August 1, 2024

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

Re: K240035
Trade/Device Name: TACTIX Vector Syndesmosis System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HTN
Dated: June 28, 2024
Received: July 11, 2024

Dear Mr. 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

for

Jesse Muir, Ph.D.
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)*

K240035

Device Name

TACTIX Vector Syndesmosis System

Indications for Use *(Describe)*

The TACTIX Vector Syndesmosis System is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the TACTIC Vector Syndesmosis System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

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.

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510(k) #: K240035

510(k) Summary

Prepared on: 2024-07-29

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	8019164157
Applicant Contact	Mr. Brock Johnson
Applicant Contact Email	brock.johnson@vilex.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	TACTIX Vector Syndesmosis System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Washer, Bolt Nut
Regulation Number	888.3030
Product Code	HTN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201522	Arthrex Syndesmosis TightRope XP Buttress Plate Implant Syste	HTN
K173278	ToggleLoc System (Only ToggleLoc with ZipTight Fixation Device	MBI
K230204	Alphalok Plating System (reference device)	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The TACTIX Vector Syndesmosis System is intended to provide fixation during the healing process following a syndesmotic trauma using a TACTIX Vector suture loop and buttons.

The TACTIX Vector System features the following advantageous characteristics: a tensioner to apply suture tension for surgical repair, line lock suture technology without the need to tie a knot, removal of periosteum through a minimal medial skin nick, a larger medial button, and a small thru hole in the bone, only large enough to pass a 2.0 mm suture loop. The TACTIX Vector Syndesmosis System can be used in conjunction with Vilex fibular bone plates and screws, as deemed necessary by the surgeon.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The TACTIX Vector Syndesmosis System is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the TACTIC Vector Syndesmosis System is intended to provide fixation during the healing process following a syndesmotic trauma, such as fixation of syndesmosis (syndesmosis disruptions) in connection with Weber B and C ankle fractures.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use of the TACTIX Vector Syndesmosis System are identical to the indications for use of the primary predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The TACTIX Vector Syndesmosis System is composed of two titanium alloy buttons and one UHMWPE suture. The predicate devices are also composed of two titanium alloy buttons and one UHMWPE suture. The TACTIX Vector suture and buttons have the same basic design and intended use as the suture and buttons of the predicate devices.

The TACTIX Vector Syndesmosis System uses a tensioner instrument to place tension on the implanted suture loop. The predicate devices also utilize an instrument for the same intended use. The TACTIX Vector System uses a threader rod to install the suture. The predicate devices also use an instrument for the same intended use. The instruments of TACTIX System are composed of stainless steel, UHMWPE, and nylon material. The instruments of the predicate devices are composed of stainless steel, UHMWPE, and plastic materials.

The TACTIX Vector Syndesmosis System is intended for single use and provided sterile to the end user via ethylene oxide sterilization. The predicate devices are intended for single use and provided sterile to the end user via ethylene oxide sterilization.

Therefore, the technological characteristics of the TACTIX Vector Syndesmosis System are substantially equivalent to those of the predicate device. The differences in the technological characteristics between the TACTIX Vector System and the predicate device are considered minor and raise no questions of safety or effectiveness.

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

The following nonclinical tests were performed for the TACTIX Vector Syndesmosis System:

- Cyclic fatigue testing compared against the additional predicate device (K173278)
- Static pullout testing compared against the additional predicate device (K173278)
- Stability testing on product packaging
- Packaging performance testing
- Biocompatibility evaluation per ISO 10993-1
- Bacterial endotoxin testing

No clinical data was used used in the support of this submission.

The nonclinical testing showed that the TACTIX Vector Syndesmosis System performs substantially equivalent to a predicate device. Therefore, the TACTIX Vector Syndesmosis System raises no new questions of safety or effectiveness and is substantially equivalent to the predicate devices.