



December 20, 2019

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

Re: K190929

Trade/Device Name: xvision Spine system (XVS)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: December 16, 2019
Received: December 16, 2019

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,

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

510(k) Number (if known)

K190929

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, 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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K190929

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: December 20, 2019

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

StealthStation S8 Spine Software V1.0.0, manufactured by Medtronic Navigation, USA (K170011)

Reference Devices

OpenSight, manufactured by Novarad Corporation, USA, (K172418)

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.

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, 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.

Summary of Technological Characteristics

The xvision Spine System is similar in its technological features to its predicate device, the StealthStation S8 Spine Software V1.0.0 (K170011). Both systems are intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic procedures and both systems consist of similar types of components and involve similar principles of operation. Both systems use optical infrared camera(s) to track the position of the surgical instruments in relation to the surgical anatomy. A rigid reference point representing patient's anatomy, is connected to patient's anatomy throughout the procedure, in both systems. Additionally, in both the subject and predicate device, tool adaptors are used for affixing the tracked reflective markers to the surgical instruments. The xvision Spine system includes a Headset, which 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. In the predicate system, this navigation information is displayed on a monitor, which is part of the system's cart and is positioned to the side or in front of the surgeon. The use of a headset for presenting stereoscopic augmented reality (AR) display of patient's anatomy is not a new feature and has been previously cleared under K172418 for the OpenSight (reference device), although this device is not cleared to be used for intraoperative use. Similarly to the xvision Spine Headset, the reference device uses a see-through near eye display (Microsoft HoloLens) for displaying superimposed information of 2D images and 3D holograms from DICOM compliant medical imaging modalities onto patient's anatomy.

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

	xvision Spine	StealthStation (K170011) [predicate device]	OpenSight (K172418) [reference device]
Intended Use / Indications for Use	<p>The xvision Spine System, with xvision Spine 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 sacro-lumbar region.</p> <p>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.</p> <p>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.</p>	<p>The StealthStation System, with StealthStation Spine Software, is intended as an aid for precisely locating anatomical structures in either open or percutaneous neurosurgical and orthopedic 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 images of the anatomy. This can include the following spinal implant procedures, such as:</p> <ul style="list-style-type: none"> • Pedicle Screw Placement • Iliosacral Screw Placement • Interbody Device Placement 	<p>OpenSight is intended to enable users to display, manipulate, and evaluate 2D, 3D, and 4D digital images acquired from CR, DX, CT, MR, and PT sources. It is intended to visualize 3D imaging holograms of the patient, on the patient, for preoperative localization and pre-operative planning of surgical options. OpenSight is designed for use only with performance-tested hardware specified in the user documentation.</p> <p>OpenSight is intended to enable users to segment previously acquired 3D datasets, overlay, and register these 3D segmented datasets with the same anatomy of the patient in order to support pre-operative analysis.</p> <p>OpenSight is not intended for intraoperative use. It is not to be used for stereotactic procedures.</p> <p>OpenSight is intended for use by trained healthcare professionals, including surgeons, radiologists, chiropractors, physicians, cardiologists, technologists, and medical educators. The device assists doctors to better understand anatomy and pathology of patient</p>
Intended Use Environment	Operating Room	Operating Room	Healthcare settings, such as hospitals and clinics

	xvision Spine	StealthStation (K170011) [predicate device]	OpenSight (K172418) [reference device]
Main system components	<ul style="list-style-type: none"> • Headset with near eye see-through display and tracking camera • Software application • Reflective markers-Flat • Instrument universal adaptors • Reference point 	<ul style="list-style-type: none"> • Platform including cart, computer, monitor and tracking cameras • Software application • Reflective markers - Spheres • Accessories (Instrument adaptors, referencing system) 	<ul style="list-style-type: none"> • Headset with near eye see-through display • Software application
Modes of Operation	<ul style="list-style-type: none"> • Patient Preparation • System Set-up • Intraoperative scan • Scan Import • Patient Registration • Navigation 	<ul style="list-style-type: none"> • Patient Preparation • System Set-up • Intraoperative scan • Scan Import • Planning • Patient Registration • Navigation 	<ul style="list-style-type: none"> • System Set-up • Scan import • Patient Registration
Localization Technology	Optical	Optical	Time of flight
Optical Tracker	Single infrared camera, positioned 0.5m above tracked objects	Two infrared cameras, positioned 2-3m away from tracked objects	No tracking– spatial mapping provides a representation of real-world surfaces around the device
Tracking	6 DOF	6 DOF	No tracking– spatial mapping provides a representation of real-world surfaces around the device
Tracking Algorithm	Perspective N-point	Triangulation	No tracking– spatial mapping provides a representation of real-world surfaces around the device
System Accuracy Requirement	System Level Accuracy with a mean 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°	Not relevant
Imaging Modality	X-Ray Based Imaging	X-Ray Based Imaging	CR, DX, CT, MR, and PT
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 ISO-C 3D C-Arm Orbic 3D C-Arm	The system does not interface directly with the imaging modality

