March 5, 2025

Vilex LLC
Scott Armacost
VP, OUS R&D Engineering
111 Moffitt Street
McMinnville, Tennessee 37110

Re: K250304
Trade/Device Name: TITANEX Screw Systems
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 29, 2025
Received: February 3, 2025

Dear Scott Armacost:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Shumaya Ali -S

Shumaya Ali, MPH
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)*

K250304

Device Name

TITANEX® Screw Systems

Indications for Use *(Describe)*

The TITANEX® 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #:

510(k) Summary

Prepared on: 2025-01-31

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Vilex LLC
Applicant Address	111 Moffitt Street McMinnville TN 37110 United States
Applicant Contact Telephone	(901)488-1662
Applicant Contact	Mr. Scott Armacost
Applicant Contact Email	scott.armacost@vilex.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TITANEX® Screw Systems
Common Name	Smooth or threaded metallic bone fixation fastener
Classification Name	Screw, Fixation, Bone
Regulation Number	888.3040
Product Code(s)	HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K 2 31504	TITANEX MICROBEAM Screw System, TITANEX ARTEMIS Scr	HWC
K991197	Vilex / Duval / Orthex Cannulated Bone Screw	HW C
K014154	Vilex / Duval / Orthex Cannulated Bone Screw Double Thread	HW C

Device Description Summary

21 CFR 807.92(a)(4)

The TITANEX® Screw Systems contain cannulated bone screws and general instrumentation as a reconstruction solution for foot and ankle applications. The screws are provided in various diameters and lengths with headed, headless, partially, and fully threaded configurations. The implants are composed of titanium alloy. The instrumentation are composed of stainless steels. The devices are provided non-sterile and are intended to be steam sterilized prior to use.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject device are identical to the indications for use of the primary predicate device.

Technological Comparison

21 CFR 807.92(a)(6)

The subject device and predicate devices are cannulated bone screws composed of titanium alloy. The subject device and predicate

device(s) offer headed, headless, partially, and fully threaded screws. The subject device includes screws from 2.0mm - 7.0mm diameters in various lengths. The predicate device(s) include screws of the same diameters and lengths. The head and thread designs of the subject device are equivalent to those of the predicate device(s). The subject device introduces additional fully threaded screw diameters to increase bone purchase and strength, where the predicate device(s) are only partially threaded. The subject and predicate devices are both provided non-sterile and are steam sterilized prior to use. Therefore, the technological differences between the subject and predicate device do not raise new questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The non-clinical tests and analyses performed in support of the subject device include the following:

- Torsional properties testing per ASTM F543
- Driving torque testing per ASTM F543
- Axial pullout strength testing per ASTM F543
- Steam sterilization and cleaning (reprocessing) analysis
- Biological evaluation

The mechanical testing per ASTM F543 demonstrated that the subject screws perform equivalent to the predicate screws. The steam sterilization and cleaning analysis demonstrated that the subject screws may adopt into the validated Vilex reprocessing instructions. The biological evaluation demonstrated that the subject device is biocompatible for its intended use. Therefore, the subject device is substantially equivalent to the predicate device.