NRT X-ray A/S
℅ Mr. Kevin Walls
Principal Consultant
Regulatory Insight, Inc.
33 Golden Eagle Lane
LITTLETON CO 80127

July 11th, 2018

Re: K173631
Trade/Device Name: Intelli-C
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
Dated: June 30, 2018
Received: July 5, 2018

Dear Mr. Walls:

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. 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.

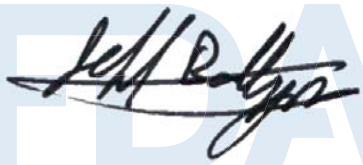
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K173631

Device Name
Intelli-C

Indications for Use *(Describe)*

The Intelli-C is indicated for use as a multipurpose diagnostic X-ray system for universal radiographic, radioscopic and fluoroscopic studies. With its C-arm and digital flat detector, it can perform a range of applications including interventional procedures, vascular and non-vascular procedures, specialized applications including angiographic studies of the entire body on adults and paediatrics.

The Intelli-C system is only indicated for use by trained professionals.
The Intelli-C is not intended for mammography studies.

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

This summary document has been prepared to meet the conditions of 21 CFR 807.92.

Date of summary:	June 25, 2018

Submitter information:

510(k) owner:	NRT X-Ray A/S Birkegaardsvej 16 8361 Hasselager DENMARK
Establishment Registration no.:	1000188474
Contact person:	Jan Malling, Quality Manager
Phone:	+4586283500
E-mail:	jm@nrtxray.com

New device:

Trade name:	**Intelli-C**
Common name:	Multi-purpose tilt C
Classification name:	Interventional Fluoroscopic X-Ray System
Classification:	Class II
CFR Section:	892.1650
Product Code (primary):	OWB
(secondary):	JAA

Predicate device:

Trade name:	GE Precision MPi
Premarket Notification No.:	K033486
Manufacturer:	NRT X-Ray A/S Birkegaardsvej 16 8361 Hasselager DENMARK

Device description for new device:

The Intelli-C device that we wish to bring to market is a multi-purpose - also sometimes known as a universal C-arm fluoroscopy system, designed for diagnostic medical imaging examinations, from barium studies to interventional and angiography studies.

This type of device is typically used in departments with a single fluoroscopy installation that benefit from the versatility of multi-purpose systems that allow a wider range of examinations than a standard fluoroscopy unit. In larger departments such systems can provide backup for other fluoroscopy installations, for example in case of breakdown.

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As with most multi-purpose systems, the Intelli-C has the patient tabletop and C-arm assembly supported on a main column from which the complete unit can be elevated and tilted. The tabletop is supported only at the foot end providing good, all round access to the patient.
The C-arm supports the X-ray tube and image detector assembly and patient coverage is achieved through a combination of C-arm movements and table top movements. The C-arm has angulation and rotational movements, and the source to detector distance is variable. The image detector can be positioned above or below the tabletop depending on the specific examination requirement.
The control room control panel for gantry movements, imaging system, generator and collimator are located in the control room. To facilitate interventional studies to be performed on this type of system, most controls are duplicated on a mobile tableside control panel. The imaging system is normally connected to PACS and Hospital Information System, e.g. patient lists, through the hospital network.

The Intelli-C device will be offered in two main variants:

NRT REF No.:	**Device name:**
03400000	Intelli-C, Right side suspended table
03400010	Intelli-C, Left side suspended table

The main systems will be offered with a range of options and accessories as listed in section 11 of this application.

Electrical safety, EMC and QMS:
The Intelli-C device is tested to the below listed international standards, including FDA performance standards 21 CFR 1020.30, 31 and 32. Design and production controls are carried under a Quality Management System in compliance with 21 CFR 820 and ISO 13485 requirements.

Standard	Title	Revision	Date
IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (including US national differences)	Edition 3.1	(2012-08)
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance Collateral standard: Electromagnetic disturbances - Requirements and tests	Edition 4.0	(2014-02)
IEC 60601-1-3	Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance Collateral Standard: Radiation protection in diagnostic X-ray equipment	Edition 2.1	(2013-04)
IEC 60601-2-43	Medical electrical equipment – Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures	Edition 2.0	(2010-03)
IEC 60601-2-54	Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	Edition 1.1	(2015-04)

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Comparison with predicate device:

The Intelli-C and GE Precision MPi are very similar on all comparable parameters. The predicate device comparison in section 12 of this application, contains a detailed discussion of all differences between the Intelli-C and its predicate device, the GE Precision MPi.

