February 10, 2026

Biodynamik, Inc.
Johnny Chen, CEO
11 Orchard Road
Suite 107
Lake Forest, California 92630

Re: K260073
Trade/Device Name: XT3 System; XT3 System, Mini; XT3 System, 40mm; XT3 System, Mini, 40mm
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: JWD, KTT
Dated: January 9, 2026
Received: January 9, 2026

Dear Johnny Chen:

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 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and 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 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 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,

LIXIN LIU -S

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.	K260073

Please provide the device trade name(s).

XT3 System;
XT3 System, Mini;
XT3 System, 40mm;
XT3 System, Mini, 40mm

Please provide your Indications for Use below.

The Biodynamik XT3 System is indicated for fracture fixation, nonunion and transverse bone transport of the tibia and the correction of bony or soft tissue defects or deformities in adults.

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)

510(k) #: K260073

510(k) Summary

Prepared on: 2026-02-10

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Biodynamik, Inc.
Applicant Address	11 Orchard Suite 107 Lake Forest CA 92630 United States
Applicant Contact Telephone	+1-949-295-9868
Applicant Contact	Mr. Johnny Chen
Applicant Contact Email	jchen@biodynamik.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	XT3 System; XT3 System, Mini; XT3 System, 40mm; XT3 System, Mini, 40mm
Common Name	Pin, Fixation, Threaded
Classification Name	Smooth or threaded metallic bone fixation fastener
Regulation Number	888.3040
Product Code(s)	JDW, KTT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241357	XT3 System	JDW, KTT
K242861	Orthofix TrueLok Elevate	KTT

Device Description Summary

21 CFR 807.92(a)(4)

The XT3 System is an external fixation system intended for fracture fixation and bone transport procedures. The system includes fixator assemblies, implantable components, and single-use surgical instruments. These components enable controlled bone segment transport, alignment, and stabilization.

The XT3 System consists of both sterile and non-sterile components. Implantable components, such as half pins, are supplied sterile. Instruments and fixator assemblies are provided non-sterile and are intended to be end-user steam sterilized prior to use.

System components are manufactured from biocompatible materials, including surgical-grade stainless steel and anodized aluminum alloys. The XT3 System is intended for single use and supports treatment of complex orthopedic conditions requiring gradual bone transport.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Biodynamik XT3 System is indicated for fracture fixation, nonunion and transverse bone transport of the tibia and the correction of bony or soft tissue defects or deformities in adults.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject XT3 System has the same intended use and fundamental external fixation principles as the primary predicate XT3 System previously cleared under K241357. The proposed change expands the indications for use to explicitly include treatment of nonunion and correction of bony or soft tissue defects or deformities in adults.

This expanded indication does not constitute a new intended use. The XT3 System continues to function as an external skeletal fixation system that mechanically stabilizes and positions bone segments using percutaneous fixation elements and an external frame. Treatment of nonunion is an established application of external fixation systems and is consistent with the previously cleared use of the XT3 System. The inclusion of soft tissue defects or deformities reflects mechanical correction or support of adjacent soft tissues that may occur secondary to bone positioning and fixation, consistent with established external fixation practices.

The expanded indication is consistent with legally marketed predicate devices, including the Orthofix Truelok Elevate system (K242861), which is indicated for treatment of nonunion and correction of bony or soft tissue defects or deformities. The XT3 System employs similar external fixation principles and does not introduce new technological characteristics or modes of action.

Technological Comparison 21 CFR 807.92(a)(6)

The subject XT3 System has the similar technological characteristics as the primary predicate XT3 System previously cleared under K241357. The XT3 System consists of an external fixation frame mechanically fixated to the tibia using fixation elements such as half pins to provide stabilization, positioning, and controlled mechanical adjustment of bone segments and soft tissue. The system operates through mechanical adjustment of fixation components. The subject device components (e.g. lift plates and pins) are provided non-sterile and end-user steam sterilized prior to implantation.

The proposed indication expansion does not introduce any changes to the device's fundamental technological characteristics, mode of operation, or performance specifications. The XT3 System continues to employ established external fixation principles consistent with those of the predicate XT3 System and other legally marketed external fixation devices, including Orthofix Truelok Elevate.

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

Non-clinical performance testing previously conducted for the XT3 System in accordance with ASTM F1541, Standard Specification and Test Methods for External Skeletal Fixation Devices, demonstrated acceptable mechanical performance under axial compression, four-point bending, and torsional loading conditions. These tests evaluated construct stiffness, fatigue resistance, and torsional stability under clinically relevant loading and met established acceptance criteria for external fixation systems.

A supporting analytical evaluation was also performed to assess the axial pullout strength of the threaded plate–lift pin interface used in certain XT3 configurations for soft tissue elevation. Acceptance criteria were established using a calculation-based methodology derived from FDA's Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway. The calculated pullout strength of the plate–lift pin interface exceeded the reference benchmark for a nominal 3.0 mm orthopedic metallic bone screw, demonstrating equivalent or greater fixation strength.

In addition, cadaveric evaluations previously performed for the XT3 System demonstrated the system's ability to achieve the intended clinical application.

Based on the mechanical performance testing, cadaveric evaluations previously provided from the K241357 submission, and the supporting analytical evaluation, the XT3 System continues to meet applicable safety and performance requirements for its intended use and demonstrates substantial equivalence with the predicate devices.