March 13, 2025

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

Re: K250255
Trade/Device Name: xvision Spine system
Regulation Number: 21 CFR 882.4560
Regulation Name: Orthopedic Augmented Reality
Regulatory Class: Class II
Product Code: SBF
Dated: January 28, 2025
Received: March 13, 2025

Dear Janice M. 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) 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

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.

510(k) Number *(if known)*
K250255

Device Name
xvision Spine System

Indications for Use *(Describe)*
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.

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.

510(k) Summary Augmedics'

xvision Spine system

SUBMITTER

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

Contact person: Tami Harel

Date prepared: January 28, 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 (K241481)

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

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.

This special 510(k) submission outlines minor software and hardware modifications to the cleared XVS system, aimed at enhancing the 2D-3D registration process. Changes include minor updates to the C-ARM Ring adaptor, XVS sterile kits with C- and X-markers, and the addition of a patient marker extender for improved reflectors' visibility. A new software version introduces enhancements to the GUI, ease of use, and bug fixes.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the modified XVS system are identical to the technological characteristics of the predicate device. Both the cleared and the subject 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 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.

This submission outlines a series of minor hardware and software modifications aimed at enhancing the 2D-3D registration workflow, improving component reliability, and adding transportation package option for XVS sterile kits. To enhance the registration process, hardware changes were applied to the C-ARM Ring Adapter and a new component (i.e., Patient Marker Extender) was introduced. Software modifications include cybersecurity and HIPPA enhancement, adding GUI guidance and enforce allowable distances and angles for markers during registration. Reliability of components has been improved through minor deign changes. Lastly, a new transportation package for XVS sterile kits holding 3-unit package, was introduced to complement the existing 10-unit package. Performance tests verified that mechanical stability of the attachment of the new component, overall system accuracy and compliance with existing sterilization, cleaning and transportation standards is maintained.

The minor hardware and software changes do not impact clinical use, and do not raise any new questions of safety or efficacy. Together these modifications enhance ease of use and reliability while preserving the device's fundamental technology, safety, and effectiveness.

To conclude, while the modified XVS system offers minor enhancements to some hardware components and some software features, the basic technology remains the same and is validated using the same method and the same success criteria.

A substantial equivalence table summarizing the similarities and differences between the xvision Spine system and its predicate device is provided below.

Augmedics Ltd.

xvision Spine system
Substantial Equivalence Comparison Table

	xvision Spine (subject device)	xvision Spine (K241481)	Conclusion
Intended 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	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	Identical
Indications for Use	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	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	Identical
User Population	Orthopedic surgeons or neurosurgeons	Orthopedic surgeons or neurosurgeons	Identical
Intended Use Environment	Operating Room	Operating Room	Identical
Main System Components	• Headset with near eye see-through display and tracking camera. • Software application • Flat reflective markers	• Headset with near eye see-through display and tracking camera. • Software application • Flat reflective markers	Identical

	xvision Spine (subject device)	xvision Spine (K241481)	Conclusion
	• Tool adaptors • Reference point: Patient Clamp and Perc Pin • Computer, roll stand or Cart C-ARM Ring Adapter	• Tool adaptors • Reference point: Patient Clamp and Perc Pin • Computer, roll stand or Cart • C-ARM Ring Adapter	
Registration Methods	• IntraOp – requiring IntraOp 3D scan (Z-link & X-link) 2D-3D (PreOp), requiring PreOp 3D CT scan and at least two IntraOp X-ray images	• IntraOp – requiring IntraOp 3D scan (Z-link & X-link) • 2D-3D (PreOp), requiring PreOp 3D CT scan and at least two IntraOp X-ray images	Identical
Rigid Reference Point	• Patient Clamp attached to the spinous process • Perc Pin inserted into the PSIS A Patient Marker can be directly attached to the Patient Clamp or the Perc Pin. Alternatively, a **Patient Marker Extender** can be attached to the Patient Clamp or the Perc Pin, providing an interface for securing the Patient Marker.	• Patient Clamp attached to the spinous process • Perc Pin inserted into the PSIS A Patient Marker is directly attached to either the Patient Clamp or the Perc Pin	Similar. A new component, the Patient Marker Extender, is introduced in this market application. The Patient Marker Extender extends the Patient Marker to prevent partial coverage of its reflectors by the C-ARM detector during the 2D/3D registration process. However, there is no change in the registration workflow or in the principal technology that supports it. Performance testing demonstrated that the mechanical stability of the Patient Marker Extender assembly meets the same acceptance criteria as the cleared Patient Marker assembly (K241481). Additionally, the overall system accuracy, including positional and angular accuracy during 2D/3D registration, was validated successfully using the same methods and acceptance criteria as K241481.

