December 28, 2022

nView medical
Lisa Last
Chief Operating Officer
2681 E Parleys Way STE 107
SALT LAKE CITY, UT 84109

Re: K221344
Trade/Device Name: nView s1 with nav option
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, JAK, OXO, OLO
Dated: November 28, 2022
Received: November 28, 2022

Dear Lisa Last:

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,

Esther O. Akinnagbe-zusterzeel -S

Digitally signed by Esther O. Akinnagbe-zusterzeel -S
Date: 2022.12.28 13:14:15 -05'00'

For
Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
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)*

K221344

Device Name
nView s1 with nav option

Indications for Use *(Describe)*

The nView s1 is intended as an imaging system to provide both 2D and 3D imaging of adult and pediatric populations over 6 years of age. The device is intended to provide fluoroscopic and tomographic imaging of patients during orthopedic surgical procedures where the clinician benefits from 3D visualization of complex anatomical structures, such as high contrast objects, bones, joints, cervical, thoracic, and lumbar regions of the spine, and joint fractures of the upper and lower extremities.

The nView s1 is indicated to image human anatomy up to 30 cm thickness.
The nView s1 is not indicated for mammographic or lung nodule applications.

The nView s1 with navigation option is intended as a navigation system to localize anatomical structures in spine fusion procedures for tasks such as identifying vertebrae, and identifying entry points in the thoracic and lumbar spine regions; and for the task of pilot hole verification for pedicle screw placement of 4.5 mm screws in the thoracic and lumbar spine regions. The navigation option is indicated for posterior approach open spinal procedures in pediatric populations over 6 years of age in which the use of stereotactic surgery may be appropriate, and where reference to a rigid spinous process can be identified relative to nView s1 images of the anatomy.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for K221344

The following statement is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter Information

Submitter: nView medical, Inc.
2681 E. Parleys Way, Suite 107
Salt Lake City, Utah 84109

Contact: Ms. Lisa Last
Chief Operating Officer/ Regulatory Affairs
lisa.last@nviewmed.com
T 617.283.7053

Preparation Date: November 28, 2022

Subject Device Information

Device Name:	nView s1 with nav option
Common/Usual Name:	Mobile Fluoroscopic C-Arm
Primary Regulation Number:	CFR 892.1650
Primary Regulation Name:	Image-intensified fluoroscopic x-ray system
Primary Regulatory Class:	II
Primary Product Code:	OWB
Secondary Product Codes:	OXO, JAA, JAK, OLO

Predicate Device Information

Device Name (510(k) number):	nView s1 with nav option (K211064)
Common/Usual Name:	Mobile Fluoroscopic C-Arm
Regulation Number:	CFR 892.1650
Regulation Name:	Image-intensified fluoroscopic x-ray system
Regulatory Class:	II
Primary Product Code:	OWB
Secondary Product Codes:	OXO, JAA, JAK, OLO

Reference Device Information

Device Name (510(k) number):	Medtronic Navigation Inc - StealthStation™ S8 system (K162309)
Common/Usual Name:	Neurological Stereotaxic Instrument
Regulation Number:	CFR 882.4560
Regulation Name:	Stereotaxic Instrument
Regulatory Class:	II
Product Codes:	HAW, OLO, PGW

Device Description:

Device Identification: The nView s1 with nav option mobile fluoroscopic system is a cone beam computed fluoroscopic and tomographic X-ray system consisting of two mobile units: a mobile C-arm and a monitor cart. The mobile C-arm is comprised of a fixed anode X-ray tube with a high voltage generator, X-ray controls, markers for image registration during navigation, and a mechanical “C" shaped structure which supports the X-ray chain, the image receptor flat panel detector, and navigation tracking markers. The tracking camera is rigidly attached to the operating table and connects to the C-arm via a cable.

The monitor cart is a mobile platform containing a flat panel display and a GPU computer that connects to the mobile C-arm by ethernet cable.

Navigation instrumentation consists of a navigated surgical probe and a patient reference.

Device Characteristics: The device contains software. The nav option tracks single-use sterile navigation instrumentation. It does not contain biologics, drugs, coatings, or additives.

Environment of Use: The device is intended to be used in a hospital facility immediately before, during, or after surgery.

Brief Written Description of the Device: The nView s1 with nav option employs X-rays as its imaging technology for visualizing human anatomy in both 2D and 3D. The X-ray tube powered by a generator produces X-rays, which image the patient under control of the user, at the direction of a physician. The images from the system assist the physicians in visualizing the patient’s anatomy during surgical procedures. The device provides both real-time image capture and post capture visualization suitable for use immediately before, during, or after surgery. The optional navigation feature uses optical camera technology to display a surgeon's probe on the image in real time during the surgery.

