May 27, 2022

Novarad Corporation
Doug Merrill
Compliance Manager
3152 North University Avenue, Suite 200
Provo, Utah 84604

Re: K220146
Trade/Device Name: VisAR
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO, LLZ
Dated: April 28, 2022
Received: April 28, 2022

Dear Doug Merrill:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K220146

Device Name
VisAR

Indications for Use *(Describe)*
The VisAR System is intended as an aid for precisely locating anatomical structures in either open or percutaneous spine procedures. VisAR is indicated for any medical condition in which the use of stereotaxic surgery may be appropriate, and where reference to at least one rigid anatomical structure, such as the spine or iliac crests, can be identified relative to CT imagery of the anatomy. This can include guidance for procedures, such as Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region.

VisAR displays a virtual screen for stereoscopic 3D images acquired from CT sources. It is intended to enable users to segment previously acquired 3D datasets, overlay, and register these 3D segmented datasets with the anatomy of the patient in order to support intraoperative analysis and guidance.

The virtual screen is indicated for displaying the virtual instrument location in relation to the virtual anatomy to assist in visualization and trajectory planning for both open and percutaneous surgeries.

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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K220146
510(K) SUMMARY

Submitter

Novarad Corporation

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Phone: 801-642-1001

Contact Person: Doug Merrill

Date Summary Prepared: 21 December 2021

Device Name

Trade Name: VisAR

Common or Usual Name: Stereotaxic Guidance System and Imaging Software

Classification Name: Orthopedic Stereotaxic Instrument

Regulation Number: 21 CFR 882.4560

Regulatory Class: Class II

Product Code: OLO and LLZ

Primary Predicate Device

K190929	xvision Spine system (XVS)	Augmedics Ltd.

Additional Predicate Device

K172418	OpenSight	Novarad Corporation

Device Description

The VisAR system is an image-guided navigation system that is designed to assist surgeons in placing pedicle screws accurately, during open or percutaneous spinal surgery. The system consists of Novarad's immersive augmented

reality software running on the Microsoft Hololens 2 headset, image visible ARTags (AprilTags), a pre-operative planning workstation and the Novarad PACS server. It uses optical tracking technology to co-localize the virtual 3D image datasets to the patient and displays to the surgeon the location of pre-operatively planned operative tracks and the tracked surgical instruments relative to the acquired intraoperative patient's scan, onto the surgical field. The 3D scanned image, along with tracking information, are projected to the surgeons' retina using a transparent near-eye-display stereoscopic headset, allowing the surgeon to both look at the patient and the navigation data at the same time.

Indication for Use

The VisAR System is intended as an aid for precisely locating anatomical structures in either open or percutaneous spine procedures. VisAR is indicated for any medical condition in which the use of stereotaxic surgery may be appropriate, and where reference to at least one rigid anatomical structure, such as the spine or iliac crests, can be identified relative to CT imagery of the anatomy. This can include guidance for procedures, such as Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region.

VisAR displays a virtual screen for stereoscopic 3D images acquired from CT sources. It is intended to enable users to segment previously acquired 3D datasets, overlay, and register these 3D segmented datasets with the anatomy of the patient in order to support intraoperative analysis and guidance.

The virtual screen is indicated for displaying the virtual instrument location in relation to the virtual anatomy to assist in visualization and trajectory planning for both open and percutaneous surgeries.

Summary of Technological Characteristics

The VisAR System is similar in its technological features to its primary predicate device, the xvision Spine System (K190929). Both systems are intended as an aid for precisely locating anatomical structures in either open or percutaneous orthopedic procedures and both systems consist of similar types of components and involve similar principles of operation. Both systems retrieve and display images from DICOM compliant medical imaging modalities and/or systems. They are intended to be used in healthcare settings, such as hospitals, clinics, and procedure rooms. They are intended to provide qualified medical professionals with a variety of tools and software features for the viewing, analysis, and annotation of medical images. Both systems includes a see-through near eye display headset, which is positioned on the surgeon's head, for displaying overlaid navigation information of stereoscopic 3D images from DICOM compliant medical imaging modalities onto patient's anatomy.

The VisAR System is similar in its technological features to predicate device OpenSight (K172418) although this device has been previously cleared for pre-operative use only.

