October 29, 2021

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

Re: K211064
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, OXO, OLO, JAK
Dated: September 28, 2021
Received: September 29, 2021

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,

, for

Thalia Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K211064

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 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.

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 K211064

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: October 21, 2021

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
Additional Product Codes:	OXO, JAA, JAK, OLO

Primary Predicate Device Information

Device Name (510(k) number):	nView medical - nView system 1 (K190064)
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
Additional Product Codes:	OXO, JAA, JAK

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:	Stereotactic Instrument
Regulatory Class:	HAW
Primary Product Code:	OLO, PGW
Additional Product Codes:	

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.

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 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 population 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:

The technological principle of operation for both the subject and the primary predicate device is limited angle cone beam CT X-ray imaging. It is based on the collection of a series of projection images of the same anatomy, and applying iterative reconstruction techniques to generate a 3D tomographic reconstruction. The technological principle of operation for both the subject and the reference device is optical tracking technology using passive reflective markers. Table 1 and Table 2 compare the intended use and technological characteristics of the subject and predicate devices.

Table 1 – Intended Use statements for the proposed device and predicate devices

PROPOSED 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 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.
PRIMARY PREDICATE DEVICE nView system 1 (K190064)	nView system 1 is intended 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 device is indicated to image human anatomy up to 30 cm thickness. The device is not indicated for mammographic or lung nodule applications.
REFERENCE DEVICE Medtronic Navigation Inc StealthStation™ S8 system (K162309)	The StealthStation™ System is intended as an aid for precisely locating anatomical structures in either open or percutaneous surgical procedures. The StealthStationTM System 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 skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

EQUIVALENT - nView's indications are a subset of the predicates, fully encompassed by the predicates indications. nView s1 with nav option intended use is limited to navigation during orthopedic procedures on the nView s1 images only.

Table 2 – Comparison of attributes for the proposed device and predicate devices

ATTRIBUTE	PROPOSED DEVICE nView s1 with nav option	PRIMARY PREDICATE DEVICE nView system 1 (K190064)	REFERENCE DEVICE Medtronic Navigation Inc StealthStation™ S8 system (K162309)	SUBSTANTIAL EQUIVALENCE DISCUSSION
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	all adult and pediatric populations	EQUIVALENT nView's target population is a subset, fully encompassed by the predicates.
anatomical site	high contrast bony anatomy for imaging, thoracic and lumbar spine for navigation	high contrast bony anatomy	rigid anatomy such as the skull, a long bone, or vertebra,	EQUIVALENT nView's target population is identical to the primary predicate for imaging and is a subset, fully encompassed by the reference device for navigation.
where used	Hospital/ clinic	Hospital/ clinic	Hospital	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	N/A	EQUIVALENT The proposed device has the same degrees of freedom, with an added encoder for one DOF.
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
Acquisition time (s)	2, 4, 8	2 or 4	N/A	EQUIVALENT Both systems provide a range of acquisition times based on the clinical scenario
Reconstruction Time (s)	1 to 30	1 to 30	N/A	IDENTICAL
3D resolution (mm)	0.721 x 0.721 x 0.721	1.00 x 1.00 x 1.00	N/A	EQUIVALENT The proposed device has increased resolution
3D Reconstruction Type (deg)	Maximum of 117 multi arc	117 multi arc	N/A	EQUIVALENT Both systems predicated on a limited angle reconstruction
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	N/A	X-Ray based, MR based, Nuclear Medicine based	EQUIVALENT The proposed device works only using nView s1 images, instead of generic third-party images.
Patient Registration Options	Automatic image registration with patient reference	N/A	PointMerge® registration, Tracer™ registration, Touch registration, StealthAiR® registration, O-arm® registration, Mechanical based	EQUIVALENT The proposed device uses only one registration method, a subset of the reference device.

