nView medical, Inc.
℅ Ms. Lisa Last
Regulatory Affairs Leader
2681 E. Parleys Way, Suite 107
SALT LAKE CITY UT 84109

July 8, 2019

Re: K190064
Trade/Device Name: nView system 1
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO, JAA, JAK
Dated: June 7, 2019
Received: June 12, 2019

Dear Ms. 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 T. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190064

Device Name
nView system 1

Indications for Use *(Describe)*

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.

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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510(k) Summary

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: June 7, 2019

Subject Device Information

Device Name:	nView system 1
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

Predicate Device Information

Device Name (510(k) number):	Ziehm Vision RFD 3D (K142740)
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

Device Description:

Device Identification: The nView system 1 mobile fluoroscopic system is cone beam computed tomography X-ray system and a fluoroscopic X-ray imaging 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, a high voltage generator, X-ray controls, and a mechanical “C" shaped structure which supports the X-ray tube

and generator and the image receptor flat panel detector.

The monitor cart is a mobile platform that connects to the mobile C-arm by USB and HDMI cables, and which integrates the flat panel display monitors and user controls.

Device Characteristics: The device contains software. It does not contain biologics, drugs, patient-contacting materials, coatings, additives, single-use, or sterile components.

Environment of Use: The device is intended to be used in a hospital facility during surgery.

Brief Written Description of the Device: The nView system 1 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 both during surgery or immediately pre or post-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 orthogonal tomographic views.

Indications for Use:

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.

Comparison of Technology with Predicate:

The technological principle of operation for both the subject and the predicate devices 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 following tables compare the intended use and technological characteristics of the subject and predicate device.

Table 1 – Intended Use statements for the subject device and predicate device

SUBJECT DEVICE nView system 1	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.
PREDICATE DEVICE Ziehm Vision RFD 3D (K142740)	The Ziehm Vision RFD 3D system is intended for use in providing both 2D and 3D medical imaging for all adult and pediatric populations, using pulsed and continuous fluoroscopic imaging. The device provides 2D medical imaging for fluoroscopy, digital subtraction, and acquisition of cine loops during diagnostic interventional and surgical procedures where intraoperative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required. Such procedures may include but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional angiography, electrophysiology, pediatrics, endoscopic, urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room procedures, and those procedures visualizing structures of the cervical, thoracic, and lumbar regions of the spine and joint fractures of the upper and lower extremities, and where digital image data is required for Computer-Assisted Surgery procedures. The device is also intended to provide 3D medical imaging of patients during orthopedic, neurological, intraoperative surgical procedures and where the clinician benefits from 3D visualization of complex anatomical structures, such as but not limited to those of high contrast objects, bones, joints, maxillofacial, cervical, thoracic, and lumbar regions of the spine, pelvis, acetabulum and joint fractures of the upper and lower extremities, and where digital image and C-arm positioning data is required for Computer-Assisted Surgery procedures. The visualization of such anatomical structures assists the clinician in the clinical outcome. At the discretion of a physician, the device may be used for other imaging applications. This device does not support direct radiographic film exposures and is not intended for use in performing mammography. The system is not intended for use near MRI systems.

EQUIVALENT - nView's indications are a subset of the predicate, fully encompassed by the predicate indications. nView system 1 intended use is limited to high contrast imaging only and applicable to a more restricted patient population.

