV. Device Description

The Correx Software, intended for use with the Dynex Ring Fixation System (K202054), is an optional-use computational environment that can be used for determining the orientation of bone segments and external fixator elements attached to a bone to treat fractures and bone deformities.

The software includes user interface, processing, data storage, and display functions.
The Correx Software can be used to visualize the position of a moving bone segment and to compute the strut lengths necessary to implement any desired translation or rotation. The Software program does not control the device. The Software program does not control any hardware (such as rings, struts, wires) directly. The goal of the Software program is to provide the Surgeon with a tool for determining the length of the six struts connecting the two circular

rings. The Surgeon must decide where a bone segment should line up and the angulation and translation necessary for the treatment. The magnitude and direction of any rotation or translation is ultimately the responsibility of the Surgeon.

V. Indications for Use

The Correx Software is intended to be used as a component of multilateral external fixation system for the Vilex External Fixation System with the indications listed below:

- 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 subject and predicate device share the same intended use and technological characteristics.

A comparison of products technological characteristics is provided in the table below.

	Correx Software	**P&C Software K151881**
Intended User	Healthcare Professional	Same
Software Use	Optional	Same
Principles of Operation	The Software can be used to visualize the position of a moving bone segment and to compute the strut lengths necessary to implement any desired translation or rotation.	Same
Inputs	Surgeon Inputs based on X-Ray positioning	Same
Image Requirements	A/P and M/L radiographs after External Frame attached to bone segments	Same
System Fields (Data Inputs)	Ring Size, Struts, Preference Side, Deformity, Correction, Bone Alignment, Separation Rate	Same
Output	Daily schedule of strut lengths necessary to adjust the frame so that the bone segments are aligned as desired and translated to the desired position within a minimum number of days	Same

VII. Performance Data

Software verification and validation testing was undertaken to ensure that the product requirements and specifications were met.

VIII. Conclusion

Based on the information provided above and within this submission, the Correx Software is substantially equivalent to the predicate device.

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