For the purpose of this 510(k) Summary, please find a comparison of the Intended Use, Indications for Use, target population and selected technology aspects below:

Comparison table, Intended Use, Indications for Use and target population:

	Intelli-C	**Precision MPi**
Intended use:	The Intelli-C is an all-digital multipurpose tilt-C X-ray system, intended for a multitude of diagnostic procedures, including: universal radiographic, radioscopic and fluoroscopic diagnostic X-ray, interventional procedures, vascular and non-vascular procedures, and specialized applications including angiographic studies of the entire body on adults and pediatrics.	The GE Precision MPi is an all-digital multipurpose tilt-C X-ray system, intended for a multitude of diagnostic procedures, including: R&F, radiology, fluoroscopy, interventional procedures, vascular and non-vascular procedures, and specialized applications including angiographic studies
Indications for use:	The Intelli-C is indicated for use as a multipurpose diagnostic X-ray system for universal radiographic, radioscopic and fluoroscopic studies. With its C-arm and digital flat detector, it can perform a range of applications including interventional procedures, vascular and non-vascular procedures, specialized applications including angiographic studies of the entire body on adults and pediatrics. The Intelli-C is not indicated for mammography studies.	The GE Precision MPi is a multi-purpose system that can perform general R&F, radiography, fluoroscopy, interventional and angiography procedures/applications.
Target population:	Adults and pediatrics	All, no limitations

Technological differences:

The Intelli-C is the successor to the predicate device, GE Precision MPi, which was also manufactured by NRT X-ray A/S. The main difference between the Intelli-C and the Precision MPi is the introduction of a digital flat panel detector (FPD). The FPD adds benefits such as improved patient access, lower patient radiation doses, and wider dynamic ranges when compared to the Image Intensifier, utilized in the predicate device.

The difference in other X-ray critical components from when the predicate device was produced are reflecting the current state-of-the-art developments from the manufacturers of X-ray High Voltage Generator, X-ray tube and Beam Limiting Device. As it can be seen from the comparison table below, the manufacturers of the X-ray critical components are the same as for the Precision MPI.

Component	**Intelli-C**	**Precision MPi**
High Voltage Generator	Model: Indico IQ, 80kW Manufacturer: Communications & Power Industries Canada Inc.	Model: Indico 100, 100kW Manufacturer: Communications & Power Industries Canada Inc.
X-ray tube	Model: G1592/B180 or G1092/B160 Manufacturer: Varex Imaging Corporation	Model: G1592/B180 or G1092/B160 Manufacturer: Varex Imaging Corporation

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Imaging system	Model: Nexus DRF Digital X-ray Imaging System (with PaxScan 4343CB). Manufacturer: Varex Imaging Corporation	Model: Platinum One Imaging System Manufacturer: Infimed Inc. (now Varex Imaging Corporation)
Collimator	Model: R 806Q Manufacturer: Ralco S.R.L.	Model: R 806ASFL Manufacturer: Ralco S.R.L.

The Intelli-C is by no means an early mover into the FPD technology. We believe that the use of FPD technology is the state-of-the-art standard of today and since the majority of transitions from II to FPD took place years ago, we have decided to provide scientific literature that supports the transition from the II based systems to FPD systems. In this search we found the following peer reviewed articles, discussing the advantages and disadvantages using an FPD in place of an II:

Peer reviewed articles supporting FPD technology:

ID	Article title	Author(s)	Published in	Assessment remarks and conclusion
1	AAPM/RSNA Physics Tutorial for Residents: Physics of Flat-Panel Fluoroscopy Systems Survey of Modern Fluoroscopy Imaging: Flat-Panel Detectors versus Image Intensifiers and More	Edward Lee Nickoloff, DSc	radiographics.rsna.org	The author concludes that Solid-state FPD image receptors have better stability, lower radiation dose rates, and improved dynamic range, and they eliminate glare and geometric distortions such as vignetting and defocusing effects. It is concluded that the fact that FPDs are smaller than image intensifiers allows for more flexible positioning of the angiography and cardiac fluoroscopy systems. The few disadvantages of FPD systems include higher costs and lower spatial resolution with very small and very large FOVs.
2	The design and imaging characteristics of dynamic, solid-state, flat-panel x-ray image detectors for digital fluoroscopy and fluorography	A.R. Cowen, A.G. Davies, M.U. Sivananthan	The Royal College of Radiologists. Published by Elsevier Ltd.	The authors conclude that the use of FPD technology brings a range of advantages over the II-TV system such as more stable performance, zero geometrical distortion and vignetting, less physical dimensions with great versatility.

Materials and control elements used for the Intelli-C and the predicate device are comparable and not significantly different.

Conclusions:

We believe that the Intelli-C will perform as safe and as effective or better than the predicate device. We base our conclusions on the Substantial Equivalence Discussion and Literature summary, documenting the technological differences which include the digital x-ray receptor, user interfaces, x-ray generation component upgrades, and other minor modifications.

The use of a previously cleared digital x-ray receptor and adequate verification and validation testing results document adequate image quality and integration.

We do not see that new issues of safety or effectiveness are raised with the introduction of the Intelli-C X-ray device.