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

January 30, 2024

Re: K231343
Trade/Device Name: Redemption Duo Hindfoot Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: December 21, 2023
Received: December 21, 2023

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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.01.30 10:26:04 -05'00'

for: Farzana Sharmin, PhD
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)*

K231343

Device Name

Vilex Redemption Duo Hindfoot Nail System

Indications for Use *(Describe)*

The Vilex Redemption Duo Hindfoot Nail System is intended for tibiotalocalcaneal arthrodesis (fusion)

Specific indications include:
• Post-traumatic or degenerative arthritis
• Previously infected arthrosis
• Revision ankle arthrodesis
• Failed total ankle arthroplasty
• Avascular necrosis of the talus
• Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
• Rheumatoid arthritis
• Osteoarthritis
• Pseudarthrosis
• Trauma (malunited tibial pilon fracture)
• Charcot foot
• Severe endstage degenerative arthritis
• Severe defects after tumor resection
• Pantalar arthrodesis
• Post-traumatic arthrosis
• Neuroarthropathy

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: 20 April 2023

II. Device

Device Proprietary Name:	Redemption Duo Hindfoot Nail System
Common or Usual Name:	Rod, Fixation, Intramedullary and Accessories
Classification Name:	Intramedullary Fixation Rod
Regulation Number:	21 CFR 888.3020
Product Code:	HSB
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Device Type	510(k) Number	Trade Name	Applicant	Product Code
Subject Device	-	Redemption Duo Hindfoot Nail System	Vilex	HSB
Primary Predicate	K091976	Biomet Phoenix Ankle Nail and Ankle Arthrodesis Nail	Zimmer Biomet	HSB
Reference Device	K221031	Arthrex DualCompression Hindfoot Fusion Nail Implant System	Arthrex	HSB
Reference Device	K051678	Synthes Hindfoot Arthrodesis Nail System	Depuy Synthes	HSB
Reference Device	K173811	TRIWAY Tibiotalocalcaneal (TTC) Arthrodesis System	In2Bones SAS	HSB HWC
Reference Device	K102413	FUZE: Intramedullary Internal Fixation Nail	Vilex	HSB

IV. Device Description

The Vilex Redemption Duo system consists of implantable intramedullary nails, endcaps, and locking screws manufactured from titanium alloy (Ti-6Al-4V ELI per ASTM F136 and PEEK per ASTM F2026) that are implanted into the talocrural region to facilitate tibiotalocalcaneal arthrodesis (fusion). A variety of implant sizes are provided to accommodate individual patient anatomy. The Vilex Redemption Duo system includes device specific instrumentation for use in site preparation, implantation, and removal of the implants. Implants and instruments are

packaged clean and non-sterile in a sterilization tray with instructions for sterilization prior to surgery.

V. Indications for Use

The Vilex Redemption Duo Hindfoot Nail System is intended for tibiotalocalcaneal arthrodesis (fusion)

Specific indications include:

- Post-traumatic or degenerative arthritis
- Previously infected arthrosis
- Revision ankle arthrodesis
- Failed total ankle arthroplasty
- Avascular necrosis of the talus
- Severe deformity or instability as a result of talipes equinovarus, cerebral vascular accident, paralysis or other neuromuscular disease
- Rheumatoid arthritis
- Osteoarthritis
- Pseudarthrosis
- Trauma (malunited tibial pilon fracture)
- Charcot foot
- Severe endstage degenerative arthritis
- Severe defects after tumor resection
- Pantalar arthrodesis
- Post-traumatic arthrosis
- Neuroarthropathy

VI. Comparison of Technological Characteristics with the Predicate Devices

The subject and predicate devices have similar intended uses and share identical core characteristics. The subject and predicate devices are implanted into the talocrural region to facilitate tibiotalocalcaneal arthrodesis (fusion). At a high level, the subject and predicate devices share the following technological characteristics:

- Product code
- Indications for Use
- Principles of Operation
- Material of construction
- Nail lengths
- Nail diameters
- Cap lengths
- Screw lengths
- Screw diameter
- Sterilization method

The technological differences between the subject device and predicate devices include minor dimensional differences and differences in raw material and sterilization method. These changes are

considered minor and 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:

- Bending Fatigue per ASTM F1264-16e1
- Static Torsion per ASTM F543-17
- Driving Torque per ASTM F543-17
- Removal Torque per ASTM F543-17
- Axial Pullout Strength per ASTM F543-17
- Static Four-Point Bending per ASTM F1264-16e1
- Static Torsion per ASTM F1264-16e1
- Dynamic Four-Point Bending per ASTM F1264-16e1

VIII. Conclusion

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