			registrations	
Tracking Technology	Optical infrared Camera	N/A	Optical infrared Camera	IDENTICAL
Instrument Tracking Method	passive marker sensor system	N/A	passive marker sensor system	IDENTICAL
Patient Tracking Method	Via patient reference		Via patient reference	IDENTICAL
Clinical Accuracy	3D positional accuracy with a positional error ≤ 3.0 mm and trajectory angle accuracy error ≤ 3.0 degrees with patient reference for spine applications	N/A	3D positional accuracy with a mean error ≤ 2.0 mm and trajectory angle accuracy with a mean error ≤ 2.0 degrees for cranial applications	EQUIVALENT The proposed has narrower claims of spine applications only. The accuracy numbers are adjusted based on the reduced clinical applications.
Visualization Characteristics				
Visualization Viewports	3 user selectable slice/projection viewports	3 slice viewports, 3 projection viewports	2 or 4 user configurable slice viewports with instrument overlay.	EQUIVALENT All devices have user configurable viewports.
Visualization Crosshairs	3 plane system with tick marks, controlled by navigated tool when navigating.	3 plane system with no tick marks	Controlled by navigated tool, with or without tick marks.	EQUIVALENT The proposed device utilizes the same crosshairs, but with tick marks added and controlled by navigated tool when navigating.
Measurements	Euclidean distances and angle measurements when moving cross-hairs	N/A	Measurements available based on the type of view the user selects	EQUIVALENT Both devices utilize measurement features
Image scrolling	User driven based on position of anatomy and axis or by navigated tool when navigating.	User driven based on position of axis	User driven based on navigated tool	EQUIVALENT Both imaging systems display images and scrolling with respect to the displayed axises. The proposed device can adjust the axis and therefore scrolling of images to align with anatomy. Both navigation systems control

				image scrolling with the navigated tool.

Discussion of similarities and differences vs predicates

The proposed subject device has an intended use that, for imaging, is identical to the primary predicate device, nView medical nView system 1 (K190064) and, for navigation, a subset of the reference device, Medtronic Navigation Inc, StealthStation™ S8 System (K162309). The subject device's indications are a reduction of claims from the reference device (less clinical applications and smaller patient population) but are fully encompassed in the reference device indications. There are no new indications or claims for the subject device.

Intended Use

The intended use of the proposed device and the predicate devices are the same within the guidance of "*The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* Guidance for Industry and Food and Drug Administration Staff. Document issued on: July 28, 2014". The intended use of the imaging portion is identical to the primary predicate device. For the navigation system, the proposed device has a narrow indication for verifying pilot holes when placing pedicle screws. This indication is within the broad indications of the reference device. Additionally, for navigation the proposed device has a narrow patient population, pediatrics over the age of six. This population is within the broad patient population of the reference device. The proposed device intended use is fully encompassed by the reference device and does not include any new indications. A reduction in the clinical applications and patient population does not result in a new intended use.

Technological Characteristics

The technological characteristics governing how the device produces images of human anatomy are the equivalent in the proposed device and the cleared nView medical nView s1 (K190064) system. Both systems use X-ray to image the anatomy. Both systems are used for fluoroscopic and tomographic imaging. The technological characteristics governing how the device navigates a surgical tool on images of human anatomy are the equivalent in the proposed device and the cleared Medtronic Navigation Inc, StealthStation™ S8 System (K162309) system. Both systems use an optical tracker and reflective markers on instruments to dynamically display a tool on an image.

Primary Predicate

Both systems display 2D fluoroscopic views in real-time via a digital projection through the 3D tomographic volume. Both systems result in real-time 2D fluoroscopic projection views displayed to the user.

Both systems reconstruct 3D images from a series of fluoroscopic images collected at different angles using the same reconstruction algorithms. The proposed system allows for easier positioning of the C-arm for stereotactic imaging by utilizing an encoder to measure the C-arm position instead of requiring the user to move the system exactly to -30 and + 30 degrees. The proposed device has additional imaging modes to better suit different anatomies.

The proposed device has improved interaction with the images on the monitor. It utilizes the identical monitor and touchscreen, and a similar multi viewport viewer. It adds improved scrolling through images by adjusting the scrolling axis to align with the anatomy.

The proposed device has the ability to combine two adjacent images to create a longer view of the anatomy. This is done through the same acquisition and reconstruction process as a stereotactic image.

Reference Device

The subject device uses an equivalent optical camera and reflective spheres for navigation as the reference device. The subject uses the same methodology of tracking the C-arm and patient with passive markers. The subject device only navigates on the nView s1 images, the reference device navigates on several third-party imaging technologies such as CT, MRI, fluoroscopy, and an internal technology, the O-arm. The reference device offers several types of registration based on the clinical application and surgeon preference. The subject device utilizes one of those registration types, automatic registration. The subject device has accuracy requirements based on the clinical application of spine. The reference device has a more stringent accuracy requirement to support the additional claims in cranial and ENT procedures.

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 3 below. The nView s1 with nav option was developed in accordance with the FDA guidance documents listed in Table 4.

Table 3 - 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
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 4 - 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.

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 primary and reference device. The subject device has, for imaging, an intended use that is identical to the primary predicate intended use and, for navigation, a narrow subset of the reference device intended use and essentially the same technological characteristics as the predicates nView medical nView system 1 (K190064) and Medtronic Navigation Inc StealthStation™ S8 system (K162309). Minor differences that do not impact the decision of substantial equivalency include: the subject device having additional imaging and dose modes, an integrated navigation option equivalent to the reference device, and improved image visualization.