December 13, 2022

Vilex, LLC
% Roshana Ahmed
Sr. Regulatory Specialist
Telos Partners, LLC
2850 Frontier Drive
Warsaw, Indiana 46582

Re: K221342
Trade/Device Name: REDEMPTION Beaming System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 6, 2022
Received: May 9, 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 -S

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)*
K221342

Device Name

REDEMPTION(TM) Beaming System

Indications for Use *(Describe)*

The REDEMPTION Beaming System is indicated for fracture fixation, osteotomies, reconstruction procedures, and fusions of bones in the foot and ankle including the Metatarsals, Cuneiforms, Cuboid, Navicular, Calcaneus and Talus. Specific examples include: Medial Column Fusion and Lateral Column Fusion resulting from neuropathic osteoarthropathy (Charcot).

The REDEMPTION Ø3.5mm Headless Screws are indicated for small bone fragments fracture and osteotomy in the lower extremities primarily the foot.

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: Scott Armacost, Director of Research and Development
Phone: (901) 488-1662
Date Prepared: December 13, 2022

## II. Device

| | |
|---|---|
| Device Proprietary Name: | REDEMPTION™ Beaming System |
| Common or Usual Name: | Bone Fixation Fastener |
| Classification Name: | Smooth or threaded metallic bone fixation fastener |
| Regulation Number: | 21 CFR 888.3040 |
| Product Code: | HWC |
| Device Classification | II |

## III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Primary Predicate
  - Vilex/Duval/Orthex Cannulated Bone Screw Double Thread, K014154, Vilex, Inc.
- Additional Predicates
  - Vilex Bone Plate System, K041287, Vilex, Inc.
  - Monster Screw System™, K124027, K151418, K190586, & K203011, Paragon 28, Inc.

The following devices are referenced in the submission:

- FUZE Intramedullary Internal Fixation Nail, K102413, Vilex, Inc.
- X-Fix Line Additions, K151881, Vilex in Tennessee, Incorporated
- Bone Screw Line Addition, K191289, Vilex in Tennessee, Incorporated

## IV. Device Description

The REDEMPTION™ Beaming System, consisting of the REDEMPTION™ Beams and the REDEMPTION™ Nails, is a reconstruction solution providing various diameters of cannulated screws.

The REDEMPTION™ Beams are provided in diameters of Ø5.0 mm, Ø6.5 mm, and Ø8.0 mm, and are cannulated and either partially or fully threaded. The Ø5.0 mm beams are available in 35 mm to 130 mm lengths (5 mm increments) and the Ø6.5 mm and Ø8.0 mm beams are available in 40 mm to 160 mm lengths (5 mm increments).

The REDEMPTION™ Nails are provided in diameters of Ø7.5 mm and Ø8.2 mm and are partially threaded. The nails range in length from 50 mm to 160 mm (5 mm increments).

The REDEMPTION™ Headless 3.5 mm screw can be used as a cross screw with the nail and are offered in lengths from 12 mm to 60 mm.

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

Specific instrumentation including wires, drills, torx drivers, drill guides, implant inserters, implant drivers, and a targeting guide are required for use with the system. The REDEMPTION™ instruments are manufactured from stainless steel and radel (plastic).

## V. Indications for Use

The REDEMPTION Beaming System is indicated for fracture fixation, osteotomies, reconstruction procedures, and fusions of bones in the foot and ankle including the Metatarsals, Cuneiforms, Cuboid, Navicular, Calcaneus and Talus. Specific examples include: Medial Column Fusion and Lateral Column Fusion resulting from neuropathic osteoarthropathy (Charcot).

The REDEMPTION Ø3.5mm Headless Screws are indicated for small bone fragments fracture and osteotomy in the lower extremities primarily the foot.

## VI. Comparison of Technological Characteristics

The subject and predicate devices share identical core characteristics. All systems are comprised of cannulated beams/screws with fully and partially threaded options, all the systems include implants made of titanium alloy material, and all of the systems have similar diameters and lengths.

The subject device introduces additional beam and nail sizes as well as additional style designs to increase the surgical options in treating a variety of conditions. These larger sizes do not raise new or different questions of safety and effectiveness. The Agency has cleared a Ø8.5 mm beam, and Ø9.0 mm, and Ø10 mm nails for use in the same indications.

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:

- Static Four Point Bend Testing per ASTM F1264-16
- Mechanical testing per ASTM F543-17
    - Insertion Torque
    - Removal Torque
    - Pull-out Force
    - Ultimate Torque
- Computational Analysis

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 REDEMPTION™ Beaming System is as safe and effective as the predicate devices. 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 REDEMPTION™ Beaming System is substantially equivalent to the predicate devices.