September 25, 2025

Auxano Medical LLC
Stephen Mezget
Project Engineer
8006 Katherine Boulevard
Brecksville, Ohio 44141

Re: K251791
Trade/Device Name: Auxano® Wedge Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PLF
Dated: June 11, 2025
Received: June 11, 2025

Dear Stephen Mezget:

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, MS.
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)*

K251791

Device Name

Auxano® Wedge Fixation System

Indications for Use *(Describe)*

The Auxano® Wedge Fixation System is intended to be used as internal bone fixation for bone fractures or osteotomies in the ankle and foot. Specific indications include:
• Cotton (opening wedge) osteotomies of the medial cuneiform
• Evans lengthening osteotomies

The Auxano® Wedge Fixation System is indicated for use with ancillary plating fixation.

The Auxano® Wedge Fixation System is not intended for spinal use.

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) Summary

Auxano® Wedge Fixation System

SUBMITTER

Auxano Medical LLC
8006 Katherine Boulevard
Brecksville, OH 44141
Phone: 440-262-2519

Contact Person: Stephen Mezget – Project Engineer
Email: Stephen.Mezget@AuxanoMedical.net
Date Prepared: August 28, 2025

DEVICE INFORMATION

Trade/Device Name: Auxano® Wedge Fixation System
Common Name: Bone Wedge
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: PLF

PREDICATE INFORMATION

Primary Predicate : K240461 (OsteoSinter® EVANS and COTTON wedge and related accessories; AMES MEDICAL Prosthetic Solutions S.A.U)

Additional Predicate : K130185 (4Web Osteotomy Bone Wedge; 4-Web, Inc.)

Additional Predicate : K201314 (Restor3d Utility Wedge; Restor3d, Inc.)

INDICATIONS FOR USE:

The Auxano® Wedge Fixation System is intended to be used as internal bone fixation for bone fractures or osteotomies in the ankle and foot. Specific indications include:

- Cotton (opening wedge) osteotomies of the medial cuneiform
- Evans lengthening osteotomies

The Auxano® Wedge Fixation System is indicated for use with ancillary plating fixation.

The Auxano® Wedge Fixation System is not intended for spinal use.

DEVICE DESCRIPTION

The Auxano® Wedge Fixation System (WFS) is a titanium implant that is designed to be used for internal bone fixation and angular correction of foot geometry. The implants are offered in different length x width profiles (16x11, 20x14, 18x18, 20x20, and 22x22 mm) and heights (4.50, 5.50, 6.50, 8, 10, and 12 mm) to address different anatomic locations and size variations. All implants are made from Ti-6AL-4V ELI Titanium alloy per ASTM F3001. The Auxano® Wedge Fixation System includes implants, the instruments necessary to implant them, and the tray system for transport, storage and sterilization.

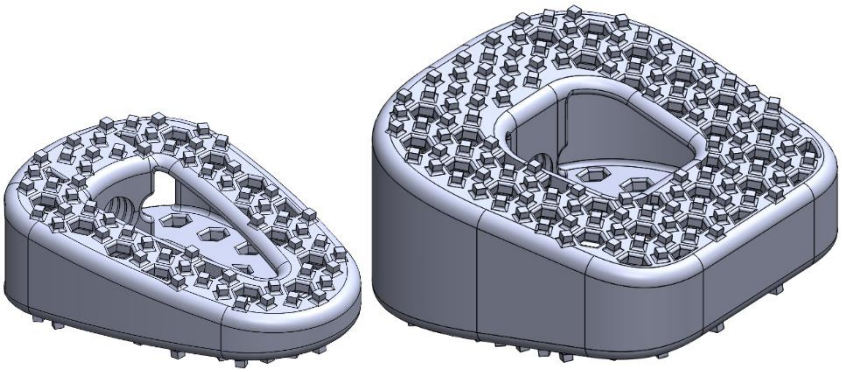

Figure 1: Auxano® Wedge Fixation System

Table 1: General System Descriptive Information

System Description	**Auxano® Wedge Fixation System**
Intended Use	Internal bone fixation of bone fractures, fusions, or osteotomies in the foot
Product Code	PLF
Target Population	Skeletally mature adults only
Anatomical Sites(s) of Use	Size appropriate sites of the foot and ankle
Provided Sterile / Non-Sterile	Provided non-sterile
Sterilization Method	Steam sterilization
Shelf Life	Metallic implants (single use) are time stable. Reusable instruments are inspected in reprocessing for conditions compromising function.
System Components that can be Reprocessed	All instruments (except for k-wires) are reusable and can be reprocessed. See Instructions for Use and Processing Instructions.
Summary of Fixation Function	In addition to supplemental fixation, the implant's fixation geometry temporarily stabilizes the fragments/bodies of bone until bone fusion occurs. The implant is hollow, which allows packing of bone graft material, and fenestrated, which allows bone growth and formation throughout the implant.