Key Performance Specifications/Characteristics of the Device: The device performs both 2D and 3D medical imaging generated by means of an iterative algorithm. The system uses the images of a scan captured with relation to a predefined scan reference frame to compute the three-dimensional representation of the imaged object. The images are displayed on the screen of the monitor cart. It is possible to display projection views as well as tomographic views. The navigation option utilizes optical camera technology to track the C-arm, the instruments, and the patient.

Changes to predicate: The changes to the currently cleared nView s1 with nav option are as follows:

- a phrase change in the indications for use to modify the ordering of the navigation tasks indicated for the device
- an additional navigation registration mode where the patient reference is attached to the patient after the image and then a paired point registration is performed to register the imaging and navigation coordinate frames

Indications for Use:

The nView s1 is intended as an imaging system to provide both 2D and 3D imaging of adult and pediatric populations over 6 years of age. The device is intended to provide fluoroscopic and tomographic imaging of patients during orthopedic surgical procedures where the clinician benefits from 3D visualization of complex anatomical structures, such as high contrast objects, bones, joints, cervical, thoracic, and lumbar regions of the spine, and joint fractures of the upper and lower extremities.

The nView s1 is indicated to image human anatomy up to 30 cm thickness.

The nView s1 is not indicated for mammographic or lung nodule applications.

The nView s1 with navigation option is intended as a navigation system to localize anatomical structures in spine fusion procedures for tasks such as identifying vertebrae, and identifying entry points in the thoracic and lumbar spine regions; and for the task of pilot hole verification for pedicle screw placement of 4.5 mm screws in the thoracic and lumbar spine regions. The navigation option is indicated for posterior approach open spinal procedures in pediatric populations over 6 years of age in which the use of stereotactic surgery may be appropriate, and where reference to a rigid spinous process can be identified relative to nView s1 images of the anatomy.

Comparison of Technology with Predicate

Intended Use

SUBJECT DEVICE nView s1 with nav option	The nView s1 is intended as an imaging system to provide both 2D and 3D imaging of adult and pediatric populations over 6 years of age. The device is intended to provide fluoroscopic and tomographic imaging of patients during orthopedic surgical procedures where the clinician benefits from 3D visualization of complex anatomical structures, such as high contrast objects, bones, joints, cervical, thoracic, and lumbar regions of the spine, and joint fractures of the upper and lower extremities. The nView s1 is indicated to image human anatomy up to 30 cm thickness. The nView s1 is not indicated for mammographic or lung nodule applications. The nView s1 with navigation option is intended as a navigation system to localize anatomical structures in spine fusion procedures for tasks such as identifying vertebrae, and identifying entry points in the thoracic and lumbar spine regions; and for the task of pilot hole verification for pedicle screw placement of 4.5 mm screws in the thoracic and lumbar spine regions. The navigation option is indicated for posterior approach open spinal procedures in pediatric populations over 6 years of age in which the use of stereotactic surgery may be appropriate, and where reference to a rigid spinous process can be identified relative to nView s1 images of the anatomy.
PREDICATE DEVICE nView s1 with nav option (K211064)	The nView s1 is intended as an imaging system to provide both 2D and 3D imaging of adult and pediatric populations over 6 years of age. The device is intended to provide fluoroscopic and tomographic imaging of patients during orthopedic surgical procedures where the clinician benefits from 3D visualization of complex anatomical structures, such as high contrast objects, bones, joints, cervical, thoracic, and lumbar regions of the spine, and joint fractures of the upper and lower extremities. The nView s1 is indicated to image human anatomy up to 30 cm thickness. The nView s1 is not indicated for mammographic or lung nodule applications. The nView s1 with navigation option is intended as a navigation system to aid in pilot hole verification for pedicle screw placement of 4.5 mm screws in the thoracic and lumbar spine regions. The navigation option is indicated for posterior approach open spinal procedures in pediatric populations over 6 years of age in which the use of stereotactic surgery may be appropriate, and where reference to a rigid spinous process can be identified relative to nView s1 images of the anatomy.

EQUIVALENT- nView's subject device has essentially the same indications as the predicate. Both devices are indicated for tasks in spine fusion procedures. The phrasing has been updated for formatting only. Both devices have the same patient population, the same reference to a rigid spinous process, and the same use of the nView s1 image.

