January 22, 2025

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

Re: K241357
Trade/Device Name: XT3 System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Codes: JDW, KTT
Dated: December 24, 2024
Received: December 26, 2024

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 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,

Peter G. Allen -S

Digitally signed by Peter G. Allen -S
Date: 2025.01.22 17:45:27 -05'00'

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

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)*

K241357

Device Name

XT3 System

Indications for Use *(Describe)*

The BioDynamik XT3 System is indicated for fracture fixation and bone transport of the tibia in adults.

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.

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510(k) #: K241357

510(k) Summary

Prepared on: 2025-01-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	BioDynamik, Inc.
Applicant Address	11 Orchard Road Suite 107 Lake Forest CA 92630 United States
Applicant Contact Telephone	(949)295-9868
Applicant Contact	Mr. Johnny Chen
Applicant Contact Email	jchen@biodynamik.tech

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	XT3 System
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
K955848	Orthofix Modulsystem	JDW
K200518	Pitkar External Fixation System - Rail Mechanism	KTT

Device Description Summary

21 CFR 807.92(a)(4)

The XT3 System is composed of the XT3 fixator, Half Pins, and instrumentation, which includes a Spacer, a Drill and Cut Guide, and drivers. The XT3 Fixator and instruments are single-use devices and are supplied non-sterile intended to be steam sterilized prior to use. The Half Pins are provided sterile by gamma irradiation and are for single use only. The XT3 fixator can be adjusted via an incorporated lifting plate to provide fracture fixation or bone transport.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The BioDynamik XT3 System is indicated for fracture fixation and bone transport of the tibia in adults.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The BioDynamik XT3 System is indicated for fracture fixation and bone transport of the tibia in adults.

While the indications for use statement is not identical to the predicate device, the intended use for both devices is the same; the subject and predicate devices are both fixation devices that utilize an external fixator device and accessories for fixation of fractures and bone transport. The predicate device, Orthofix Advanced ModulSystem, is indicated for fracture, joint fixation, bone transport, lengthening and angular correction in long bones.

Although the XT3 System is indicated to be used specifically for fracture fixation and bone transport of the tibia in skeletally mature

adults, both devices are external fixation devices that provide stabilization of tibial fractures with mechanisms to facilitate bone transport. The differences in the predicate device's indications and the subject device's indications do not alter the intended use or application; both devices are intended for bone fracture fixation.

Technological Comparison

21 CFR 807.92(a)(6)

The design of the XT3 System is similar to the LRS - Limb Reconstruction System components of the predicate device Orthofix Modulsystem (K955848). Both the subject XT3 System and Orthofix Modulsystem utilize an external fixator component and half pins for fracture stabilization and instrumentation to facilitate fracture fixation and bone transport by principles of locked skeletal fixation and distraction osteogenesis and is implanted using the same surgical technique. Although the indications for use between the subject XT3 System and the predicate mechanism are not identical, new questions about safety and effectiveness are not raised.

In summary, the key technological features and principles of operation of the subject XT3 System are substantially equivalent to the primary predicate Orthofix Modulsystem. The minor differences in technological characteristics do not affect safety and effectiveness. Additional performance testing demonstrates that the XT3 System performs in a manner that is substantially equivalent to the performance of the predicate Orthofix Modulsystem.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Comprehensive testing was performed on the XT3 System and the Orthofix LRS components of the Modulsystem per ASTM F1541-17 Annex 7: axial load test, four-point bend test, and torsion test. The objective comparison of performance testing results demonstrate the XT3 System is substantially equivalent to the predicate device.

In addition, cadaver testing was performed to demonstrate that the XT3 System could be used successfully in accordance with the intended use.

Comprehensive testing on the XT3 System was performed per ASTM F1541-17 Annex 7: axial load test, four-point bend test, and torsion test. These tests are designed to determine the stiffness, strength, and dynamic loading performance characteristics of the external skeletal fixator-bone constructs of the XT3 System when subjected to force loading and moment loading. All XT3 samples passed their respective acceptance criterion for static axial compression, dynamic axial compression, A-P and M-L four-point bending, and torsion. Additionally, mechanical testing of the Orthofix Modulsystem was performed per ASTM F1541-17 in order to provide objective comparison of mechanical performance testing data. The mechanical testing results of the XT3 system are verified to meet the design inputs and are substantially equivalent to the predicate device.

Cadaver testing was performed to demonstrate that the XT3 System could be used successfully in accordance with the intended use.