



February 19, 2026

MiRus, LLC
Anuradha Nagulapati
Senior Regulatory Affairs Engineer
1755 W. Oak Parkway
Suite 100
Marietta, Georgia 30062

Re: K252733

Trade/Device Name: ATLAS™ Expandable Osteotomy Wedge 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: January 20, 2026

Received: January 20, 2026

Dear Anuradha Nagulapati:

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

Indications for Use

Submission Number (if known)

K252733

Device Name

ATLAS™ Expandable Osteotomy Wedge System

Indications for Use (Describe)

The ATLAS™ Expandable Osteotomy Wedge System is an expandable osteotomy wedge fusion device used for internal bone fixation for bone fractures, fusions, or osteotomies in the foot and ankle.

The ATLAS™ Expandable Osteotomy Wedge System is intended for use with supplemental fixation for use in the foot or ankle.

The ATLAS™ Expandable Osteotomy Wedge System is not intended for use in the spine.

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) #: K252733

510(k) Summary

Prepared on: 2026-01-20

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	MiRus, LLC
Applicant Address	1755 W. Oak Parkway Suite 100 Marietta GA 30062 United States
Applicant Contact Telephone	470-428-8684
Applicant Contact	Ms. Anuradha Nagulapati
Applicant Contact Email	anagulapati@mirusmed.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	ATLAS™ Expandable Osteotomy Wedge System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Bone Wedge
Regulation Number	888.3030
Product Code(s)	PLF

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K162241	TITAN 3-D™ Wedge System	PLF
K201314	Restor3d Utility Wedge	PLF
K210800	IO™ Expandable Lumbar Interbody Fusion System	MAX

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The ATLAS™ Expandable Osteotomy Wedge System is an expandable osteotomy wedge fusion device used for internal bone fixation for bone fractures, fusions, or osteotomies in the foot and ankle.

The ATLAS™ Expandable Osteotomy Wedge System consists of implants manufactured from Titanium-6 Aluminum-4 Vanadium ELI per ASTM F136. Expansion mechanism components are manufactured from Molybdenum-47.5 Rhenium Alloy (MoRe) per ASTM F3273. Instrumentation are manufactured from Stainless Steel per ASTM F899.

The ATLAS™ Expandable Osteotomy Wedge System implants are offered in multiple configurations and different sizes to accommodate various patient anatomical requirements. The implants (osteotomy wedges) will be provided sterile packed and are intended for single use only. The instruments will be provided non-sterile and will be steam sterilized by the end user.

Intended Use/Indications for Use

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

The ATLAS™ Expandable Osteotomy Wedge System is an expandable osteotomy wedge fusion device used for internal bone fixation for bone fractures, fusions, or osteotomies in the foot and ankle.

The ATLAS™ Expandable Osteotomy Wedge System is intended for use with supplemental fixation for use in the foot or ankle.

The ATLAS™ Expandable Osteotomy Wedge System is not intended for use in the spine.

Indications for Use Comparison

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

The indications for the use are identical for the subject device and predicate devices.

Technological Comparison

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

The ATLAS™ Expandable Osteotomy Wedge System has the same intended use, indications for use, labeling, and technological characteristics as the predicate systems, including the same design features, geometries, sizes, and materials. The predicate device components are manufactured from titanium alloy. The ATLAS™ Expandable Osteotomy Wedge System components are manufactured from titanium alloy (ASTM F136) and molybdenum-rhenium alloy (ASTM F3273), which are the same materials as the IO™ Expandable Lumbar Interbody Fusion System (Reference device – K210800).

Performance data demonstrate that the ATLAS™ Expandable Osteotomy Wedge System is substantially equivalent to other legally marketed predicate systems.

Non-Clinical and/or Clinical Tests Summary & Conclusions

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

The mechanical performance profile of the ATLAS™ Expandable Osteotomy Wedge System was assessed through static and dynamic testing in accordance with the following test methods:

- Static and dynamic compression testing (ASTM F2077-18)
- Static and dynamic compression shear testing (ASTM F2077-18)
- Subsidence testing (ASTM F2267-04)
- Expulsion testing (ASTM Draft Standard F-04.25.02.02)

The ATLAS™ Expandable Osteotomy Wedge System has the same intended use, indications for use, labeling, and technological characteristics as the predicate systems, including the same design features, geometries, sizes, and materials. The predicate device components are manufactured from titanium alloy. The ATLAS™ Expandable Osteotomy Wedge System components are manufactured from titanium alloy (ASTM F136) and molybdenum-rhenium alloy (ASTM F3273), which are the same materials as the IO™ Expandable Lumbar Interbody Fusion System (Reference device – K210800).

Performance data demonstrate that the ATLAS™ Expandable Osteotomy Wedge System is substantially equivalent to other legally marketed predicate systems.