September 8, 2023

OnPoint Surgical, Inc.
Amy Odonnell
Sr. Director Quality and Regulatory Affairs
19 Crosby Drive, Suite 120
Bedford, Massachusetts 01730

Re: K231284
Trade/Device Name: OnPoint Augmented Reality Spine System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: May 2, 2023
Received: May 3, 2023

Dear Amy Odonnell:

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

510(k) Number *(if known)*
K231284

Device Name
OnPoint Augmented Reality Spine System

Indications for Use *(Describe)*
The OnPoint Augmented Reality Spine System, with OnPoint Augmented Reality Spine System Software, is intended as an aid for precisely locating anatomic structures in either open or percutaneous spine procedures. The use of the OnPoint Augmented Reality Spine System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a bony anatomical structure, such as the spine or pelvis, can be identified relative to CT images of the anatomy. This can include spinal implant procedures, such as pedicle screw placement, where the surgeon wants to see a tracked instrument location in relationship to the stereotaxic display of the CT images of the anatomy.

The optical head mounted display of the OnPoint Augmented Reality Spine System displays 2D stereotaxic screens and an optional virtual anatomy screen, paired with optional graphical targeting tools and alphanumeric displays. The stereotaxic screen is indicated for correlating the tracked instrument location to the registered patient images. 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 graphical targeting tools and alphanumeric display are indicated for providing visual and quantitative tracking information of the tracked instrument location including deviation from plan.

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

OnPoint Augmented Reality Spine System

Submitter	OnPoint Surgical, Inc.
Address	19 Crosby Drive, Suite 120 Bedford, MA 01730
Phone:	(781) 218-9742
Contact Person	Amy O'Donnell
Date Prepared	May 2, 2023

Device Information:

Device Name	OnPoint Augmented Reality Spine System
Common Name	Spine Navigation System
Classification Name & Regulation	Orthopedic Stereotaxic Instrument 21 CFR 882.4560
Regulatory Class	Class II
Product Code	OLO
Predicate Device	Xvision Spine System, manufactured by Augmedics, Ltd. (K220905)
Reference Device	S8 Stealthstation, manufactured by Medtronic Navigation, Inc. (K201189)

Intended Use / Indications for Use

The OnPoint Augmented Reality Spine System, with OnPoint Augmented Reality Spine System software, is intended as an aid for precisely locating anatomic structures in either open or percutaneous spine procedures. The use of the OnPoint Augmented Reality Spine System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a bony anatomical structure, such as the spine or pelvis, can be identified relative to CT images of the anatomy. This can include spinal implant procedures, such as pedicle screw placement, where the surgeon wants to see a tracked instrument location in relationship to the stereotaxic display of the CT images of the anatomy.

The optical head mounted display of the OnPoint Augmented Reality Spine System displays 2D stereotaxic screens and an optional virtual anatomy screen, paired with optional graphical targeting tools and alphanumeric displays. The stereotaxic screen is indicated for correlating the tracked instrument location to the registered patient images. 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 graphical targeting tools and alphanumeric display are indicated for providing visual and quantitative tracking information of the tracked instrument location including deviation from plan.

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 OnPoint Augmented Reality Spine System is intended as an aid for precisely locating anatomic structures in either open or percutaneous spine procedures. Infrared tracking technology is used to track the patient's anatomy as well as surgical instrumentation. The tracking information is registered with image information of the patient's anatomy in a common coordinate system. To guide the surgeon through the pedicle screw placement process, the system will display a visual representation of the following elements in an augmented reality optical head mounted display in addition to being displayed on a workstation monitor:

- Target position and orientation of toolpath
- Current position and orientation of instrument
- Cross sectional images
- 3D model of the patient's spine

Depending on surgeon preference, different combinations of these elements can be displayed. Optional planning steps allow the surgeon to define the target position and orientation as well as length and diameter of the pedicle screws.

The OnPoint Augmented Reality Spine System consists of the following components:

- Tracking camera, workstation, and cart
- Headsets with supplemental battery
- Software
- Tracked instruments and adapters

Summary of Technological Characteristics

The OnPoint Augmented Reality Spine System is similar in its technological features to its predicate device, the Augmedics Xvision Spine System. Both systems include similar hardware and software components, with the following basic components: software, optical head mounted display (OHMD), tracking camera, rigid spinal or pelvic reference point, and reusable instrument adaptors.