There are no clinical tests to compare VisAR and predicate device xvision Spine system (XVS), as they are software products that retrieve and display images and information.

There are minor differences between the subject and predicate devices; however, these differences do not raise different questions of safety or effectiveness when compared to the primary predicate device. Both systems utilize stereotaxic technologies within the same surgical workflow. Minor differences in the optical tracking systems, display features, and medical device interfaces are addressed by performance testing.

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

Item	Subject Device VisAR	Predicate Device (primary) xvision Spine system (XVS) K190929	Predicate Device OpenSight K172418	Comments
Intended Use / Indidcations for Use	The VisAR System is intended as an aid for precisely locating anatomical structures in either open or percutaneous spine procedures. VisAR is indicated for any medical condition in which the use of stereotaxic surgery may be appropriate, and where reference to at least one rigid anatomical structure, such as the spine or iliac crests, can be identified relative to CT imagery of the anatomy. This can include guidance for procedures, such as Posterior Pedicle Screw Placement in the thoracic and sacro-lumbar region. VisAR displays a virtual screen for stereoscopic 3D images acquired from CT sources. It is intended to enable users to segment previously acquired 3D datasets, overlay, and register these 3D segmented datasets with the anatomy of the patient in order to support intraoperative analysis and guidance. The virtual screen is indicated for displaying the virtual instrument location in relation to the virtual anatomy to assist in visualization and trajectory planning for both open and percutaneous surgeries.	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	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 pre-operative localization and pre-operative planning of surgical options. OpenSight is designed for use only with performance-tested hardware specified in the user documentation. 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. OpenSight is not intended for intraoperative use. It is not to be used for stereotactic procedures. OpenSight is intended for use by trained healthcare professionals, including surgeons, radiologists, chiropractors, physicians, cardiologists, technologists, and medical educators. The device assists doctors	Equivalent

		and should always be used in conjunction with the displayed stereotaxic information.	to better understand anatomy and pathology of patient.	
Intended Use Environment	Operating Room	Operating Room	Healthcare settings, such as hospitals and clinics	Equivalent
Main System Components	- Headset with near eye see-through display and tracking camera - Software application - Image visible ARTags (AprilTags) - Optical tracking technology	- Headset with near eye see-through display and tracking camera - Software application - Reflective markers-Flat - Instrument universal Adaptors - Reference point	- Headset with near eye see-through display and tracking camera - Software application - Optical tracking technology	Utilizes the same process
Modes of Operation	- Patient Preparation - System Set-up - Preoperative scan - Preoperative planning - Intraoperative scan - Scan Import - Patient Registration - Navigation	- Patient Preparation - System Set-up - Intraoperative scan - Scan Import - Patient Registration - Navigation	- System Set-up - Preoperative scan - Preoperative planning - Scan Import - Patient Registration	Equivalent
Localization Technology	Optical	Optical	Mesh surface maps	Equivalent
Optical Tracker	Has 3d sensors, and cameras for detecting the environment	Single infrared camera, positioned 0.5m above tracked objects	Has 3d sensors, and cameras for detecting the environment	Equivalent
Tracking	6 DOF	6 DOF	6 DOF	Equivalent
Tracking Algorithm	Perspective N-point followed by center ray optimization	Perspective N-point	Not relevant	Equivalent
System Accuracy Requirement	System Level Accuracy with a mean positional error of 3.0mm and mean trajectory error of 3°	System Level Accuracy with a mean positional error of 2.0mm and mean trajectory error of 2°	Not relevant	Equivalent to Orthopedic requirement
Imaging Modality / Data Sources	CT sources	X-Ray Based Imaging	CR, DX, CT, MR, and PT sources	Equivalent
Medical Device Interfaces	Pre-operative planning workstation Novarad PACS server	O-arm Imaging System Ziehm Vision FD Vario 3D C-Arm and RFD 3D	Pre-operative planning workstation Novarad PACS server	Utilizes the same process