Technological Characteristics

ATTRIBUTE	SUBJECT DEVICE nView s1 with nav option	PREDICATE DEVICE nView s1 with nav option (K211064)	REFERENCE DEVICE Medtronic StealthStation (K162309)	SUBSTANTIAL EQUIVALENCE
target population	adult and pediatric populations over 6 years of age with imaged anatomy up to 30 cm thickness (pediatric only for the navigation option)	adult and pediatric populations over 6 years of age with imaged anatomy up to 30 cm thickness (pediatric only for the navigation option)	all adult and pediatric populations	IDENTICAL to predicate
anatomical site	high contrast bony anatomy for imaging, thoracic and lumbar spine for navigation	high contrast bony anatomy for imaging, thoracic and lumbar spine for navigation		IDENTICAL
where used	Hospital/ clinic	Hospital/ clinic	Hospital/ clinic	IDENTICAL
Input Power (VAC)	120	120	120	IDENTICAL
Mobile Platform	Yes	Yes	Yes	IDENTICAL
Imaging Platform				
C-arm Gantry	Yes	Yes	N/A	IDENTICAL
# of Axes	6 axes of motion, 1 motorized, one tracked with encoders	6 axes of motion, 1 motorized, one tracked with encoders	N/A	IDENTICAL
User Interface	Touch control	Touch control	N/A	IDENTICAL
Fluoroscopic	Yes - via real-time digital projections	Yes - via real-time digital projections	N/A	IDENTICAL
Tomographic	Yes	Yes	N/A	IDENTICAL
Tube Type	Stationary Reflective Anode	Stationary Reflective Anode	N/A	IDENTICAL
Tube Focal Spot Size	0.6mm	0.6 mm	N/A	IDENTICAL
X-Ray Tube Max kV/ mA/ W	75/12/350	75/12/350	N/A	IDENTICAL
Detector Type	CMOS Digital Detector	CMOS Digital Detector	N/A	IDENTICAL
Detector Shape	Square	Square	N/A	IDENTICAL
Detector Size (cm)	30 cm x 30 cm	30 cm x 30 cm	N/A	IDENTICAL
Detector Resolution	1952 x 1952	1952 x 1952	N/A	IDENTICAL
Distortion Free Imaging	Yes	Yes	N/A	IDENTICAL
Collimator/Beam Limiter	Yes	Yes	N/A	IDENTICAL
Anatomy Alignment	Physical Markers	Physical Markers	N/A	IDENTICAL
Reconstruction Geometry	Multi Arc Source Trajectory	Multi Arc Source Trajectory	N/A	IDENTICAL
Dataset Capabilities	2D and 3D	2D and 3D	N/A	IDENTICAL

ATTRIBUTE	SUBJECT DEVICE nView s1 with nav option	PREDICATE DEVICE nView s1 with nav option (K211064)	REFERENCE DEVICE Medtronic StealthStation (K162309)	SUBSTANTIAL EQUIVALENCE
Acquisition time (s)	2, 4, 8	2, 4, 8	N/A	IDENTICAL
Reconstruction Time (s)	1 to 30	1 to 30	N/A	IDENTICAL
3D resolution (mm)	0.721 x 0.721 x 0.721	0.721 x 0.721 x 0.721	N/A	IDENTICAL
3D Reconstruction Type (deg)	Maximum of 117 multi arc	Maximum of 117 multi arc	N/A	IDENTICAL
3D reconstruction algorithm	Iterative reconstruction with positivity, denoising regularizers	Iterative reconstruction with positivity, denoising regularizers	N/A	IDENTICAL
Navigation Characteristics				
Imaging Modality	nView s1 images	nView s1 images	CT, MRI, or fluoro images	EQUIVALENT, the subject and predicate work on the same nView s1 images, the reference device uses generic third-party images.
Patient Registration Options	Automatic image registration with patient reference placed before imaging, paired point registration with patient reference placed after imaging	Automatic image registration with patient reference placed before imaging	PointMerge® registration, Tracer™ registration, Touch registration, StealthAiR® registration, O-arm® registration, Mechanical based registrations	EQUIVALENT, the subject device supports the identical Automatic registration mode as the predicate, and a paired point registration mode that is equivalent to the PointMerge registration in the reference device.
Tracking Technology	Optical infrared Camera	Optical infrared Camera	Optical infrared Camera	IDENTICAL
Instrument Tracking Method	passive marker sensor system	passive marker sensor system	passive marker sensor system	IDENTICAL
Patient Tracking Method	Via patient reference	Via patient reference	Via patient reference	IDENTICAL
Registration Accuracy	3D positional accuracy with a positional error < 2.0 mm and trajectory angle accuracy error < 2.0 degrees immediately after automatic or paired point registration	3D positional accuracy with a positional error < 2.0 mm and trajectory angle accuracy error < 2.0 degrees immediately after automatic	Not stated	EQUIVALENT, The subject and predicate have the same accuracy for all supported registration modes
Clinical Accuracy	3D positional accuracy with a positional error ≤ 3.0 mm	3D positional accuracy with a positional error ≤	3D positional accuracy with a mean error ≤ 2.0 mm and trajectory angle	EQUIVALENT, The subject has the same accuracy numbers as