The OHMD in both systems is positioned on the surgeon's head and is designed to provide 2D and 3D augmented reality (AR) display with overlaid navigation information to aid in pedicle screw placement. 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:

Characteristic	OnPoint Augmented Reality Spine System (this submission)	Predicate Device Augmedics Xvision Spine System (K220905)	Conclusion
Indications for Use	The OnPoint Augmented Reality Spine System, with OnPoint Augmented Reality Spine System software, is intended as an aid for precisely locating anatomic structures in either open or percutaneous spine procedures. The use of the OnPoint Augmented Reality Spine System is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a bony anatomical structure, such as the spine or pelvis, can be identified relative to CT images of the anatomy. This can include spinal implant procedures, such as pedicle screw placement, where the surgeon wants to see a tracked instrument location in relationship to the stereotaxic display of the CT images of the anatomy.	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. 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	Same intended use. The predicate has slightly different wording.

Characteristic	OnPoint Augmented Reality Spine System (this submission)	Predicate Device Augmedics Xvision Spine System (K220905)	Conclusion
	The optical head mounted display of the OnPoint Augmented Reality Spine System displays 2D stereotaxic screens and an optional virtual anatomy screen, paired with optional graphical targeting tools and alphanumeric displays. The stereotaxic screen is indicated for correlating the tracked instrument location to the registered patient images. 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 graphical targeting tools and alphanumeric display are indicated for providing visual and quantitative tracking information of the tracked instrument location including deviation from plan. 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.	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.	
Spinal implant procedures	Posterior pedicle screw placement in the thoracic and sacro-lumbar region.	Spinal implant procedures: • Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region • Posterior Screw • Placement in C3-C7 vertebrae • Iliosacral Screw	Similar. Even though the predicate is cleared for a broader range of spinal implant procedures, OnPoint is requesting clearance for posterior pedicle screw placement in the thoracic and sacro-lumbar region.
Intended User Population	Orthopedic surgeons or neurosurgeons	Orthopedic surgeons or neurosurgeons	Same
Intended Use Environment	Operating Room	Operating Room	Same
System Components	• Headset with near eye see-through display • Software application • Instrument adaptors	• Headset with near eye see-through display and tracking camera • Software application • Flat reflective markers	Similar. There are minor differences with the instrumentation and the workstation, but the

Characteristic	OnPoint Augmented Reality Spine System (this submission)	Predicate Device Augmedics Xvision Spine System (K220905)	Conclusion
	• Rigid Spinal Reference point: Spinal Clamp and Iliac Crest Pin • Workstation cart with computer, tracking camera, router, monitors, keyboard, and universal power supply	• Instrument adaptors • Reference point: Patient clamp and perc pin • Accessories: Panel PC, roll stand, 8'' tablet (Remote UI)	principles of operation are still the same.
Modes of Operation	• Patient preparation • System set-up • Intraoperative scan • Scan import • Patient registration • Surgical planning • Navigation	• Patient preparation • System set-up • Intraoperative scan • Scan import • Patient registration • Navigation	Similar. There are minor differences between the modes of operations, but the general workflow follows standard surgical technique.
Localization Technology	Optical	Optical	Same
Optical Tracker	Infrared cameras, positioned 2-3 meters from the surgical site	Single infrared camera, positioned 0.5m above tracked objects	Similar. The position of the tracking camera is different due the tracking camera location.
Tracking	6 DOF	6 DOF	Same
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°	Same
Imaging Modality	X-Ray Based Imaging	X-Ray Based Imaging	Same
Medical Device Interfaces	• O-arm Imaging System by Medtronic • Airo TruCT system by Stryker • Globus Excelsius 3D	• O-arm Imaging System by Medtronic • Ziehm Vision FD Vario 3D C-Arm and RFD 3D • Siemens CIOS Spin • Airo TruCT system by Stryker • GE OEC 3D scanner	Similar. Even though the predicate is cleared for a broader range of device interfaces, OnPoint Surgical is going to support the O-Arm, the Airo, and the Excelsius3D.
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	Same.
Communication between Scanner	USB & LAN connectivity using DICOM	USB & LAN connectivity using DICOM	Same.

