July 19, 2021

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

Re: K211188
Trade/Device Name: xvision Spine (XVS)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: April 20, 2021
Received: April 20, 2021

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,

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: 06/23/2023
See PRA Statement below

510(k) Number *(if known)*

K211188

Device Name

xvision Spine (XVS)

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 spinal implant procedures, such as Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region.

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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K211188

510(k) SUMMARY

Augmedics' xvision Spine system

Submitter

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Contact Person: Tami Harel
Date Prepared: April 20, 2021

Name of Device: xvision Spine

Common or Usual Name: XVS

Classification Name: Orthopedic Stereotaxic Instrument (21 CFR 882.4560)

Regulatory Class: Class II

Product Code: OLO

Predicate Devices: xvision Spine, manufactured by Augmedics Ltd. Israel (K190929)

Reference Device: VV FLUORO 3D, manufactured by Brainlab AG, Germany (K070106)

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 spinal implant procedures, such as Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region.

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 principal technological differences between the XVS and its predicate include the addition of another registration method (X-link) compared to the single registration method for the predicate (Z-link); an additional option of a rigid reference point on the pelvis, in addition to the rigid reference point on the spine included in the predicate device; and improvements to the registration and tracking algorithms enabling successful registration and continuous tracking even when not all radiopaque beads and reflective points are detected.

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 the same 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 (K190929) (predicate device)**	**Conclusion**
Intended Use / Indication 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 spinal implant procedures, such as Posterior Pedicle Screw	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, can be identified relative to CT imagery of the anatomy. This can include the spinal implant procedures, such as Posterior Pedicle Screw Placement in the thoracic and	Similar. The pelvis was added as an additional rigid anatomical structure to support the addition of the XVS Perc Pin. This change does not alter the intended use of the device and does not change its fundamental technology or

	xvision Spine (subject device)	xvision Spine (K190929) (predicate device)	Conclusion
	Placement in the thoracic and sacro-lumbar region. 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	sacro-lumbar region. 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	principles of operation.
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 • Accessories: Panel PC, Roll Stand, 8'' Tablet (Remote UI), VESA docking station for 8" Tablet	• Headset with near eye see-through display and tracking camera • Software application • Flat reflective markers • Tool adaptors • Reference point	Similar. Providing accessories as opposed to requiring the user to purchase them separately does not raise any new questions of safety and effectiveness.
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
Registration Methods	• Z link – registration transformation matrix is calculated based on the known mechanical position of	Z link – registration transformation matrix is calculated based on the known mechanical position of the registration marker from the	Similar. Both registration methods are

	xvision Spine (subject device)	xvision Spine (K190929) (predicate device)	Conclusion
	the registration marker from the reference frame • X link – registration transformation matrix is calculated based on the calculated relative position of an optical registration marker positioned near the reference frame	reference frame	based on the same fundamental technology and principles of operation. No new questions of safety or effectiveness are raised based on the difference between the Z-link and X-link methods, and the use of the Automatic Registration of the reference device further supports the substantial equivalence of this additional feature
Rigid reference point	• Patient Clamp attached to the spinous process • Perc Pin inserted into the PSIS • Off-the-shelf Schantz screws	• Patient Clamp attached to the spinous process	Similar. Additional options for a rigid reference point do not alter the intended use of the device or raise new safety or performance questions. The questions of stability, biocompatibility and sterility are common to all configurations of a rigid reference point.
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)	Similar. All configurations of Tool Adaptors share the same risk of improper fixation of the reflective marker to the surgical

	xvision Spine (subject device)	xvision Spine (K190929) (predicate device)	Conclusion
			system. The design mitigation for this risk is identical for all configurations. Thus, no new questions of safety and performance are raised
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
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
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	O-arm Imaging System Ziehm Vision FD Vario 3D C-Arm and RFD 3D Siemens CIOS SPin Airo system by Brainlab	Identical
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	2.4GHZ & 5 GHz;	2.4GHz;	Similar.

	xvision Spine (subject device)	xvision Spine (K190929) (predicate device)	Conclusion
Frequencies & Transmission protocols	802.11g/n/ac	802.11g	Support additional transmission frequency and protocol increases communication rate. No new safety or efficacy questions are raised due to this modification
Frame rate of displayed images	60 fps	60 fps	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:

- Bench testing was conducted in order to demonstrate that the xvision-Spine system performs according to its requirements and specifications. In particular, overall system accuracy, image registration accuracy and tracking accuracy were tested using phantoms, under different conditions simulating clinical conditions such as: Headset mounted statically and Headset moving above the markers, different distances between the Headset and the markers, different angles, partial detectability of the radiopaque beads and reflective points in the scan and IR image, and different registration methods (Z-link and X-link). The Z-link method uses a known mechanical position between the registration marker and the rigid reference marker, and the X-link method, calculates this position using the optical tracker. Under all test conditions, the average and standard deviation of the system's positional and angular errors were substantially equivalent to the predicate and met acceptance criteria.

  Additionally, tracking accuracy was verified per ASTM F2554-18.

- The System's accuracy was also validated in a cadaver study, in which pedicle screws were positioned percutaneously in thoracic and sacro-lumbar vertebrae, using the Perc Pin as the rigid reference point. Both Z-link and X-link registration methods were used. The positional

error was calculated as the difference between the actual screw tip position, derived from the post-op scan, and its virtual tip, as recorded by the xvision-Spine system. The trajectory error was calculated as the difference between the screw orientation and its recorded virtual trajectory. An overall mean positional error of 2.32mm (99% UBL*= 2.58mm) and angular error of 1.66^0 (99% UBL*=1.93^0) was measured. Thus, the system has demonstrated performance in 3D positional accuracy with a mean error statistically significantly lower than 3mm and in trajectory angle accuracy with a mean error statistically significantly lower than 3 degrees, both in phantom and cadaver studies.

- The System's clinical accuracy, using the X-link registration method was validated in a prospective, single arm multicenter study. System's accuracy was evaluated using the Gertzbein score by viewing the post-op scans. A total accuracy of 97.7% was demonstrated for seventeen (17) subjects who were scheduled for elective open spinal surgery that required posterior pedicle screw placement in the sacral/lumbar vertebrae. The accuracy of the XVS system was found to be very similar to the literature control rate of 95%.

- Electrical safety was tested in accordance with ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012,C1:2009/(R)2012 and A2:2010/(R)2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

- Electromagnetic Compatibility (EMC) was tested in accordance with IEC 60601-1-2:2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.

- Sterilization validation for the single use components was conducted in accordance with the ANSI AAMI ISO 11137-1:2006/(R)2015. Additionally, shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.

- Reusable components were validated for cleaning, in accordance with the AAMI TIR30:2011 guidance, and for steam sterilization, in compliance with the partial cycle validation approach outlined in ANSI/AAMI/ISO 17665-1:2006/(R)2013 and the validation approach outlined in ANSI/AAMI/ISO 14937:2009/(R)2013

- The biocompatibility of all patient contact materials was verified according to ISO 10993-1:2018 and FDA guidance on the use of ISO 10993-1, June 16, 2016. All tests were successfully completed.

- 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 and similar indications, technological characteristics, and principles of operation. The minor differences in 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 raise new types of safety or effectiveness questions. Performance data demonstrated that the xvision Spine system functions as intended.