ATTRIBUTE	SUBJECT DEVICE nView s1 with nav option	PREDICATE DEVICE nView s1 with nav option (K211064)	REFERENCE DEVICE Medtronic StealthStation (K162309)	SUBSTANTIAL EQUIVALENCE
	and trajectory angle accuracy error ≤ 3.0 degrees with patient reference for spine applications	3.0 mm and trajectory angle accuracy error ≤ 3.0 degrees with patient reference for spine applications	accuracy with a mean error ≤ 2.0 degrees for cranial applications	the predicate. The subject and predicate have narrower claims of spine applications only. The accuracy numbers are adjusted from the reference device based on the reduced clinical applications.
Visualization Characteristics				
Visualization Viewports	3 user selectable slice/projection viewports	3 user selectable slice/projection viewports	N/A	IDENTICAL
Visualization Crosshairs	3 plane system with tick marks, controlled by navigated tool when navigating.	3 plane system with tick marks, controlled by navigated tool when navigating.	N/A	IDENTICAL
Measurements	Euclidean distances and angle measurements when moving cross-hairs	Euclidean distances and angle measurements when moving cross-hairs	N/A	IDENTICAL
Image scrolling	User driven based on position of anatomy and axis or by navigated tool when navigating.	User driven based on position of anatomy and axis or by navigated tool when navigating.	N/A	IDENTICAL

13.2 Discussion of similarities and differences vs predicate/reference

13.2.1 Intended Use

The indications for use for the subject and predicate are essentially the same in the subject device and the cleared nView medical nView s1 with nav option (K211064). Both devices are indicated for tasks in spine fusion procedures. The phrasing has been changed for formatting only as discussed in a pre-submission. Both devices have the same patient population, the same reference to a rigid spinous process, and the same use of the nView s1 image.

13.2.2 Technological Characteristics

The technological characteristics governing how the device produces images of human anatomy are identical in the subject device and the predicate nView medical nView s1 with nav option (K211064) system. The technological characteristics governing how the device navigates a surgical tool on images of human anatomy are equivalent in the subject device and the predicate nView medical nView s1 with nav option (K211064) system. Both systems use an optical tracker and reflective markers on instruments to dynamically display a tool on an image. Both systems use a patient reference to track patient motion. Both systems use an automatic registration when the patient reference is attached before the image is taken.

The characteristics of the subject device paired point registration and the reference device (Medtronic Navigation Inc - StealthStation™ S8 system (K162309)) PointMerge registration are technologically equivalent. This registration methodology allows for registration of images taken without a patient reference to register the image to the navigation coordinate system. The method is equivalent in both systems in that it uses points found in the image and the same points touched physically on the anatomy to register the image and navigation coordinate frames. The subject device requires the user to set a minimum of 10 points on the anatomy. The reference device allows the user to set a maximum of 8 and a minimum of 4 points on the anatomy. More points will give equivalent or better registration accuracy. Both systems allow the position of the selected point to be refined in the viewer. Both systems register the two sets of points (image based and navigation based) using a point set registration method to find the spatial transformation (e.g.,rotation and translation) that aligns the two sets of points. The subject device uses divots in the bone of the spine as the points. The reference device recommends using “an identifiable anatomical landmark or a fiducial on the skin”. A well defined divot made with a specified tool of a fixed diameter and depth such as in the subject device should provide better registration accuracy than the user selecting an identifiable landmark without a defined size. The subject device has the user set the points on the anatomy first, and then the navigation system places the crosshair of the tool at the point in the viewer for the user to manually refine. The reference device has the user find points in the image first, and then touch them on the anatomy in order. The order in which the point sets are collected does not impact the registration accuracy. Both systems provide an accuracy verification method after completing the registration by touching one or more of the set points and confirming the crosshairs are centered on the set point in the image. The accuracy of the subject device is identical to the predicate device both with the cleared automatic registration mode, and with the proposed paired point registration mode.