Characteristic	OnPoint Augmented Reality Spine System (this submission)	Predicate Device Augmedics Xvision Spine System (K220905)	Conclusion
and Platform/ Computer			
Display and Optics Technology	• Augmented Reality using near eye see-through display • Workstation monitors	• Augmented Reality using near eye see-through display • Workstation monitor	Same.
Communication between OHMD and Computer	Wireless, encrypted	Wireless, encrypted	Same.
Supported Frequencies & Transmission Protocol	2.4GHZ & 5 GHz 802.11g/n/ac	2.4GHZ & 5 GHz 802.11g/n/ac	Same
Frame Rate of Displayed Images	60 fps	60 fps	Same
OHMD Field of View	~52 degree FoV, 42 pixels per degree (PPD)	32.50 (vertical) X 180 (horizontal)	Similar. The OnPoint OHMD has a larger FoV which should result in less peripheral vision risk.
OHMD Resolution	3840 by 1080 pixels (1920x1080 per eye)	1280x720 per eye	Similar. The OnPoint OHMD has more pixels which should result in a clearer display.
OHMD Power Source	Li-ion rechargeable battery	Li-ion rechargeable battery	Same.
Number of Supported OHMDs	Three	Two	Similar. The OnPoint Augmented Reality Spine System can support up to 3 headsets at one time.
Rigid Reference Point	• Spinal clamp with spinal array is attached to the spinous process • Iliac crest pin is inserted into posterior superior iliac spine (PSIS) with adapter for spinal array	• Patient clamp attached to the spinous process • Perc pin inserted into the PSIS	Similar. The rigid reference points are the same with respect to where they touch the patient and their intended function. There may be differences with how the tracking arrays are attached.
Instrument (Tool) Adaptors	• Reusable • Universal and power instrument adapters (connects to various rotating 3rd party instruments) • System specific adapters to allow the universal adapter to	• Reusable • Universal (connects to various instruments) - not system specific • VP & Ergonomic (system specific adaptors)	Similar. The instrument adapters allow tracking arrays to be connected to 3rd party devices. There may be minor differences in the connection

Characteristic	OnPoint Augmented Reality Spine System (this submission)	Predicate Device Augmedics Xvision Spine System (K220905)	Conclusion
	connect to the 3rd party instrument • Fixed adapters that connect to instruments that do not rotate		mechanisms and/or instrument dimensions.

Performance Data

The following testing was conducted to evaluate the device:

- The system's accuracy was validated in a cadaver study, in which pedicle screws were positioned in the thoracic and sacro-lumbar vertebrae. 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. Clinical accuracy was evaluated using the Gertzbein-Robbins score by viewing the post-op scans. Additionally, tracking accuracy was verified per *ASTM F2554-22 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems*.

- Registration Testing – The auto-registration accuracy was tested using multiple 3D CT scanners. Supported scanners were determined to provide at least the same level of accuracy as a manual registration using a standard 2D CT scan.

- OnPoint AR Image Quality Testing – The augmented reality glasses display performance was verified for the intended use. Performance specifications assessed included primary visual characteristics (luminance, color, transmission, field of view, and eye-box), virtual image resolution, interocular photometric differences, and vergence-accommodation measurements.

- Human Factors Usability Testing was conducted in accordance with internal SOPs and *FDA Guidance Applying Human Factors and Usability Engineering to Medical Devices (issued February 2016)* 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.

- Electrical safety – The system was tested in accordance with *IEC 60601-1 Edition 3.2 2020-08 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*.

- Electromagnetic Compatibility (EMC) – The system was tested in accordance with *IEC 60601-1-2 Edition 4.1 2020-09 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.*

- Biocompatibility - The biocompatibility of all tissue contacting materials was assessed according to *ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and the *FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (issued September 2020)*.

- Software verification and validation testing – The software design and development life cycle processes are aligned with *IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes*. Software testing was conducted in accordance with internal SOPs that are based on the *FDA Guidance General Principles of Software Validation (issued January 2002).*

Verification/validation testing of the OnPoint Augmented Reality Spine System has been successfully completed and demonstrates that the device is safe for its intended use and is substantially equivalent to the predicate device.

Conclusions

The OnPoint Augmented Reality Spine System is substantially equivalent to its predicate, the cleared Augmedics Xvision Spine System. The OnPoint Augmented Reality Spine System has the same intended use, technological characteristics, and principles of operation as the predicate. None of the minor differences in technology raise new types of safety or effectiveness questions. Performance data demonstrated that the OnPoint Augmented Reality Spine System functions as intended.