	xvision Spine (subject device)	xvision Spine (K241481)	Conclusion
Instrument (Tool) Adaptors	• Reusable • Universal (connects to various tools, not system-specific) VP & Ergonomic (system specific adaptors)	• Reusable • Universal (connects to various tools, not system-specific) • VP & Ergonomic (system specific adaptors)	Identical
Localization Technology	Optical	Optical	Identical
Reflective Markers	• Flat • Single use, provided sterile Sterilized by Gamma Radiation	• Flat • Single use, provided sterile • Sterilized by Gamma Radiation	Identical
Optical Tracker	Single infrared camera, positioned 0.5m above tracked objects	Single infrared camera, positioned 0.5m above tracked objects	Identical
Tracking	6 DOF	6 DOF	Identical
Tracking Algorithm	Perspective N-point	Perspective N-point	Identical
System Accuracy Requirement	System Level Accuracy with a mean 3D positional error of 2.0mm and mean trajectory error of 2°	System Level Accuracy with a mean 3D positional error of 2.0mm and mean trajectory error of 2°	Identical
Deep-Learning Based Spine Segmentation Algorithms	• Full spine anatomy segmentation from background • Segmentation of single spine vertebra	• Full spine anatomy segmentation from background • Segmentation of single spine vertebra	Identical
Imaging Modality	X-ray based imaging	X-ray based imaging	Identical
Medical Device Interfaces	• O-arm Imaging System • Ziehm Vision FD Vario 3D C-Arm and RFD 3D • Siemens CIOS SPin • Airo system by Brainlab • ExcelsiusGPS Round C-ARMS: • GE OEC 9900 Elite, GE OEC 9800 and 9800 plus all 9” & 12” models	• O-arm Imaging System • Ziehm Vision FD Vario 3D C-Arm and RFD 3D • Siemens CIOS SPin • Airo system by Brainlab • ExcelsiusGPS Round C-ARMS: GE OEC 9900 Elite, GE OEC 9800 and 9800 plus all 9” & 12” models	Identical
Display Optics and Technology	Augmented Reality using near eye see-through display; data displayed on patient’s anatomy	Augmented Reality using near eye see-through display; data displayed on patient’s anatomy	Identical

	xvision Spine (subject device)	xvision Spine (K241481)	Conclusion
Communication Between Headset and Computer	Wireless, encrypted	Wireless, encrypted	Identical
Supported Frequencies & Transmission Protocol	5 GHz 802.11g/n/ac	5 GHz 802.11g/n/ac	Identical
Frame Rate of Displayed Images	60 fps	60 fps	Identical
OE Field of View	32.5° (vertical) X 18° (horizontal)	32.5° (vertical) X 18° (horizontal)	Identical
Pixel Resolution	1280x720 per eye	1280x720 per eye	Identical
Optical Distortion	<5%	<5%	Identical
Headset Power Source	Li-ion rechargeable battery	Li-ion rechargeable battery	Identical
Number of Supported Headsets	Two	Two	Identical

PERFORMANCE DATA

Minor design modifications were made to the C-ARM Ring adaptor, XVS sterile kits with C- and X-markers, and the addition of an extender to the patient marker. These changes aim to improve reliability, enhance workflow, and enable additional kit packaging configurations, without altering the principles of operation or technology.

To assess the impact of the modifications on the device and its components, a Risk Analysis was conducted according to ISO 14971 - Medical Devices - Application of Risk Management to Medical Devices. Verification and validation activities required to comply with 21 CFR 820.30 were determined based on this analysis.

All modifications underwent verification following the same protocols and acceptance criteria as the cleared XVS system (K241481), with additional Form, Fit, and Function (FFF) tests for the modified components. Verification used established methods, including CMM and calculations, demonstrating substantial equivalence.

The XVS software includes minor updates from the cleared version, such as support for the new component, GUI enhancements for a more intuitive 2D-3D registration process, and cybersecurity and HIPAA enhancements. Software changes were validated per FDA guidance and Augmedics' Software Lifecycle Procedure, ensuring the software operates as intended.

CONCLUSIONS

The modified XVS system and cleared XVS system have the same intended use and indications for use, same technological characteristics and the same principles of operation. The minor design changes that are introduced in the proposed system are aimed at enhancing the parts reliability or facilitating the execution of the cleared workflow. These differences do not present different questions of safety or effectiveness than the predicate device. Performance data (bench), demonstrate that the modified parts meet the same acceptance criteria as the cleared parts and that the accuracy performance of the modified XVS system is comparable to the accuracy results of the predicate device.

Thus, the modified XVS system is substantially equivalent to its predicate device, the cleared XVS system (K241481).