



March 12, 2026

Allevion Medical, LLC  
Stephen Inglese  
Quality Manager  
915 Clint Moore Rd  
Boca Raton, Florida 33487

Re: K252546  
Trade/Device Name: Vantage™ Lumbar Decompression Kit  
Regulation Number: 21 CFR 888.1100  
Regulation Name: Arthroscope  
Regulatory Class: Class II  
Product Code: HRX, HAE  
Dated: October 31, 2025  
Received: October 31, 2025

Dear Stephen Inglese:

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), 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 Medical Device File (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**JESSE MUIR -S** Digitally signed by JESSE MUIR  
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Date: 2026.03.12 16:09:14  
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Jesse Muir, Ph.D.  
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

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

K252546

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Please provide the device trade name(s).

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Vantage™ Lumbar Decompression Kit

Please provide your Indications for Use below.

?

The Vantage™ Lumbar Decompression Kit by Allevion Medical is a specialized set of surgical instruments intended to be used to perform lumbar decompression procedures used in the treatment of various spinal conditions.

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

- Prescription Use (Part 21 CFR 801 Subpart D)  
 Over-The-Counter Use (21 CFR 801 Subpart C)

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## 510(k) Summary

**Submitter:** Allevion Medical, LLC  
915 Clint Moore Rd  
Boca Raton, FL 33487

**Primary Contact:** Mr. Stephen Inglese  
Allevion Medical, LLC  
915 Clint Moore Rd  
Boca Raton, FL 33487

**Date Prepared:** March 6, 2026

**Trade Name:** Vantage™ Lumbar Decompression Kit

**Common Name:** Arthroscope and Accessories

**Regulatory Class:** II

**Classification Name:** Arthroscope (21 CFR 888.1100)

**Product Code:** HRX, HAE

**Predicate Devices:** ELID System, LESspine Innovations, K243774

### Device Description:

The Vantage™ Lumbar Decompression Kit is a sterile, single-use device designed to facilitate lumbar spine decompression procedures. It includes a variety of specialized instruments intended to be used together to access and remove bone and soft tissue during decompression.

The kit supports multiple procedural approaches by utilizing different components of the kit. The physician can utilize Vantage™ Lumbar Decompression Kit in open, direct visualization or indirect visualization approaches. All kits contain a disposable light source to assist with visualization if desired.

### Indications:

The Vantage™ Lumbar Decompression Kit by Allevion Medical is a specialized set of surgical instruments intended to be used to perform lumbar decompression procedures used in the treatment of various spinal conditions.

### Comparison of Technological Characteristics with the Predicate Device:

The subject and predicate devices share the same intended use. Both the subject and predicate devices include specialized instruments that are intended to be used to perform lumbar decompression procedures for the treatment of various spinal conditions.

The subject device includes similar instruments compared to the predicate system. Additionally, the subject and predicate device incorporate different materials.

The assessments performed on the subject device demonstrate that any differences in technological characteristics do not raise difference questions of safety and effectiveness and that the subject device is substantially equivalent to the cited predicate.

**Performance Data:**

The following assessments have been performed on Vantage™ Lumbar Decompression Kit.

- Biocompatibility Assessment per ISO 10993-1
  - Cytotoxicity
  - Sensitization
  - Irritation
  - Acute System & Pyrogenicity
- Sterilization Validation per ISO 11137
- Shelf-Life Validation
- Packaging Validation per ASTM D4169, ASTM F2096, ISO 11607
- Cadaveric Testing
- Performance Assessments to demonstrate the devices are able to withstand physiological loading
- Particulate Assessment per ASTM F1877

**Conclusion:**

Based on Indications for Use, design, technological characteristics, and the results of all performance testing, it has been determined that the Vantage™ Lumbar Decompression Kit is substantially equivalent to the predicate device.