November 17, 2022

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

Re: K220905
Trade/Device Name: xvision Spine System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: October 20, 2022
Received: October 20, 2022

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jesse Muir -S

For: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220905

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 CT imagery of the anatomy. This can include the following spinal implant procedures:

- Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region.
- Posterior Screw Placement in C3-C7 vertebrae
- Iliosacral Screw Placement

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

Augmedics Ltd.
1 Ha-Tsmikha St.
Yokneam Illit, 2069205 Israel

Phone:+972-4-3730111
Facsimile: +972-4-3730850

Contact Person: Tami Harel
Date Prepared: November 17, 2022

Name of Device: xvision Spine System

Common or Usual Name: XVS

Classification Name: Orthopedic Stereotaxic Instrument (21 CFR 882.4560)

Regulatory Class: Class II

Product Code: OLO

Predicate Device: xvision Spine, manufactured by Augmedics Ltd. Israel (K211188)

Reference Devices:
AI-Rad Companion (Musculoskeletal), manufacture by Siemens Medical Solutions USA (K193267)
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 CT imagery of the anatomy. This can include the following spinal implant procedures:

- Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region.
- Posterior Screw Placement in C3-C7 vertebrae
- Iliosacral Screw Placement

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.

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 a 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 intraoperative 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 following modifications have been applied to the previously cleared XVS system:

The indications for use of the subject device are expanded compared to the cleared predicate device and include screw instrumentation in additional spine segments, i.e., cervical C3-C7 vertebrae and iliosacral region. Additionally, an Artificial Intelligence (AI) spine segmentation algorithm, based on Convolutional Neural Network (CNN), has been added to provide an improved virtual 3D spine model. The virtual 3D model can be built from the original CT scan or from the AI segmented CT scan. Neither of these modifications alters the intended use of the device as an aid in localization during spine surgery or its principles of operation.

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 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 patient's anatomy. Both systems share the same safety features and are compatible with similar intraoperative scanners. Both systems follow similar fundamental principles of operation.

A table comparing the key features of the subject and the predicate devices is provided below:

	xvision Spine (Subject device)	**xvision Spine (K211188) (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	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	Identical

	xvision Spine (Subject device)	xvision Spine (K211188) (Predicate device)	Conclusion
	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 CT imagery of the anatomy. 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	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 CT imagery of the anatomy. 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	
Indication for Use	Spinal implant procedures: - Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region. - Posterior Screw Placement in C3-C7 vertebrae - Iliosacral Screw Placement	Spinal implant procedures, such as Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region.	Expanded indication for use for placing screws in additional spine segments. This change does not alter the intended use of the device for its use as an aid in localization during spine surgery.
User Population	Orthopedic surgeons or neurosurgeons	Orthopedic surgeons or neurosurgeons	Identical

	xvision Spine (Subject device)	xvision Spine (K211188) (Predicate device)	Conclusion
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 • Accessories: Panel PC, Roll Stand, 8'' Tablet (Remote UI)	• Headset with near eye see-through display and tracking camera • Software application • Flat reflective markers • Tool adaptors • Reference point: Patient Clamp and Perc Pin • Accessories: Panel PC, Roll Stand, 8'' Tablet (Remote UI)	Identical
Modes of Operation	• Patient Preparation • System Set-up • Intraoperative scan • Scan Import • Patient Registration • Navigation	• Patient Preparation • System Set-up • Intraoperative scan • Scan Import • Patient Registration • Navigation	Identical
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
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
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
Imaging Modality	X-Ray Based Imaging	X-Ray Based Imaging	Identical

	xvision Spine (Subject device)	xvision Spine (K211188) (Predicate device)	Conclusion
Medical Device Interfaces	• O-arm Imaging System • Ziehm Vision FD Vario 3D C-Arm and RFD 3D • Siemens CIOS Spin • Airo system by Brainlab • GE OEC 3D scanner	• O-arm Imaging System • Ziehm Vision FD Vario 3D C-Arm and RFD 3D • Siemens CIOS Spin • Airo system by Brainlab	Similar The additional intra-op scanner has similar technological characteristics as the other scanners that the predicate device is compatible with (i.e., DICOM scans, resolution and FOV). No new questions of safety or effectiveness are raised
Display Features	2D images: axial and sagittal 3D model Trajectories Trajectory guidance Instrument's tip view 3D transparent 3D OFF (only 2D) 3D follow instrument movement	2D images: axial and sagittal 3D model Trajectories Trajectory guidance Instrument's tip view 3D transparent 3D OFF (only 2D) 3D follow instrument movement	Identical
Segmentation and 3D model generation	Two thresholds are used to select the input CT values (i.e., HU) to the algorithm that creates the 3D model, to distinguish the spine from the background: • Threshold on the CT scan values (HU) • Threshold on the AI segmented CT values that were masked as Spine. AI segmented CT values are derived from an AI based spine segmentation algorithm that is applied on the CT scan	A single threshold is used to select the input CT values (i.e., HU) to the algorithm that creates the 3D model, to distinguish the spine from the background: • Threshold on the CT scan values (HU)	Similar In both systems the 3D model is created from CT values, that are higher than applied threshold, to distinguish spine from background. Adding the option to use AI spine segmented CT values for improved 3D model does not alter the system intended use, its fundamental technology or principals of operation. Thus,

	xvision Spine (Subject device)	xvision Spine (K211188) (Predicate device)	Conclusion
			no new safety or effectiveness questions are raised. Using AI based algorithms for spine segmentation of the reference devices further supports the substantial equivalence of this additional feature
Communication between Scanner and platform/computer	USB & LAN connectivity using DICOM	USB & LAN connectivity using DICOM	Identical
Display and Optics 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	2.4GHZ & 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
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:

- The system's accuracy was validated in two cadaver studies, in which screws were positioned in C3-C7 cervical vertebrae and in the sacro-iliac segment. 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 AI segmentation algorithm was validated on a set of intra-op 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.

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.