



Agfa HealthCare N.V.
% Ms. Shaeann Cavanagh
Regulatory Affairs Manager
Agfa HealthCare Corporation
10 South Academy Street
GREENVILLE, SC 29601

April 5, 2018

Re: K180589

Trade/Device Name: DR 800 with MUSICA Dynamic™
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: JAA
Dated: March 5, 2018
Received: March 6, 2018

Dear Ms. Cavanagh:

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); labeling (21 CFR Part 801); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,



Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K180589

Device Name

DR 800 with MUSICA Dynamic

Indications for Use (Describe)

The DR 800 system is indicated for performing dynamic imaging examinations (fluoroscopy and/or rapid sequence) of the following anatomies/procedures:

- Positioning fluoroscopy procedures
- Gastro-intestinal examinations
- Urogenital tract examinations
- Angiography

It is intended to replace fluoroscopic images obtained through image intensifier technology. In addition, the system is intended for project radiography of all body parts.

The DR 800 is not intended for mammography 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.

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

Agfa HealthCare DR 800 with MUSICA Dynamic

I. SUBMITTER

Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Wim Govaerts, Prepared: March 5, 2018
Telephone: + 32 3444 6246

II. DEVICE

Name of Device: DR 800 with MUSICA Dynamic™
Common Name: System, X-Ray, Fluoroscopic, Image-Intensified
Classification Name: Image-Intensified Fluoroscopic X-ray System
Regulatory Classification: Class II, 21 CFR 892.1650
Product Code: JAA

III. PREDICATE DEVICE

This is a 510(k) for Agfa's DR 800 with MUSICA Dynamic, which is an image-intensified fluoroscopic x-ray system. It is substantially equivalent to General Medical Merate S.P.A.'s OPERA Swing (K140380).

Name of Device: OPERA Swing
Common Name: System, X-Ray, Fluoroscopic, Image-Intensified
Classification Name: Image-Intensified Fluoroscopic X-ray System
Regulatory Classification: Class II, 21 CFR 892.1650
Product Code: JAA

This predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Agfa HealthCare's DR 800 is an image-intensified fluoroscopic x-ray system (product code JAA) intended to capture images of the human body. The DR 800 is a floor-mounted R/F system that consists of a tube and operator console with a motorized tilting patient table and bucky with optional wall stand, FLFS overlay and ceiling suspension. The new device uses Agfa's NX workstation with MUSICA Dynamic™ image processing and flat-panel detectors for digital and wide dynamic range image capture. It is capable of replacing other direct radiography, image intensifying tubes and TV cameras, including computed radiography systems with conventional or phosphorous film cassettes.

This submission is to add the DR 800 with MUSICA Dynamic software to Agfa's radiography portfolio.

The optional image processing allows users to conveniently select image processing settings for different patient sizes and examinations. The image processing algorithms in the new device are similar to those previously cleared and used in Agfa's radiography portfolio today which includes the DR 600 (K152639) and DR 400 (K141192). The addition of the dynamic image processing is identical to the predicate device (K140380).

Principles of operation and technological characteristics of the new and predicate device are the same. The new device is virtually identical to predicate K140380 with the exception that it has Agfa's MUSICA Dynamic software instead of the predicate's ATS software. It uses the same flat panel detectors to capture and digitize the image. Differences in devices do not alter the intended diagnostic effect.

Laboratory data and image quality evaluations conducted with independent radiologists confirm that performance is equivalent to the predicates.

Configuration information for the flat-panel detectors can be found in the DR 14s (K161368) and DR 800. User Manuals. The DR 14s and RF FL4343 detectors can be integrated in an X-ray system that communicates to a workstation. The Service Manual details the possible configurations and integrations with the NX workstation and X-ray generator. All of Agfa HealthCare's DR X-ray systems (i.e. DX-D 100-K103597, DX-D 300-K103050, DX-D 600-K112670, DR 400-K141192, DR 600-K152639) will integrate with the detectors. The NX4.0 Service Manual, Chapter 4 and associated appendices addresses the installation and configuration with other system components.

V. INDICATIONS FOR USE

The DR 800 system is indicated for performing dynamic imaging examinations (fluoroscopy and/or rapid sequence) of the following anatomies/procedures:

- Positioning fluoroscopy procedures
- Gastro-intestinal examinations
- Urogenital tract examinations
- Angiography

It is intended to replace fluoroscopic images obtained through image intensifier technology. In addition, the system is intended for project radiography of all body parts.

The DR 800 is not intended for mammography applications.

NOTE: The mammography applications embedded in the MUSICA software are for previously cleared CR imaging applications (K081963) and not intended for DR or fluoroscopic imaging. Furthermore, the additional mammography software is only available through additional license keys that must be purchased. These licenses are only available outside of the USA.

