August 31, 2021

Agfa N.V.
% Ms. ShaeAnn Cavanagh
Regulatory Affairs Manager, North America
Agfa US Corp.
10 South Academy Street
GREENVILLE SC 29601

Re: K212145
Trade/Device Name: DR 800 with DSA
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA
Dated: July 8, 2021
Received: July 9, 2021

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. 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212145

Device Name
DR 800 with DSA

Indications for Use *(Describe)*
The DR 800 with DSA 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
- Digital Subtraction Angiography

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

In addition, the system provides the Agfa Tomosynthesis option, which is intended to acquire tomographic slices of human anatomy and to be used with Agfa DR X-ray systems. Digital Tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep.

Not intended for cardiovascular and cerebrovascular contrast studies.
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.

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510(K) SUMMARY

K212145

Agfa N.V.
DR 800 with DSA

I. SUBMITTER

Agfa N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Wim Govaerts, Prepared: July 8, 2021
Telephone: + 32 3444 6246

II. DEVICE

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

III. PREDICATE DEVICE(S)

This is a 510(k) for Agfa's DR 800 with DSA which is a fluoroscopic x-ray system, including digital angiography. It is substantially equivalent to Shimadzu Corporation's primary predicate device A, SONIALVISION G4 (K190373) and Agfa's predicate device B, DR 800 with Tomosynthesis (K183275).

1. Primary Predicate Device (A): SONIALVISION G4
   Common Name: System, X-Ray, Fluoroscopic Image-Intensified
   Classification Name: Fluoroscopic Image-Intensified X-Ray System
   Regulatory Classification: Class II, 21 CFR 892.1650
   Product Code: JAA

2. Predicate Device (B): DR 800 with Tomosynthesis
   Name of Device: DR 800 with Tomosynthesis
   Common Name: System, X-Ray, Tomographic
   Classification Name: Tomographic X-ray System
   Regulatory Classification: Class II, 21 CFR 892.1740
   Product Code: IZF

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

The SONIALVISION G4 (K190373) primary predicate device has not been subject to a design-related recall. The DR 800 with Tomosynthesis (K183275) predicate device was part of a Class II recall initiated on February 10, 2020. The recall was related specifically to the tomosynthesis software functionality where an image acquisition sequence did not stop automatically after expected number of exposures. No injuries were reported. Agfa has taken these reported defects into consideration and is mindful of these events while developing the subject device, DR 800 with DSA.

IV. DEVICE DESCRIPTION

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

This submission is to add the newest version of the DR 800 with Digital Subtraction Angiography (DSA) to Agfa's radiography portfolio.

The image processing algorithms in the new device are similar to those previously cleared in the DR 800 with Tomosynthesis (K183275) and other devices in Agfa's radiography portfolio today which includes DR 600 with Tomosynthesis (K193262) and DR 400 (K141192). The addition of the angiographic image processing is similar to the primary predicate device (K190373).

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is virtually identical to Agfa's DR 800 with Tomosynthesis (K183275) with the exception that it has additional DSA software for processing digital angiographic studies. The SONIALVISION G4 (primary predicate A, K190373) contains similar software algorithms for processing angiographic studies of the human body. The DR 800 with Tomosynthesis (predicate B, K183275) 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) user manuals. The DR 14s and RF FL 4343 flat-panel 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'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, DR 800 with MUSICA Dynamic –K180589, DR 800 with Tomosynthesis – K 183275, DR 100s – K191884 & DR 600 with Tomosynthesis – K193262) will integrate with the detectors. The NX4.x.23 Service Manual, Chapter 4 and associated appendices addresses the installation and configuration with other system components.

V. INDICATIONS FOR USE

The DR 800 with DSA 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
- Digital Subtraction Angiography

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

In addition, the system provides the Agfa Tomosynthesis option, which is intended to acquire tomographic slices of human anatomy and to be used with Agfa DR X-ray systems. Digital Tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep.

Not intended for cardiovascular and cerebrovascular contrast studies.
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 direct radiography (DR) imaging. Furthermore, the additional mammography software is only available through additional license keys that must be purchased. These license keys are only available outside of the USA.

PEDIATRIC USE SUMMARY

The DR 800 with DSA medical device is intended for general populations, including adult and pediatric patients. Specific design features of the DR 800 with DSA 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. The following specific design features and instructions enable safer use of the device with pediatric patients:

Pediatric Imaging Design Features	**Standard or Optional**
Protocols or exposure indices	Standard - make own exam tree optional - make use of age groups
Filter and removable grid	Standard
Collimator alignment	Standard
Variable focal spot size	Standard
Post-processing application	Standard/ no specific pediatric post processing for tomosynthesis
Reconstruction algorithm	no specific pediatric reconstruction algorithm

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICES

Agfa's DR 800 with DSA, Shimadzu Corporation's SONIALVISION G4 primary predicate device (K190373) and Agfa's DR 800 with Tomosynthesis predicate device (K183275) are all fluoroscopic x-ray imaging devices, Product Code JAA. Agfa's DR 800 with DSA is substantially equivalent to the primary predicate device (K190373) in that it uses similar technology to capture and transmit angiographic images. The DR 800 is a floor-mounted radiographic, fluoroscopic and tomographic system that consists of a tube and operator console with a motorized tilting patient table, FLFS overlay and bucky with optional wall stand and ceiling suspension. The new device uses Agfa's NX workstation with MUSICA image processing and flat-panel detectors for digital, wide dynamic range and angiographic image capture. It is capable of replacing other direct radiography, tomography, 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 devices are the same. The new device is virtually identical to Agfa's DR 800 with Tomosynthesis (K183275) with the exception that it has additional DSA software for processing digital angiographic studies. The SONIALVISION G4 (primary predicate A, K190373) contains similar software algorithms for processing angiographic studies of the human body. The DR 800 with Tomosynthesis (predicate B, K183275) uses the same flat panel detectors to capture and digitize the image. Differences in devices do not alter the intended diagnostic effect.