Summary of non-clinical test data

The demonstration of substantial equivalence is based on a comparison of features to the predicate devices and on an assessment of non-clinical performance data.

The nView s1 with nav option complies with the mandatory and voluntary standards listed in Table 1 below. The nView s1 with nav option was developed in accordance with the FDA guidance documents listed in Table 2.

Table 1 - Standards used in the development of nView s1 with nav option

Standards development organization, reference number, and date	**Standard name**
21 CFR 1020.30, 32	Federal Performance Standard for Diagnostic X-ray Systems
ES60601-1:2005/(R)2012 and A1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
IEC 60601-1-2: Edition 4.0 2014-02	Medical Electrical Equipment, General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-3: Edition 2.1 2013-04	Medical Electrical Equipment, General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6: Edition 3.1 2013-10	Medical electrical equipment, General requirements for basic safety and essential performance – Collateral standard: Usability

Standards development organization, reference number, and date	Standard name
IEC 60601-2-43: Edition 2.1 2017-05	Medical electrical equipment, Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-54: Edition 1.2 2018-06	Medical electrical equipment, Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
ISO 14971: Third Edition 2019-12	Application of risk management to medical devices
ISO 10993-1:2018: Fifth edition 2018-08	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
ISO 17665-1:2006: First edition 2006-08-15	Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ASTM F2554-18	Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems

Table 2 - Guidance documents used in the development of nView s1 with nav option

Guidance Document Name	Issue Date
Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]	July 28, 2014
Guidance for Industry and FDA Staff: Guidance for the Submission Of 510(k)'s for Solid State X-ray Imaging (SSXI) Devices	September 1, 2016
Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submission for Software in Medical Devices	May 11, 2005
Guidance for Industry and FDA Staff: Applying Human Factors and Usability Engineering to Medical Devices	February 3, 2016
Guidance for Industry and FDA Staff: Pediatric Information for X-ray Imaging Device Premarket Notifications	November 28, 2017
Guidance for Industry and FDA Staff: Content of Premarket Submissions for Management of Cybersecurity in Medical devices	October 18, 2018
Guidance for Industry and FDA Staff: Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices	July 11, 2016
Guidance for Industry and Food and Drug Administration Staff: Medical X-Ray Imaging Devices Conformance with IEC Standards	May 8, 2019
Guidance for Industry and Food and Drug Administration Staff: Policy Clarification for Certain Fluoroscopic Equipment Requirements	May 8, 2019
Draft Guidance for Industry and Food and Drug Administration Staff: Remanufacturing of Medical Devices	June 24, 2021

Verification and Validation

Software Documentation for a Moderate Level of Concern software per FDA's Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" issued on May 11, 2005 is also included as part of this submission. Non-clinical tests were conducted on the subject device during product development.

The risk analysis was completed and risk control implemented to mitigate identified hazards. The testing results support that all requirements have met the acceptance criteria. Testing for verification and validation for the device was found acceptable to support the claims of substantial equivalence.

Test protocols and quality controls ensure the subject device is safe and effective for intended users, uses and use environments through the design control verification and validation process. The human factor usability validation showed that human factors are addressed in the system in simulated clinical use tests.

Under representative worst-case configuration, the nView s1 with nav option has demonstrated 3D positional accuracy with a positional error < 2.0 mm and trajectory angle accuracy error < 2.0 degrees immediately after automatic or paired point registration. This performance was determined using a cadaveric specimen and utilizing a subset of system components and features that represent the worst-case combinations of all potential system components.

The subject device conforms to the cybersecurity requirements by implementing a process of preventing unauthorized access, modifications, misuse or denial of use, or unauthorized use of information that is stored, accessed or transferred from a medical device to an external recipient.

Conclusion as to substantial equivalence

In summary, the subject device is substantially equivalent to the predicate device. The subject device has an intended use that is essentially the same as the predicate device and essentially the same technological characteristics as the predicate nView medical nView s1 with nav option (K211064). The proposed additional registration method utilizes the same scientific methodology as the reference device Medtronic Navigation Inc StealthStation™ S8 system (K162309). Performance testing demonstrates the nView s1 with nav option performs as intended and demonstrates substantial equivalence to the predicate device. No new questions of safety and effectiveness are raised in the subject device.