		Siemens CIOS SPin Airo system by Brainlab		
Display Features	2D images: axial, sagittal, coronal and oblique 3D real time rendering Trajectories Trajectory guidance Instrument's tip view 3D transparent	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, sagittal, coronal and oblique 3D or 4D real time rendering Trajectories 3D transparent 3D OFF (only 2D)	Equivalent - VisAR does not use a 3D model
Software Interface (GUI)	Multiple heads up menu displays Voice controls Hand gestures	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	Multiple heads up menu displays Voice controls Hand gestures	Equivalent
Communication between Scanner and platform/computer	WiFi communication with Novorad server, provides medical scan	USB & LAN connectivity using DICOM	WiFi communication with Novorad server, provides medical scan	Equivalent
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	Augmented Reality using near eye see-through display; data displayed on patient's anatomy	Equivalent
Communication between Headset and computer	Wireless, encrypted	Wireless, encrypted	Wireless, encrypted	Equivalent
Frame rate of displayed images	60 fps	60 fps	60 fps	Equivalent
Headset power source	Li-ion rechargeable battery	Li-ion rechargeable battery	Li-ion rechargeable battery	Equivalent

Performance Data

The following testing was conducted to evaluate the device:

- **Accuracy**
  Bench testing was performed on 7 cadavers. 124 pedicle screws were positioned using VisAR augmented reality navigation/guidance. The angular error and distance error were calculated.

  Following CT, the pedicle entry point, trajectory, and depth were determined and annotated using NovaPACS software (Novarad, Provo, Utah) by a neuroradiologist. The annotated images were uploaded to VisAR and transformed to 3D images for surgical guidance. Spine surgeons used VisAR as the guidance device for pedicle

screw insertion. The preoperative CT was fused with the postoperative CT and spatial locations of both the annotated virtual pathway and the actual screw placement were determined with vector coordinates.

The following tables summarize the results:

Overall Positional Error:

Registration Method	Mean Overall Positional Error [mm]	STD Overall Positional Error [mm]	99% Upper Bound Limit Overall Positional Error [mm]
Optical Codes (ARTags, AprilTags) alignment	1.9	0.9	1.85-1.94

Overall Trajectory Angle Error:

Mean Overall Trajectory Angle Error [deg]	STD Overall Trajectory Angle Error [deg]	99% Upper Bound Limit Overall Trajectory Angle Error [deg]
2.4	1.2	2.35-2.44

- **Pedicle Screw Positioning Accuracy: Gertzbein-Robbins Scale[1]**

Screw placement was also evaluated with the Gertzbein-Robbins scale, which is the clinical measurement of pedicle screw placement accuracy.

Gertzbein-Robbins Scale	Grades of pedicle screws positioned in 3 cadavers
A: No breach	113
B: 0-2 mm	6
C: 2.1-4.0 mm	5
D: 4.1-6.0 mm	0
E: >6.0 mm	0

- **Accuracy Summary:**

The overall mean positional error is 1.9 mm (STD: 0.9), with an angle of error of 2.4 degrees (STD: 1.2 degrees). 96% of the pedicle screws were placed correctly (grades A and B) when graded with the Gertzbein-Robbins scale.

The system has demonstrated performance in 3D positional accuracy with a mean error lower than 3mm and in trajectory angle accuracy with a mean error 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, transmittance, distortion, contrast ratio, temporal, display noise and motion-to-photon 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, 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 disturbances - Requirements and tests.

- Sterilization validation for the single use components was conducted in accordance with the ANSI/AAMI/ISO 11137-1, Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices. Additionally, shelf life and packaging testing were performed to support the labeled shelf life. All tests were successfully completed.

- Reusable components are validated for cleaning and sterilization per manufacturer instructions.

- Headset cleaning and disinfection validation was performed according to 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, September 4, 2020. All tests were successfully completed.

- Software verification and validation testing was conducted as required by IEC 62304:2015, Medical Device Software – Software Lifecycle processes.

- Human factors and usability testing was conducted as required by IEC 62366-1:2015+AMD1:2020, Medical devices – Part 1: Application of usability engineering to medical devices.

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

Conclusions

The information provided above supports that the VisAR System is substantially equivalent to the identified predicate devices. Substantial equivalence has been demonstrated through a comparison of

intended use, technological characteristics, as well as performance evaluations. 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 VisAR System functions as intended without raising new safety or effectiveness concerns. The VisAR System can be considered substantially equivalent to the identified predicate devices.

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[1] S. D. Gertzbein and Stephen E. Robbins. Accuracy of pedicular screw placement *in vivo*. Spine,15:1:11-14, 1990.