May 2, 2022

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

Re: K212348
Trade/Device Name: ALPHALOK™ Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: March 31, 2022
Received: March 31, 2022

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,

Shumaya Ali, M.P.H.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212348

Device Name

ALPHALOK™ Plating System

Indications for Use *(Describe)*

ALPHALOK™ Plating System bone plates and screws are indicated for use in bone fractures and osteotomies of small bones or small bone fragments of the hand and wrist.

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: Louis Monaco, Director of Operations & Engineering
Phone: (435)-659-1880
Date Prepared: May 2, 2022

II. Device

Device Proprietary Name:	ALPHALOK™ Plating System
Common or Usual Name:	Plate, Fixation, Bone Screw, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Regulation Number:	21 CFR 888.3030 (primary) 21 CFR 888.3040
Product Code:	HRS HWC
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Primary Predicate:
  - Vilex Bone Plate Systems, K041287, Vilex, Inc.
- Additional Predicates
  - DePuy Synthes Variable Angle Locking Hand System (1.3 mm and 2.0 mm Plates and Screws), K150099, DePuy Synthes
  - ARIX Hand System, K131566, Jeil Medical Corporation

IV. Device Description

The ALPHALOK™ Plating System, consisting of the ALPHALOK™ Met Fx Mini Plates, is a multi-indication reconstruction solution providing polyaxial locking technology and low profile design.

All implant components are manufactured from titanium (Ti-6Al-4V, ASTM F136).

Specific instrumentation including wires, drills, torx drivers, and drill guides are required for use with the system. The ALPHALOK™ instruments are manufactured from stainless steel.

V. Indications for Use

ALPHALOK™ Plating System bone plates and screws are indicated for use in bone fractures and osteotomies of small bones or small bone fragments of the hand and wrist.

VI. Comparison of Technological Characteristics

The subject and predicate devices have similar intended uses and share identical core characteristics.

The systems are intended to be used in the hand and other small bones. Both systems include locking and non-locking screws with similar implant designs made from titanium alloy material, and instruments.

The technological differences between the subject device and predicate devices do not raise different questions of safety or effectiveness and substantial equivalence is demonstrated through the testing described below.

VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination:

- Torsional properties testing per ASTM F543-17
- Axial pullout testing per ASTM F543-17
- Driving torque testing per ASTM F543-17
- Static four point bend testing per ASTM F382-17

In addition, cleaning and sterilization validations, performed in accordance with ANSI/AAMI/ISO 17665-1, from the applicant's own predicate device were leveraged.

VIII. Conclusion

The information provided above supports that the ALPHALOK™ Plating System is as safe and effective as the predicate device. Although minor differences in design exist between the subject and predicate devices, the testing supports that these differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the ALPHALOK™ Plating System is substantially equivalent to the predicate devices.

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