September 11, 2023

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

Re: K231504
Trade/Device Name: TITANEX™ MICROBEAM Screw System, TITANEX™ ARTEMIS Screw 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 23, 2023
Received: May 24, 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 (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,

Tejen D. Soni -S

For
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)*
K231504

Device Name
TITANEX™ MICROBEAM Screw System and TITANEX™ ARTEMIS Screw System

Indications for Use *(Describe)*

The TITANEX™ MICROBEAM and TITANEX™ ARTEMIS Screw Systems are indicated for fracture fixation, osteotomies, reconstruction procedures and arthrodesis of bones in the foot and ankle.

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.

510(k) Summary

I. Submitter

Vilex LLC
111 Moffit St.
McMinnville, TN 37110

Contact Person: Brock Johnson, President
Phone: (801) 916-4157
Date Prepared May 5th, 2023

II. Device

Device Proprietary Name:	TITANEX™ MICROBEAM Screw System, TITANEX™ ARTEMIS Screw 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 for the TITANEX™ Screws is claimed to the following devices:

- Vilex Cannulated Bone Screw / DuVal Cannulated Screw, K991197 (Primary Predicate)
- Vilex FUZE®: Intramedullary Internal Fixation Nail, K102413 (Reference Device)

IV. Device Description

The TITANEX™MICROBEAMS and the TITANEX™ ARTEMIS screw systems contain fully threaded screws as a reconstruction solution providing various diameters of cannulated screws.

The TITANEX™ MICROBEAM's are provided in diameters of ∅2.0mm, ∅2.5mm, and the TITANEX™ ARTEMIS screws are ∅3.0mm, and ∅4.0mm. The Screws are a fully threaded design and come in variable lengths from 16mm – 70mm. The ∅2.0mm family: 16mm – 50mm, for the ∅2.5mm family: 16mm – 50 mm, for the ∅3.0mm family: 12mm – 50mm, for the ∅4.0mm family: 16mm – 70mm. All screws are provided in 2mm increments.

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

Specific instrumentation including wires, drills, depth gages, and torx drivers are required for use with the system. The TITANEX™ Screws instruments are manufactured from stainless steel and aluminum.

V. Indications for Use

The TITANEX™ MICROBEAM and TITANEX™ ARTEMIS Screw Systems are indicated for fracture fixation, osteotomies, reconstruction procedures and arthrodesis of bones in the foot and ankle.

VI. Comparison of Technological Characteristics

General Comparison: The subject device is labeled for the similar indications as the primary predicate device (K991197). Both devices are prescription-only medical solutions.

Implant Comparison: Both the subject and primary predicate are made of Titanium Alloy (ASTM F136). Both contain a headed screw design with cannulation. The predicate is partially threaded, while the subject is fully threaded, enhancing purchase and strength. Both the subject and predicate devices are marketed as non-sterile devices. The screw sizes for the subject range from ⌀2.0mm x 6mm to ⌀4.0mm x 70mm, which are similar to those of the predicate.

Discussion

As seen above, the subject and predicate devices are equivalent in their core characteristics. Both systems are cannulated screw designs made from titanium alloy that share equivalent indications.

The Subject devices are a headless design whereas the Predicate is a headed design. The subject devices also introduce additional size options.

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 are provided in support of the substantial equivalence determination:

- Mechanical testing per ASTM F543-17
    - Insertion Torque
    - Removal Torque
    - Pull-out Force
    - Ultimate Torque
- Computational Analysis
    - Cross sectional Analysis
    - Axial Pullout per Chapman et al.

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 the claim that the TITANEX™ Screw System, consisting of the TITANEX™ MICROBEAMS and TITANEX™ ARTEMIS screws are sustainably equivalent to the predicate device. Although minor differences in design exist between the subject and predicate device, the testing supports that these differences do not raise any new questions of safety and effectiveness. Therefore, it is concluded that the TITANEX™ Screw Systems are substantially equivalent to the predicate devices.