Table 2: Comparison of Technological Characteristics with the Predicates

	Subject Device: Auxano® Wedge Fixation System	**Predicate (K240461):** Ames Medical Osteosinter® Wedge System	**Secondary Predicate (K130185):** 4Web Osteotomy Bone Wedge System	**Tertiary Predicate (K201314):** Restor3d Utility Wedge System
Device Class and Product Code:	Class II; PLF	Class II; PLF	Class II; HRS	Class II; PLF
	Substantial Equivalence:	Same	Similar	Same
Sterilization:	Implants & Instruments – provided NON-STERILE; Steam sterilize on-site to SAL of $\leq 10^{-6}$	Implant & Instruments – provided STERILE	Implants & Instruments – provided NON-STERILE; Steam sterilize on-site to SAL of $\leq 10^{-6}$	Implant & Instruments – provided STERILE
	Substantial Equivalence:	Different	Same	Different
Prescription:	Prescription Only	Prescription Only	Prescription Only	Prescription Only
	Substantial Equivalence:	Same	Same	Same
Indications for Use:	The Auxano® Wedge Fixation System is intended to be used as internal bone fixation for bone fractures or osteotomies in the ankle and foot. Specific indications include: • Cotton (opening wedge) osteotomies of the medial cuneiform	The Ames Medical Osteosinter® Wedge System is intended to be used for internal bone fixation of bone fractures, fusions, or osteotomies in the foot. Specific indications include: • Opening wedge osteotomies of the bone of the foot (including	The 4Web Osteotomy Bone Wedge System is intended to be used for internal bone fixation or osteotomies in the foot, such as: 1. Opening wedge osteotomies of Hallux Valgus	The Restor3d Utility Wedge System is intended to be used for internal bone fixation for bone fractures or osteotomies in the ankle and foot, such as: • Opening wedge osteotomies of the bones of the foot including

	Subject Device: **Auxano® Wedge Fixation System**	**Predicate (K240461):** **Ames Medical Osteosinter® Wedge System**	**Secondary Predicate (K130185):** **4Web Osteotomy Bone Wedge System**	**Tertiary Predicate (K201314):** **Restor3d Utility Wedge System**
	• Evans lengthening osteotomies The Auxano® Wedge Fixation System is indicated for use with ancillary plating fixation. The Auxano® Wedge Fixation System is not intended for spinal use.	osteotomies for Hallux Valgus) • Opening wedge of Medial Cuneiform or Cotton Osteotomies • Lateral Column Lengthening (Evans Lengthening osteotomy or Calcaneal Z Osteotomy) • Metatarsal/Cuneiform arthrodesis. The Ames Medical Osteosinter® Wedge System is indicated for use with ancillary bone fixation. The Ames Medical Osteosinter® Wedge System is not intended for spinal use.	2. Cotton opening wedge osteotomies 3. Evan's lengthening osteotomies These devices are intended to be used with autograft bone and ancillary fixation. The 4Web Osteotomy Bone Wedge System is not intended for use in the spine.	osteotomies for Hallux Valgus • Opening wedge of Medial Cuneiform or Cotton osteotomies • Lateral Column Lengthening (Evan's Lengthening osteotomy or Calcaneal Z Osteotomy) • Metatarsal Cuneiform osteotomies • Nonunion of arthrodesis of the Midfoot including Metatarsal Cuneiform osteotomies (TMT or Lapidus) • Hindfoot osteotomies such as Ankle fusion and Subtalar fusion. The Restor3d Utility Wedge System is intended for use with supplemental fixation. The Restor3d Utility Wedge System is not intended for use in the spine.
	Substantial Equivalence:	Similar	Similar	Similar

	Subject Device: **Auxano® Wedge Fixation System**	**Predicate (K240461):** **Ames Medical Osteosinter® Wedge System**	**Secondary Predicate (K130185):** **4Web Osteotomy Bone Wedge System**	**Tertiary Predicate (K201314):** **Restor3d Utility Wedge System**
Intended Use:	Internal bone fixation for bone fractures or osteotomies in the ankle and foot.	Internal bone fixation of bone fractures, fusions, or osteotomies in the foot.	Internal bone fixation or osteotomies in the foot.	Internal bone fixation for bone fractures or osteotomies in the ankle and foot.
	Substantial Equivalence:	Similar	Similar	Same
Components:	K-wires, Trials, Threaded Inserter, Impactor, Hintermann Distractor, Osteotomes, Mallet, Slap Hammer	Sizers, Tweezer, Impactor	Trial Spacers, Threaded Inserter, Bone Tamp/Impactor	Trials, Threaded Inserter
	Substantial Equivalence:	Similar	Similar	Similar
Technical Characteristics:	- Surface features for bone stabilization - Unenclosed proximal face - Open architecture (fenestrations and graft window) along bone contacting surfaces	- Surface features for bone stabilization - Open architecture (porosity and graft window) along bone contacting surfaces	- Surface texture for bone stabilization - Open architecture (fenestrations) along all surfaces	- Surface features for bone stabilization - Open architecture (porosity and graft window) along bone contacting surfaces
	Substantial Equivalence:	Similar	Similar	Similar

PERFORMANCE DATA:

- Mechanical testing was carried out per ASTM F2077 on subject device for static and dynamic compression.
- Steam sterilization validation testing was conducted on the Auxano® Wedge Fixation System according to ISO 17665-1:2006/(R)2013, ISO 14937, and ISO 17665:2024.

CONCLUSION

The Auxano® Wedge Fixation System has the same or similar intended use/indications for use, the same or similar technology, comparable principles of operation, and same materials as the identified predicate systems: Ames Medical Osteosinter® Wedge System (K240461), 4Web Osteotomy Bone Wedge System (K130185), and Restor3d Utility Wedge System (K201314). The Auxano® Wedge Fixation System does not present any new issues of safety or effectiveness as compared to the predicate systems. Performance testing, according to ASTM F2077 (static and dynamic axial compression) demonstrates the subject implants perform as well as or better than the Ames Medical Osteosinter® Wedges currently on the market. Therefore, the Auxano® Wedge Fixation System is substantially equivalent to the identified predicate systems.