VI. PEDIATRIC USE SUMMARY

The DR 800 is intended for general populations, including adult and pediatric patients. Specific design features of the DR 800 for pediatric use include but not limited to using the FLFS application without the grid, specific AEC values, and NX protocol settings per pediatric age range.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Agfa HealthCare's DR 800 with MUSICA Dynamic and General Medical Merate S.P.A.'s OPERA Swing predicate device (K140380) are image-intensified fluoroscopic x-ray imaging devices, Product Code JAA. Agfa's DR 800 is substantially equivalent to the predicate device (K140380) in that it uses precisely the same technology to capture and transmit images. The DR 800 is a floor-mounted R/F system that consists of a tube and operator console with a motorized tilting patient table and bucky with optional wall stand, FLFS overlay and ceiling suspension. The new device uses Agfa's NX workstation with MUSICA Dynamic™ image processing and flat-panel detectors for digital and wide dynamic range image capture. It is capable of replacing other direct radiography, image intensifying tubes and TV cameras, including computed radiography systems with conventional or phosphorous film cassettes.

Principles of operation and technological characteristics of the new and predicate device are the same. The new device is virtually identical to predicate K140380 with the exception that it has Agfa's MUSICA Dynamic software instead of the predicate's ATS software. It uses the same flat panel detectors to capture and digitize the image. Differences in devices do not alter the intended diagnostic effect.

The optional image processing allows users to conveniently select image processing settings for different patient sizes and examinations. The image processing algorithms in the new device are similar to those previously cleared and used in Agfa's radiography portfolio today which includes the DR 600 (K152639) and DR 400 (K141192). The addition of the dynamic image processing is identical to the predicate device (K140380).

Agfa's DR 800 has an Indications For Use statement virtually identical to the predicate device (K140380). Intended uses are the same. The devices have the same technological characteristics.

The DR 800 indications for use is equivalent to the predicate (K140380) because both include the delineation of anatomical areas and imaging applications. The DR 800 includes the statement that the device is not indicated for mammography; however, the predicate device (K140380) Indications For Use statement does not indicate mammography in the identified list of imaging applications.

Descriptive characteristics and performance data including image quality evaluations by qualified radiologists are adequate to ensure equivalence. Differences in devices do not alter the intended therapeutic/diagnostic effect.

Table 1 on the next page summarizes the similarities and differences between the new device and predicate.

	DR 800 (New Device) Agfa HealthCare	Opera Swing (PREDICATE–K140380) General Medical Merate
Communications	Same as predicate	DICOM
Flat Panel Detectors	Same as predicate	RF FL4343, Pixium 2430 (DR10s), Pixium 3543 (DR14s)
Detector Material	Same as predicate	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator
Detector Sizes	Same as predicate	17x17 in.
Field Sizes	Same as predicate	43 x 43 cm 30 x 30 cm 20 x 20 cm 15 x 15 cm
Pixel Size	Same as predicate	148 µm
Dynamic Range	Same as predicate	16 bit
Matrix Size	Same as predicate	Static – 2880 x 2880 Dynamic – 1024 x 1024
Power Supply	Same as predicate	50-60 Hz 100-240V auto ranging
Operator Workstation	Agfa NX	Diagnostic Workstation
Image processing	MUSICA Dynamic, MUSICA ² MUSICA3/3+	ATS Software
Tabletop Features	Tilt +/- 90° 240 x 80 cm 265 kg maximum weight	Tilt +/- 90° 240 x 65 cm 227 kg maximum weight
Generators	Same as predicate	Choice of three models: 50-80 KW
Operating System	Same as predicate	Windows 7, 8, 8.1, 10
Display System	Separately cleared medical display (K051901)	Separately cleared medical display
Indications for Use Statements	The DR 800 systems is indicated for performing dynamic imaging examinations (fluoroscopy and/or rapid sequence) of the following anatomies/procedures: Positioning fluoroscopy procedures, Gastro-intestinal examinations, Urogenital tract examinations, and Angiography. It is intended to replace fluoroscopic images obtained through intensifier technology. In addition, the system is intended for project radiography of all body parts. The DR 800 is not intended for mammography applications.	The Opera Swing is indicated for performing general radiography, fluoroscopy and angiography procedures/applications. The device is intended for use in: Skeleton, Chest and lungs, Pediatrics, Emergency/traumatology, Gastroenterology, Urology and gynecology, Linear tomography, Digital angiography and Stitching.

Table 1: Device Comparison Table

VIII. PERFORMANCE DATA

Laboratory testing and software testing (for a moderate level of concern device) using equivalent test protocols were evaluated by qualified individuals employed by the sponsor and independent radiologists to demonstrate that adequate design controls (according to 21 CFR 820.30) were in place.

Verification and validation testing confirmed the device meets performance, safety, usability and security requirements. Pediatric indications were also taken into account. Results were verified and validated.

No clinical trials were performed in the development of the device. No animal or clinical studies were performed in the development of the new device. No patient treatment was provided or withheld.

Bench Testing

Clinical image quality evaluations, performance/functionality and usability data, FLFS clinical validation and dose control evaluation data has been provided. No patient treatment was provided or withheld. No clinical or animal testing was performed in the development of the DR 800.

