October 16, 2024

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

Re: K241481
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 24, 2024
Received: September 16, 2024

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)*
K241481

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.

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510(k) Summary Augmedics'

xvision Spine System

Submitter

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Contact Person: Tami Harel
Date Prepared: May 24, 2024

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 (K220905)

Reference Devices:

INTAI Surgery Navigation System, manufactured by Intai Technology Corporation (K180523).

ARAI Surgical Navigation System, Holo Surgical, Inc. (a subsidiary of Surgalign Spine Technologies) (K211254).

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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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 System (XVS) is an image-guided navigation system designed to assist surgeons in placing pedicle screws accurately, during open or percutaneous computer-assisted spinal surgery by displaying stereoscopic augmented reality (AR) navigation information onto the patient anatomy. The system consists of dedicated software running on a PC, a 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 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 introduce a new registration algorithm that enables registering a 3D CT scan that was acquired prior to surgery (pre-operative CT) using 2D X-ray images, taken intra-operatively with a C-Arm. As part of the development of this registration method, the company developed a new software algorithm that includes a deep learning-based spine segmentation algorithm that segments individual vertebrae including the sacrum and ilium. The segmentation output is used as an input to the new registration algorithm.

The indications for use of the subject device compared to its predicate are expanded and include the use of patient's X-ray images for registration and support of angular and lateral procedures requiring access to the disc space and sacro-iliac joint. These modifications do not alter the intended purpose of the system as an aid in localization of anatomical structures during spine surgery or its principles of operation, it just enables additional inputs for registration and supports navigation in additional trajectories.

Summary of Technological Characteristics

The modified xvision Spine System is similar in its technological features to its predicate device, the cleared xvision Spine System. Both systems include very similar hardware and software components, with the following basic components: software, headset with optical tracking camera, single use passive reflective markers, rigid reference point, and reusable tool adaptors. The headset in both systems is positioned on the surgeon's head and is designed to provide 2D and stereoscopic 3D augmented reality (AR) display with overlaid navigation information onto the patient's anatomy. The software in both systems is designed for real time calculation and display of the spatial position of the tip of the surgical instruments relative to the patient's anatomy. Both systems share the same safety features and follow similar fundamental principles of operation.

The modified XVS system offers an additional registration method, as an alternative to the cleared registration method using an intraoperative 3D scan. This new registration algorithm enables registering 3D scan that was taken pre-operatively with patient's anatomy using 2D X-ray images taken

intra-operatively. The aim of both cleared and proposed registration methods is to align the patient's anatomy with the patient's CT scan.

Additionally, the indications for use were broadened to support navigation in additional trajectories (angular and lateral procedures requiring access to the disc space and Sacro-Iliac joint). Expanding the navigation capabilities to additional trajectories, does not change the system's technological characteristics since, regardless to the angle or path of the trajectory, the aim of the system is to enable accurate navigated trajectory. Phantom and Cadaver studies were used to demonstrate that the performance of the modified XVS system meets the same acceptance criteria as the cleared device. A table comparing the key features of the subject and the predicate devices is provided below:

	xvision Spine System (subject device)	**xvision Spine System (K220905) (predicate device)**	**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 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	Similar. The additional registration method and spinal procedures, added to the indications for use, do not constitute a new intended use. The intended use of the XVS system is as an aid for precisely locating anatomical structures in either open or percutaneous spine procedures. All added indications for use fall within this general intended use. Moreover, the added indications, do not raise different questions of safety and effectiveness, and do not significantly increase a safety or effectiveness concern previously raised by the predicate device.

	xvision Spine System (subject device)	xvision Spine System (K220905) (predicate device)	Conclusion
			Furthermore, this change doesn't impact the anatomical structure, the patient population or the clinical context in which the device is being used. Hence, the proposed change in indications for use does not constitute a new intended use and a comparison to the predicate device is still meaningful and the product can be considered substantially equivalent with respect to Intended Use and Indications for Use.
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 • Tool adaptors • Reference point: Patient Clamp and Perc Pin • Computer, roll stand or Cart • **C-ARM Ring Adapter**	• Headset with near eye see-through display and tracking camera. • Software application • Flat reflective markers • Tool adaptors • Reference point: Patient Clamp and Perc Pin • Computer, roll stand	Similar The Ring Adapter was added to support the new registration method. This added component does not alter the intended use of the XVS system. The questions of accurate beads' detection in imaging and accurate calculation of the spatial position of the Ring Adapter from the reference frame are common to all the configurations of the XVS registration markers. Thus, adding this component does not raise any new questions of safety and effectiveness.

