July 31, 2026

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

Re: K261854
Trade/Device Name: xvision Spine system
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: SBF
Dated: June 3, 2026
Received: June 3, 2026

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 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), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

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.	K261854

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 (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

510(k) Summary

Augmedics'
xvision Spine system

SUBMITTER

Augmedics LTD.
2 Ha-Otsma St.
Yokneam Illit, 2069205, Israel
Phone: +972-4-3730111

Contact person: Tami Harel

Date prepared: June 3, 2026

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. (K251639)

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:

- Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region.
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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.

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.

An additional software version with minor enhancements that supports only the cleared IntraOp registration method is provided as an alternative to the cleared software version under K251639, which supports both the IntraOp and 2D-3D registration methods. Other minor hardware and material modifications are introduced to the cleared Gen2 headset (now called "X2") for improved ergonomics, reliability, and manufacturing.

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.

Modifications to the system are limited to the addition of an alternative software version that supports only one of the cleared registration methods (i.e., the IntraOp registration method) with minor software enhancements. The limitation to only one of the two previously cleared registration methods does not raise any new questions of safety or effectiveness because the functionality is a subset of what was already cleared, and users could already choose one of the two registration methods. The software update simply streamlines the software package without changing its functionality. Additionally, minor hardware and material modifications were introduced to the cleared Gen2 headset configuration for improved ergonomics, reliability, and manufacturability. The mechanical modifications to the headset include replacement of flexible Velcro straps with rigid plastic supports, improvements to the tilt mechanism, temples' hinges, back strap mechanism and transportation box. Electrical improvements include improved thermal management and minor changes in PCBs for components' end-of-life

support and improved reliability and manufacturability. Three new materials were incorporated to reinforce structural rigidity and ergonomic fit.

The principles of operation and fundamental technology of the modified XVS and the cleared device are the same. The minor modifications that were introduced to the XVS system do not change the way the user interacts with the system. None of the modifications raises new or different questions of safety and effectiveness compared to its predicate device.

PERFORMANCE DATA

The following tests were conducted for the verification of the device modifications:

- Software verification and validation testing was conducted as required by IEC 62304 and FDA guidance on general principles of software validation, January 11, 2002

- 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 X2 was demonstrated to be compliant for localized specific absorption rate (SAR) for uncontrolled environment/general exposure limits specified in ANSI C95.1-1999.

- Shipping validation on X2 headset was performed according to ASTM D4169 standard

- Cleaning and disinfection validation was performed on X2 headset according to ISO 17664-1:2021, AAMI TIR 12:2020/(R):2023 and ANSI/AAMI ST98:2022

- The reliability of modified mechanisms of headset X2 were verified.

- Positional accuracy was tested according to ASTM 2554

- Registration accuracy was tested using X2 headset and phantom, under different scenarios simulating clinical conditions.

- A user preference evaluation was performed in which the modified design was provided to users to gather ergonomic feedback.

All performance verification 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 technological differences between the modified XVS system and its predicate raise no new or different questions of safety or effectiveness. Performance data demonstrate that the modified system meets the same acceptance criteria as the cleared system and that the performance of the modified XVS system remains comparable to that of the predicate device.

Thus, the modified XVS system is substantially equivalent to its predicate device, the cleared XVS system (K251639).