Table 2 – Comparison of attributes for the subject device and predicate device

ATTRIBUTE	SUBJECT DEVICE nView system 1	PREDICATE DEVICE Ziehm Vision RFD 3D (K142740)	SUBSTANTIAL EQUIVALENCE DISCUSSION
target population	adult and pediatric populations over 6 years of age with imaged anatomy up to 30 cm thickness	all adult and pediatric populations	SUBSTANTIALLY EQUIVALENT nView's target population is a subset, fully encompassed by the predicate.
anatomical site	2D and 3D imaging of high contrast bony anatomy	2D imaging of high and lower contrast anatomy, 3D imaging of high contrast bony anatomy.	SUBSTANTIALLY EQUIVALENT nView's target population is a subset, fully encompassed by the predicate.
where used	Hospital/ clinic	Hospital/ clinic	IDENTICAL
Input Power (VAC)	120	120	IDENTICAL
X-Ray Tube Max kV/ mA/ W	75/12/350	120/250/25k	SUBSTANTIALLY EQUIVALENT The subject device outputs lower power X-ray to optimize image quality of thin patients at lower dose
Mobile Platform	Yes	Yes	IDENTICAL
C-arm Gantry	Yes	Yes	IDENTICAL
# of Axes	6 axes of motion, 1 motorized	4 axes of motion, all motorized	SUBSTANTIALLY EQUIVALENT The subject device does not move during acquisition so does not need motorized axes.
User Interface	Touch control	Touch control	IDENTICAL
Fluoroscopic	Yes - via digital projections	Yes - via physical projections	SUBSTANTIALLY EQUIVALENT Both systems provide 2D projection visualization.
Temporal resolution	0.5 fps	25/30 fps standard	SUBSTANTIALLY EQUIVALENT The predicate has a higher temporal resolution to allow for broader clinical applications such as interventional cardiology, hybrid procedures, and interventional angiography. For the clinical applications indicated for the subject device,

			“fluoro shots” are used in both the predicate and subject device. A temporal resolution of 0.5 fps is consistent with this clinical use.
Tomographic	Yes	Yes	IDENTICAL
Tube Type	Stationary Anode	Rotating Anode	SUBSTANTIALLY EQUIVALENT Both systems utilize similar x-ray technology. The predicate has a rotating anode to account for higher power output.
Tube Focal Spot Size	0.6mm	0.6 mm	IDENTICAL
Detector Type	CMOS Digital Detector	CMOS Digital Detector	IDENTICAL
Detector Shape	Square	Square	IDENTICAL
Detector Size (cm)	30 cm x 30 cm	20 cm x 20 cm 30 cm x 30 cm	IDENTICAL (Predicate has multiple configurations)
Detector Resolution	1952 x 1952	1024 x 1024 1536 x 1536	SUBSTANTIALLY EQUIVALENT nView utilizes a detector with higher resolution than the predicate
Distortion Free Imaging	Yes	Yes	IDENTICAL
Collimator/Beam Limiter	Yes	Yes	IDENTICAL
Reconstruction Geometry	Multi Arc Source Trajectory	Multi Arc SmartScan trajectory	SUBSTANTIALLY EQUIVALENT Both systems utilize a multi positional scan to acquire images
Dataset Capabilities	2D and 3D	2D and 3D	IDENTICAL
Acquisition time (s)	2 or 4	48	SUBSTANTIALLY EQUIVALENT nView utilizes a shorter acquisition time. This characteristic reduces radiation and motion artifacts.

Reconstruction Time (s)	1 to 30	8 to 18	SUBSTANTIALLY EQUIVALENT Both systems provide a range of reconstruction time based on imaging parameters.
3D resolution	512 x 512 x 512	512 x 512 x 512	IDENTICAL
3D Reconstruction Type (deg)	117 multi arc	180 via SmartScan predicated on 165	SUBSTANTIALLY EQUIVALENT Both systems predicated on a limited angle reconstruction
3D reconstruction algorithm	Iterative	Iterative	IDENTICAL

Discussion of similarities and differences vs predicate

The subject device has an intended use that is a subset of the predicate device, Ziehm Vision RFD 3D (K142740). Both systems are intended to be used to generate fluoroscopic and tomographic images of human anatomy. The subject device's indications are a reduction of claims from the predicate (less clinical applications and smaller patient population) but are fully encompassed in the predicate indications. There are no new indications or claims for the subject device.

Intended Use

The intended use of the subject device and the predicate device 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". Both systems are intended for 2D and 3D imaging of adult and pediatric populations. The subject device limits use in pediatric populations to patients over 6 years of age and imaged human anatomy up to 30 cm thickness. A reduction in patient population does not result in a new intended use. Both systems are indicated for orthopedic surgical procedures where the clinician benefits from 3D visualization of complex anatomical structures, such as those of high contrast objects, bones, joints, cervical, thoracic, and lumbar regions of the spine, and joint fractures of the upper and lower extremities. The predicate includes additional claims in the clinical procedures of cardiology, angiography, electrophysiology, urology, gastroenterology, etc. A reduction in the diseases a device is intended to treat do not result in a new intended use as they don't affect the safety and/or effectiveness of the new device.