- Usability and functionality evaluations were conducted with qualified independent radiographers and internal experts. The results of these tests fell within the acceptance criteria for the DR 800 R/F X-ray system and some improvements will be implemented based on these results; therefore, the DR 800 supports a radiographic and fluoroscopic workflow including dynamic and static imaging, continuous and rapid sequence exams, calibration, and positioning.
- Full Leg Full Spine (FLFS) clinical validation for the DR 800 R/F X-Ray system was conducted with a qualified internal radiographer. The results of the FLFS clinical validation for the mount stitch grid, imaging ranges of a certain tolerance and transversal collimation, and medical ruler exposure fulfilled the acceptance criteria and passed the assessment with minor fails that will be solved. A comparison test and validation of FLFS landscape was conducted for NX Luna to compare the FLFS software with the current FLFS software already on the market. This comparison test was conducted with several qualified internal experts. The results of the FLFS comparison test for NX Luna concluded that the FLFS software is equal to or better than the current FLFS software currently on the market. The results of the FLFS landscape validation for the NX Luna concluded that the FLFS landscape functional design meets to user needs.
- Dose control validation was conducted with a qualified internal expert to evaluate the level of dose control in adult and pediatric phantoms with pulsed and continuous fluoroscopy exams. The results fulfilled the acceptance criteria that none of the detector doses would measure higher than the DIN-norm or exceed the dose limit curve.
- Image Quality Validation testing was conducted using anthropomorphic phantoms and evaluated by qualified independent radiographers and internal experts. The image quality validation included testing a full range of applications for the DR 800 R/F X-ray system with MUSICA Dynamic, MUSICA3 Abdomen+ and the R/F flat-panel detector compared to reference images using anonymized phantoms. The test results indicated that the pulsed

and continuous fluoroscopy imaging of the DR 800 R/F X-ray system with MUSICA Dynamic was between good and excellent and passed the acceptance criteria. The test results showed MUSICA3 Abdomen+ images were suitable for diagnosis with an overall higher image quality. The test results proved clinical acceptability for static images made with the R/F flat-panel detector (FL4343).

Software Verification and Validation Testing

Verification and validation plans comprise of test protocols. The complete device has been certified and validated. During the final risk analysis meeting, the risk management team concluded that the medical risk is no greater than with conventional x-ray film previously released to the field.

For the NX4.0 (NX Luna) there are a total of 274 risks in the broadly acceptable region and 26 risks in the ALARP region with only three of these risks identified. Zero risks were identified in the Not Acceptable Region. Therefore, the device is assumed to be safe, the benefits of the device are assumed to outweigh the residual risk. The software risk assessment is assessed on solution level for the DR 800 and also includes separate risk assessments for the NX4.0 software and XRDI.

The term “Level of Concern” means the level of risk that the software device is determined to be if the software were to fail. The Level of Concern for the DR 800 and NX4.0 has been determined to be moderate.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing:

- IEC 60601-1: 2012 Medical Electrical Equipment: General Requirements for Safety and Essential Performance.
- IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- IEC 60601-1-3: 2008 Medical Electrical Equipment - Part 1-3: General Requirements for Safety and Essential Performance - Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment
- IEC 60601-2-54: 2009 Medical Electrical Equipment – Part 2-54: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Equipment for Radiography and Radioscopy.

The DR 800 with MUSICA Dynamic is compliant to the FDA Subchapter J mandated performance standard 21 CFR 1020.30 – 1020.32.

Agfa's in-house standard operating procedures were also used for the development of the device and software; these procedures conform to the following standards:

- ISO 13485:2003 Medical Devices - Quality Management Systems
- ISO 14971:2012 Application of Risk Management to Medical Devices
- IEC 62304:2006 Medical Device Software – Software life cycle processes
- ISO 62366:2007 Medical Devices – Application of Usability Engineering
- ACR/NEMA PS3.1-3.20: 2011 Digital Imaging and Communications in Medicine (DICOM)

Guidance Documents

Agfa utilized the following guidance documents in the development of the DR 800 with MUSICA Dynamic™

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 2005)
- Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software (January 2005)
- Off-the-Shelf Software Use in Medical Devices (September 1999)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2014)
- Guidance for Pediatric Information for X-ray Imaging Device Premarket Notifications (November 2017)

Summary

Based on the performance data as documented in the above testing, the DR 800 is found to have a safety and effectiveness profile that is similar to the predicate device.

IX. CONCLUSIONS

Agfa's DR 800 has indications for use that is consistent with those of the legally marketed predicate device (K140380). Intended uses are the same. Where technological characteristics differ lab tests concluded that the device is substantially equivalent to the predicate in that it does not alter the intended therapeutic/diagnostic effect.

The new device and the OPERA Swing predicate device (K140380) are image-intensified fluoroscopic x-ray systems Product Code JAA. Agfa's DR 800 is substantially equivalent to the predicate device (K140380) in that it uses precisely the same technology to capture and transmit images.

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.