	xvision Spine System (subject device)	Xvision Spine System (K220905) (predicate device)	Conclusion
Registration methods	• IntraOp – requiring IntraOp 3D scan (Z-link & X-link) • 2D-3D (PreOp), requiring PreOp 3D CT scan and at least two IntraOp Xray images	• IntraOp – requiring IntraOp 3D scan (Z-link & X-link):	Similar Both registration methods are based on the same fundamental technology and principles of operation. Overall system accuracy while using the 2D-3D method was verified to be comparable to the device accuracy while using the IntaOp method. Thus, no new questions of safety or efficacy are raised. The reference device (cleared under K180523) further supports the substantial equivalence of this additional registration method
Rigid reference point	• Patient Clamp attached to the spinous process • Perc Pin inserted into the PSIS	• Patient Clamp attached to the spinous process • Perc Pin inserted into the PSIS	Identical
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

	xvision Spine System (subject device)	xvision Spine System (K220905) (predicate device)	Conclusion
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 positional error of 2.0mm and mean trajectory error of 2°	Identical
Depp-learning based spine segmentation algorithms	• Full spine anatomy segmentation from background • Segmentation of single spine vertebra	• Full spine anatomy segmentation from background	Similar The single vertebra segmentation algorithm was added to support the new registration method. It does not alter the intended use of the system as an aid in localization during spine surgery. The added algorithm is based on the same CNN architecture as the full spine segmentation algorithm. The performance of the single spine vertebra algorithm was verified, using the same metrics (i.e., DICE coefficient), to be comparable to the performance of the full spine segmentation algorithm. Thus, no new questions of safety or efficacy are raised
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	Similar Support to C-ARM models was added due to adding the new registration method. Xray images that are taken by these C-ARM models, are transferred to the XVS system. Adding the ability to acquire Xray images does not alter the

	xvision Spine System (subject device)	xvision Spine System (K220905) (predicate device)	Conclusion
			intended use of the XVs system as an aid in localization during spine surgery. Transferring Xray images to the system is similar to transferring 3D CT scans and does not raise any new questions of safety or effectiveness.
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
Communication between Headset and computer	Wireless, encrypted	Wireless, encrypted	Identical
Supported Frequencies & Transmission protocol	5 GHz 802.11g/n/ac	2.4GHZ & 5 GHz 802.11g/n/ac	Identical
Frame rate of displayed images	60 fps	60 fps	Identical
OE Field of View	32.5^0 (vertical) X 18^0 (horizontal)	32.5^0 (vertical) X 18^0 (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

The following testing was conducted to evaluate the device:

- Cleaning validation according to ANSI/AAMI ST98:2022 and shipping validation according to ISTA 2A were performed on the new component, i.e., the Ring Adapter

- Registration accuracy and overall system accuracy accuracy were tested using phantoms, under different scenarios simulating clinical conditions. Phantom tests were performed when using the cleared registration methods and the added new registration method.

- The system's accuracy was validated in three cadaver studies in which screws were positioned in the sacro-iliac, sacro-lumbar, thoracic, and C3-C7 vertebrae levels. 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.

- The performance of the segmentation algorithm was validated on a set of CT scans by comparing it with manual segmentations that were approved by US physicians. The mean Dice coefficient was calculated as the measured quality of the algorithm.

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

- Human Factors Usability Testing was conducted in accordance with the FDA Guidance Documents, *Applying Human Factors and Usability Engineering to Medical Devices (2016)* and *Application of Human Factors Engineering Principles for Combination Products: Questions and Answers (2023)* and IEC 62366-1:2015 *Medical devices - Part 1: Application of usability engineering to medical devices*. Human Factors Usability Testing was conducted with intended users in a simulated use environment to ensure the user needs and intended use requirements were met.

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

Conclusions

The xvision Spine System is substantially equivalent to its predicate, the cleared xvision Spine System. Both systems have the same intended use, technological characteristics, and principles of operation. The expanded indications do not alter the intended surgical use of the device and do not affect its safety and effectiveness when used as labeled. None of the minor differences in technology raise new types of safety or effectiveness questions. Performance data demonstrated that the xvision Spine System functions as intended.