



April 17, 2026

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

Re: K260900

Trade/Device Name: DYNEX® External Fixation Systems

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories

Regulatory Class: Class II

Product Codes: KTT, JDW

Dated: March 17, 2026

Received: March 18, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Peter G. Allen Digitally signed by Peter G.
Allen -S
Date: 2026.04.17 13:31:42
-04'00'

for Lixin Liu, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260900

?

Please provide the device trade name(s).

?

DYNEX® External Fixation Systems

Please provide your Indications for Use below.

?

The DYNEX® External Fixation Systems are intended for external fixation with the following indications:

- Stabilization of Fractures & Osteotomy
- Rear and Mid-foot Arthrodesis
- Adult and Pediatric Leg Lengthening
- Correction of Bony or Soft Tissue Defects or Deformities in Upper & Lower Extremities
- Pseudoarthrosis or Non-Union of Long Bones

The DYNEX® TRIAD - TTT Fixation System is intended for external fixation in the treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities via tibial bone transport.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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510(k) #:

510(k) Summary

Prepared on: 2026-04-13

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	DYNEX External Fixation Systems
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Appliance, Fixation, Nail/Blade/Plate Combination, Multiple Component
Regulation Number	888.3030
Product Code(s)	KTT, JDW (CLASS 2) - PIN, FIXATION, THREADED

Legally Marketed Predicate Devices[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K202054	Dynex Ring Fixation System, Diametrix Ring Fixation System	KTT
K242861	TrueLok Elevate	KTT
K061493	Apex Pin Fixation System	JDW
K231343	Redemption Duo Hindfoot Nail System	HSB
K250304	TITANEX Screw Systems	HWC

Device Description Summary[21 CFR 807.92\(a\)\(4\)](#)

The DYNEX® External Fixation Systems include the following sub-systems:

- DYNEX® External Fixation System
- DYNEX® Mini Rail System
- DYNEX® TRIAD - TTT Fixation System

The DYNEX® External Fixation System includes rings, partial rings, footplates, struts, hardware, and instruments necessary for the construction of an external fixation frame to which tensioned wires and half pins are attached to the bone and to the frame itself.

The DYNEX® Mini Rail Fixation System includes rails, half pins, guidewires, and instruments necessary for the construction of external fixation rails to which half pins and wires are attached to the bone and to rails.

The DYNEX® TRIAD - TTT Fixation System includes a fixation frame, transport pins, fixation pins, and instruments necessary for the attachment of the pins and frame to the patient. The frame is fixated to the tibia to facilitate transverse tibial bone transport. The DYNEX TRIAD - TTT Fixation System is intended for use with the DYNEX External Fixation System and is compatible with the DYNEX half pins, rings, and accessories.

DYNEX® External Fixation System components are for single-use only and not designated or sold for any use except as indicated.

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The DYNEX® External Fixation Systems are intended for external fixation with the following indications:

- Stabilization of Fractures & Osteotomy
- Rear and Mid-foot Arthrodesis
- Adult and Pediatric Leg Lengthening
- Correction of Bony or Soft Tissue Defects or Deformities in Upper & Lower Extremities
- Pseudoarthrosis or Non-Union of Long Bones

The DYNEX® TRIAD - TTT Fixation System is intended for external fixation in the treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities via tibial bone transport.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The intended use of the subject device and predicate device is external fixation. The indications for use of the subject device and predicate device are similar. The subject device expands the indications for use of the predicate device to accommodate the line extension by including the following additional indications: correction of bony defects, correction of soft tissue defects and deformities, and pseudoarthrosis or non-union of long bones. The additional indications for use do not change the intended use of the subject device and therefore does not constitute a new intended use compared to the predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

This submission presents the DYNEX TRIAD - TTT Fixation System as a line extension of the DYNEX External Fixation Systems. The DYNEX TRIAD - TTT Fixation System adds a new fixation frame, transport pins, and the necessary instruments and accessories. The DYNEX TRIAD - TTT Fixation System is intended for use with the DYNEX External Fixation Systems. The transport pins are a similar design and are composed of the same material as the DYNEX half pins. The fixation frame is attached to bone using the DYNEX half pins and the transport pins. The fixation frame includes a linear bone adjustment mechanism that allows for up to 10mm of transverse bone transport. The fixation frame is composed of similar materials as the predicate rings, struts, and connectors. The instruments and accessories are composed of similar materials as the predicate instruments and accessories.

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

No clinical tests were required to demonstrate substantial equivalence of the subject device to the predicate device.

The following non-clinical tests were performed to evaluate the technological differences of the subject compared to the predicate devices:

- Static Axial Strength per ASTM F1541-24
- Slipping Torque per ASTM F1541-24
- Four-Point Bending per ASTM F1541-24
- Torsional Strength per ASTM F1541-24
- Steam Sterilization and Reprocessing Adoption Analysis
- Biological Evaluation per FDA Guidance of ISO 10993-1:2018

The results of the non-clinical tests met all acceptance criteria. Therefore, the subject device is as safe and effective as the predicate device and is substantially equivalent to the predicate device.