August 28, 2024

Vilex, LLC
Brock Johnson
President
111 Moffitt Street
McMinnville, Tennessee 37110

Re: K233816
Trade/Device Name: REDEMPTION Charcot 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: August 2, 2024
Received: August 5, 2024

Dear Brock Johnson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher Ferreira -S

Christopher Ferreira, MS, RAC
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233816

Device Name

REDEMPTION™ Charcot Plating System

Indications for Use *(Describe)*

The REDEMPTION™ Charcot Plating System bone plates and screws are indicated for use in bone fractures, osteotomies, and fixation of bones and bone fragments in the upper and lower extremities, primarily of the hand, wrist, foot, ankle, and digits. Specific examples include: medial column fusion (talus, navicular, cuboid, first metatarsal) for patients with osteopenic bone in neuropathic osteoarthropathy (Charcot).

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, President of Vilex

Phone: (801) 916-4157

brock.johnson@vilex.com

Date Prepared: May 27, 2022

II. Device

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

III. Predicate Device

Substantial equivalence is claimed to the following devices:

- Vilex ALPHALOK™ Plating System (K221558) – Primary Predicate
- Vilex ALPHALOK™ Plating System (K212348, K230204)-Reference Devices
- Stryker [Wright Medical] SALVATION® 3Di Plating System (K140792 and K140408) – Additional Predicate Devices

IV. Device Description

The REDEMPTION™ Charcot Plating System contains bone plates, screws, and accompanying instruments to aid in the surgical procedures. The system is a multi-indication reconstruction solution providing polyaxial locking technology and low-profile design. The system is optimized for use in osteopenic bone, such as those of neuropathic osteoarthropathy (Charcot) patients.

The system contains poly-axial locking and non-locking 4.0mm and 5.5mm diameter screws with threads optimized for osteopenic bone purchase.

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 REDEMPTION™ instruments are manufactured from stainless steel, with a few Aluminum and Silicone components.

V. Indications for Use

The REDEMPTION™ Charcot Plating System bone plates and screws are indicated for use in bone fractures, osteotomies, and fixation of bones and bone fragments in the upper and lower extremities, primarily of the hand, wrist, foot, ankle, and digits. Specific examples include: medial column fusion (talus, navicular, cuboid, first metatarsal) for patients with osteopenic bone in neuropathic osteoarthropathy (Charcot).

VI. Comparison of Technological Characteristics

The subject and predicate devices have similar intended uses and include explicit Charcot indications. Both systems also share equivalent core features and mechanical characteristics.

The systems are intended to be used in the hand, foot, and ankle along with other bones of the upper and lower extremities. Specific examples include: medial column fusion (talus, navicular, cuboid, first metatarsal) for patients with osteopenic bone in neuropathic osteoarthropathy (Charcot). The subject and

predicate systems include bone plates along with locking and non-locking screws with similar implant designs made from titanium alloy material. Similar instrumentation is included in all the system.

Any minor 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 F382-17
- Screw Torsional Properties per ASTM F543-17 A1
- Screw Insertion and Removal Torque per ASTM F543-17 A2
- Screw Pullout Testing per ASTM F543-17 A3

In addition, cleaning and sterilization validations, performed in accordance with ANSI/AAMI/ISO 17665-1, from the applicant's own predicate device were leveraged. Biocompatibility, cleaning and sterilization are identical to K212348, K221558, and K230204. No changes have been made with respect to material, manufacturing, cleaning, or sterilization.

VIII. Conclusion

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

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