



October 3, 2025

Augmedics Ltd.  
% Janice Hogan  
Partner  
Hogan Lovells US LLP  
1735 Market Street, Floor 23  
Philadelphia, Pennsylvania 19103

Re: K251639  
Trade/Device Name: xvision Spine system  
Regulation Number: 21 CFR 882.4560  
Regulation Name: Stereotaxic Instrument  
Regulatory Class: Class II  
Product Code: SBF  
Dated: May 29, 2025  
Received: September 4, 2025

Dear Janice Hogan:

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

Sincerely,

  
**Shumaya Ali -S**  
Shumaya Ali, M.P.H.  
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.

K251639

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Please provide the device trade name(s).

?

xvision Spine system

Please provide your Indications for Use below.

?

The xvision Spine System, with xvision Spine System Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous spine procedures.

Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to a patient's fluoroscopic or CT imagery of the anatomy. This can include the following spinal procedures:

- Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region.
- Posterior Screw Placement in C3-C7 vertebrae
- Iliosacral Screw Placement
- Angular procedures requiring access to the disc space
- Lateral trajectories required to access the Sacro-Iliac joint

The Headset of the xvision Spine System displays 2D stereotaxic screens and a virtual anatomy screen. The stereotaxic screen is indicated for correlating the tracked instrument location to the registered patient imagery. The virtual screen is indicated for displaying the virtual instrument location in relation to the virtual anatomy to assist in percutaneous visualization and trajectory planning.

The virtual display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed stereotaxic information.

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)

?

**510(k) Summary - K251639**  
**Augmedics' xvision Spine system**

**SUBMITTER**

Augmedics LTD.  
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Yokneam Illit, 2069205, Israel  
Phone: +972-4-3730111

Contact person: Tami Harel

Date prepared: May 29, 2025

Name of device: xvision Spine System

**Common or Usual Name**      XVS

**Classification Name:**      Orthopedic Augmented Reality (21 CFR  
882.4560)

**Regulatory Class:**      Class II

**Product Code:**      SBF

**Predicate Device:**      xvision Spine System, manufactured by  
Augmedics Ltd. Israel (K250255)

**INTENDED USE / INDICATIONS FOR USE**

The xvision Spine system, with xvision Spine system software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous spine procedures.

Their use is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the spine or pelvis, can be identified relative to a patient's fluoroscopic or CT imagery of the anatomy. This can include the following spinal procedures:

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The virtual display should not be relied upon solely for absolute positional information and should always be used in conjunction with the displayed stereotaxic information.

## **DEVICE DESCRIPTION SUMMARY**

The xvision Spine (XVS) system is an image-guided navigation system that is designed to assist surgeons in placing pedicle screws accurately, during open or percutaneous computer-assisted spinal surgery. The system consists of dedicated software, headset, single use passive reflective markers and reusable components. It uses wireless optical tracking technology and displays to the surgeon the location of the tracked surgical instruments relative to the acquired patient's scan, onto the surgical field. The 2D scanned data and 3D reconstructed model, along with tracking information, are projected to the surgeons' retina using a transparent near-eye-display Headset, allowing the surgeon to both look at the patient and the navigation data at the same time.

The purpose of this 510(k) submission is to add an alternative headset configuration (Gen 2) to the cleared Gen 1 configuration. The XVS software is updated to enable integration of the Gen 2 headset, along with minor enhancements to the tracking algorithm and bug fixes.

## **INDICATION FOR USE COMPARISON**

The intended use and the indications for use of the modified XVS are identical to the cleared predicate device.

## **TECHNOLOGICAL COMPARISON**

The modified xvision Spine System is similar in its technological features to its predicate device, the cleared xvision Spine System. Both the cleared and the modified devices use wireless optical tracking technology, and display to the surgeon the location of the tracked surgical instruments relative to the acquired patient's scan, onto the surgical field. The 2D scanned data and 3D reconstructed model, along with tracking information, are projected to the surgeon's retina using a transparent near-eye-display headset, allowing the surgeon to simultaneously visualize the patient and the navigation data in real time.

The modified XVS system supports an alternative headset configuration (Gen 2), with minor software enhancements to the tracking algorithm. The new headset configuration, with the updated software, incorporates ergonomic and visualization improvements while maintaining the same intended functions and fundamental technological principles as the cleared device. Both headsets are battery operated and are comprised of similar components: transparent near-eye display, monochromatic camera with infrared (IR) filter, electronics to support headset functionality and a headlamp. Improved display visualization and ergonomics of Gen 2 configuration include larger display field of view, higher display resolution, lighter weight, improved ergonomics and improved headlamp illumination intensity for better visibility.

The principles of operation of the modified XVS and the cleared device are the same. The design modifications that were introduced to the hardware components and software features are minor enhancements that do not change the system's principles of operations or the way the user interacts with the system.

## PERFORMANCE DATA

The following tests were conducted to evaluate the device:

- Software verification and validation testing was conducted as required by IEC 62304 and FDA guidance on general principles of software validation, January 11, 2002
- The performance of the Gen2 headset display was demonstrated by verifying the following elements: field of view, resolution, transmission, contrast ratio, distortion, grey level display, luminance stability over use time, latency, and accurate alignment of the virtual 3D model with reality.
- Electrical safety was tested in accordance with ANSI/AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021] - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- Electromagnetic Compatibility (EMC) was tested in accordance with IEC 60601-1-2 Edition 4.1 2020-09 (consolidated version) - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- Headset Gen 2 was demonstrated to be compliant with the RF radiation exposure limits of the FCC Part 15 requirements.
- Shipping validation on Gen 2 headset was performed according to ASTM D4169 standard
- Cleaning and disinfection evaluation was performed on Gen 2 headset according to ISO 17664-1:2021, AAMI TIR 12:2020/(R):2023 and ANSI/AAMI ST98:2022
- The reliability of new mechanisms of headset Gen2 were verified.
- Gen2 headlamp was verified to comply with its specifications
- Positional accuracy was tested according to ASTM 2554
- Registration and overall accuracy were tested using phantoms, under different scenarios simulating clinical conditions. Tests were performed using both headsets' configurations.
- The system's accuracy was validated in a cadaver study, using both headsets' configurations. Screws were positioned in different vertebrae levels using IntraOp and 2D-3D registration methods. The positional and trajectory errors were calculated as the difference between the actual and virtual screw tip position, and the difference between the screw orientation and its recorded virtual trajectory. Additionally, clinical accuracy was evaluated using the Gertzbein-Robbins score by viewing the post-op scans
- A formative human factors assessment was performed as part of the cadaver study. Each surgeon completed full clinical flow of using the XVS system while using both headsets' configurations. After completing the screw placement procedure, the participants were asked

to fill out a questionnaire regarding the use of the two headsets' configurations related to the ergonomics and visual performance.

All performance testing demonstrates that the xvision Spine System performs according to specifications and functions as intended.

## **CONCLUSIONS**

The modified XVS system and the cleared XVS system have the same intended use and indications for use, similar technological characteristics, and the same principles of operation. The minor design changes introduced in the proposed system, including the addition of an alternative headset configuration and related software updates, are intended to enhance surgeon ergonomics, optical personalization, and tracking robustness. These modifications do not present new or different questions of safety or effectiveness compared to the predicate device. Performance data (bench and cadaver), demonstrate that the modified system meets the same acceptance criteria as the cleared system and that the accuracy as well as visual performance of the modified XVS system remain comparable to that of the predicate device.

Thus, the modified XVS system is substantially equivalent to its predicate device, the cleared XVS system (K250255).