Technological Characteristics

The technological characteristics governing how the device produces images of human anatomy are the equivalent in the subject device and the cleared Ziehm Vision RFD 3D (K142740) system. Both systems use X-ray to image the anatomy. Both systems are used for fluoroscopic and tomographic imaging.

The predicate displays 2D fluoroscopic views via real-time physical projection images. The subject device displays 2D fluoroscopic views via a digital projection through the 3D tomographic volume. Both systems result in 2D fluoroscopic projection views displayed to the user.

The predicate reconstructs 3D images from a series of X-ray images collected while the gantry is

moving around the patient. The subject device reconstructs tomographic images from a series of X-ray images collected while the gantry stays in a fixed position with respect to the patient, but while the X-ray tube rotates within the system. Therefore, motorized axes are not required as the gantry is stationary during acquisition. The predicate device reconstructs tomographic images from a series of X-ray images collected while the gantry rotates and shifts around the patient. Therefore, motorized axes were implemented to automatically move the gantry while acquisitions are occurring.

The Ziehm Vision RFD 3D (K142740) is based on a predicate limited angle device employing 135 degrees (+90 degrees and -45 degrees) of orbital rotation. The Ziehm Vision RFD 3D (K142740) employs a shift-scan-shift (SmartScan) motion of this predicate to increase relative coverage to 180 degrees. 3D images are generated from this shift-scan-shift dataset. The nView system 1 is a limited angle device utilizing a 117-degree multi-arc scan for 3D reconstruction. The images are acquired in two steps, first the gantry is rotated to +30 degrees, and images are collected as the tube rotates 360 degrees. Next, the gantry is rotated to -30 degrees, and images are collected as the tube rotates 360 degrees.

Both the subject device and the predicate device have a fluoroscopic mode. The predicate has a higher temporal resolution to allow for broader clinical applications such as interventional cardiology, hybrid procedures, and interventional angiography. For the clinical applications indicated for the subject device, “fluoro shots” are used in both the predicate and subject device. A temporal resolution of 0.5 fps is consistent with this clinical use.

Both the subject device and the predicate use a 30 cm x 30 cm CMOS detector. The subject device CMOS detector has a higher resolution but is used in a binned mode to be equivalent to the resolution of the predicate device detector. The subject device has a lower power x-ray tube with a fixed anode. A higher power x-ray tube with rotating anode is not required for the intended use of the subject device with limitations on imaged anatomy thickness. The subject device is designed to operate at a lower radiation dose than the predicate.

The acquisition and reconstruction times for the subject device are faster than the predicate device. This allows the subject device to perform real-time fluoroscopic imaging via digital projections and faster 3D tomographic imaging and does not impact safety or efficacy of the device.

Summary of non-clinical test data

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

The nView system 1 complies with the mandatory and voluntary standards listed in Table 3 below. The nView system 1 was developed in accordance with the FDA guidance documents listed in Table 4.

Table 3 - Standards used in the development of nView system 1

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: 2014	Medical Electrical Equipment, General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-3:2008 + AMD1:2013	Medical Electrical Equipment, General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC 60601-1-6:2010 + AMD1:2013	Medical electrical equipment, General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-43:2010	Medical electrical equipment, Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures
IEC 60601-2-54:2009 + AMD1:2015	Medical electrical equipment, Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
ISO 14971: 2007	Application of risk management to medical devices

Table 4 - Guidance documents used in the development of nView system 1

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

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.

The subject device was tested and found to be 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.

Additional engineering bench testing was performed including the clinical and non-clinical testing identified in the guidance for submission of 510(k) s for Solid State X-Ray Imaging Devices (SSXI); demonstration of system performance; and an imaging performance evaluation.

Conclusion as to substantial equivalence

In summary, the subject device has an intended use that is a subset of the predicate intended use and essentially the same technological characteristics as the predicate Ziehm Vision RFD 3D (K142740). Minor differences that do not impact the decision of substantial equivalency include: the subject device having lower temporal fluoroscopic views generated from tomographic reconstructions, a different acquisition geometry, a lower powered x-ray tube, and faster acquisition and reconstruction times. It has been demonstrated that the subject device has clinically acceptable performance per a qualified expert evaluation. The subject device does not have new functionalities when compared to the predicate device.