	xvision Spine	StealthStation (K170011) [predicate device]	OpenSight (K172418) [reference device]
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	Look Sideways 3D Anatomic Orthogonal Trajectory 1 and 2 Trajectory Guidance Look Ahead Probe's Eye AP and Lateral Synthetic AP and Lateral Maximum Intensity Projection Video Input	Not reported
Software Interface (GUI)	Black and blue style with procedure task overview in a menu and next/back task flow. Software controls for images, instrument and planned trajectory management	Black and gray style with procedure task overview in left menu option and next/back task flow at bottom of the screen. Software controls for images, planning and instrument management are contained in a right side bar.	Software controls for window level, segmentation and rendering, registration, motion correction, virtual tools (i.e, lines, distance & volume measurements) alignment, measure image intensity values, such as standardized uptake value.
Communication between Scanner and platform/computer	USB & LAN connectivity using DICOM	Network Connectivity CD, DVD, USB DICOM Import DICOM Export	WiFi communication with Novorad server, not a scanner
Display and Optics Technology	Augmented Reality using near eye see-through display; data displayed on patient's anatomy	Data displayed on a monitor	Augmented Reality using near eye see-through display; data displayed on patient's anatomy
Communication between Headset and computer	Wireless, encrypted	No Headset	Wireless, encrypted
Frame rate of displayed images	60 fps	Not reported	60 fps
Headset power source	Li-ion rechargeable battery	No Headset	Rechargeable battery

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, and different angles. The XVS system supports a Z-link patient registration method that uses a known mechanical position between the registration marker and the rigid reference marker. The Z-link method uses two optional Z markers to accommodate for different patients' size. Under all test conditions, the overall average image registration error was

1.103 mm or less. The following tables summarize the performance results demonstrated on phantoms:

Overall Positional Error:

Registration Method	Headset	Mean Overall Positional Error [mm]	STD Overall Positional Error [mm]	99% UBL* Overall Positional Error [mm]
Z-link (Z1 marker)	Static Headset	0.932	0.657	1.105
	Moving Headset	0.954	0.631	1.12
Z-link (Z2 marker)	Static Headset	0.715	0.542	0.857
	Moving Headset	0.63	0.54	0.772

Overall Trajectory Angle Error:

Headset	Mean Overall Trajectory Angle Error [deg]	STD Overall Trajectory Angle Error [deg]	99% UBL* Overall Trajectory Angle Error [deg]
Static Headset	0.468	0.162	0.589
Moving Headset	0.683	0.44	1.08

*UBL (Upper Bound Limit)

Additionally, tracking accuracy was verified per ASTM F2554-10.

- The System's accuracy was also validated in a cadaver study, in which pedicle screws were positioned percutaneously in thoracic and sacro-lumbar vertebrae. The positional error was calculated as the difference between the actual screw tip position, derived from the post-op scan, and its planned/virtual tip, as recorded by the xvision-Spine system. The trajectory error was calculated as the difference between the screw orientation and its recorded planned/virtual trajectory. The following positional and trajectory angle errors were demonstrated:

Performance validation	Positional Error [mm]			Trajectory Angle Error [deg]		
	Mean	Standard Deviation	99% UBL*	Mean	Standard Deviation	99% UBL*
XVS system	1.98	0.90	2.22	1.3	0.65	1.47

*UBL (Upper Bound Limit)

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, in phantom and cadaver studies.

- Performance of the Headset display was demonstrated by verifying the following elements: Field of View (FOV), resolution, luminance, transmission, distortion, contrast ratio, polarization, location of the virtual image plane and latency.
- User Needs validation - The system was validated with intended users in cadaver labs and simulated use tests to ensure the user needs and intended use requirements were met. All requirements were met and no new issues of safety or effectiveness were raised.
- 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)2010. 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.
- Headset cleaning and disinfection validation was performed according to AAMI TIR 30:2011/(R)2016, AAMI TIR 12:2010, and FDA guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff" (March 17, 2015).
- 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 the StealthStation S8 Spine Software V1.0.0. The xvision Spine has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. 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. Performance data demonstrated that the xvision Spine system functions as intended without raising new safety or effectiveness questions.