The image processing algorithms in the new device are similar to those previously cleared in the DR 800 with Tomosynthesis (K183275) and other devices in Agfa's radiography portfolio today which includes DR 600 with Tomosynthesis (K193262) and DR 400 (K141192). The addition of the digital angiographic image processing is similar to the primary predicate device (K190373).

Agfa's DR 800 with DSA has an Indications For Use statement virtually identical to the predicate B device (K183275) except it includes the addition of Digital Subtraction Angiography and the contraindication for cardiovascular and cerebrovascular contrast studies. The DR 800 with DSA new device has a similar Indications For Use statement as the primary predicate A device (K190373). Intended uses are the same. The devices have the same technological characteristics.

The DR 800 indications for use is equivalent to both the predicate devices (K190373 & K183275) because both include fluoroscopic, radiographic and tomographic image processing and all are indicated for use in general and pediatric patient populations. The DR 800 with DSA and both predicate devices (K190373 & K183275) include the statement that the device is not indicated for mammography. The DR 800 with DSA and both predicates (K190373 & K183275) use DICOM for sending and receiving images and none of the devices are indicated for interventional procedures.

There is a difference between the new device and primary predicate device (K190373) Indication for Use statement regarding a general reference to the human body; however, standard practice dictates that diagnostic procedures for general human anatomy include chest and extremities. Another difference between the new device and primary predicate device (K190373) is that the new device Indications For Use statement lists out examples of imaging procedures; however, it is logical to conclude these same imaging procedures are also indicated with the predicate device based on standard medical practice. The differences between the subject device, DR 800 with DSA, and predicate devices (K190373 & K183275) do not seem to impact safety or effectiveness.

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

	PRODUCT COMPARISON TABLE			
	DR 800 with DSA (New Device)	**SONIALVISION G4 (PREDICATE A– K190373)**	**DR 800 w/ Tomo (PREDICATE B – K183275)**	**Explanation of Differences**
Communication	Same as both Predicates	DICOM	DICOM	N/A
Flat Panel Detectors	Same as both Predicates	Flat Panel Detector	Flat Panel Detector	N/A
Detector Material	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator	Cesium Iodide (CsI) scintillator	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator	Includes GOS
Detector Sizes	17x17 in. 14 x 17 in 10 x 10 in	17x17 in.	17x17 in. 14 x 17 in 10 x 10 in	Includes 14x17 in & 10x10 in as well
Pixel size	Same as Predicate K183275	139 µm	148 µm	Comparable
Dynamic Range	Same as both Predicates	16 bit	16 bit	N/A
Power Supply	Same as Predicate K183275	--	50-60 Hz 100-240V auto ranging	Unable to find info for predicate K190373
Operator Workstation	Same as Predicate K183275	Diagnostic Workstation	Agfa NX using Microsoft 7/10	
Image processing	Same as Predicate K183275	SUREengine-Advance	MUSICA 3 MUSICA 4	Agfa's image processing software
Radiography	Fluoroscopic, Tomographic, GenRad radiography & DSA	SPOT, division & serial radiography, DSA	Fluoroscopic, Tomographic, GenRad radiography	Includes DSA like predicate K190373
Display System	Same as both Predicates	Separately cleared medical display	Separately cleared medical display (K051901)	N/A
Tabletop Features	Tilt +/- 90°, 240 x 80 cm 265 kg maximum weight	Tilt +/- 90°, 240 x 89 cm 318 kg maximum weight	Tilt +/- 90°, 240 x 80 cm 265 kg maximum weight	Slight difference in height & weight doesn't affect S&E
Generators	Choice of three models: 50, 65KW, 80 KW	80 KW	Choice of three models: 50, 65KW, 80 KW	Same choice of 80KW as predicate K190373
Indications for Use	The DR 800 with DSA 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 • Digital Subtraction Angiography It is intended to replace fluoroscopic images obtained through image intensifier technology. In addition, the system is intended for projection radiography of all body parts. In addition, the system provides the Agfa Tomosynthesis option, which is intended to acquire tomographic slices of human anatomy and to be used with Agfa DR X-ray systems. Digital Tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep. Not intended for cardiovascular and cerebrovascular contrast studies. Not intended for mammography applications.	The equipment is intended to be used for the fluoroscopy/radiography diagnosis in hospital. The equipment must only be operated by qualified personnel, such as radiography technicians or those with equivalent qualifications. The equipment is used for total patient population. The equipment is NOT intended to be used for Mammography screening. The equipment is NOT intended to be used for interventional procedure. The equipment is used for radiographic, fluoroscopic, angiographic and pediatric examinations. Stored images in the equipment can be used for re-monitoring, image processing, storing to optical media (CD/DVD), and sending to DICOM server. The Tomosynthesis option for the SONIALVISION G4 is intended to generate tomographic images of human anatomy including chest or extremities. Tomosynthesis technique is used to produce a specific cross-sectional plane of the body by reconstruction of tomographic acquisition. The device is not intended for mammographic applications	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. In addition, the system provides the Agfa Tomosynthesis option, which is intended to acquire tomographic slices of human anatomy and to be used with Agfa DR X-Ray systems. Tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep. The DR 800 is not intended for mammography applications.	1. General reference to the human body versus delineation of body parts – standard practice includes chest and extremities in general 2. List of imaging procedures instead of a general statement – same imaging procedures can be completed on the primary predicate device

VII. PERFORMANCE DATA

Laboratory testing and software testing (for a moderate level of concern device) using equivalent test protocols were evaluated by qualified individuals 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

Image quality evaluations, performance/functionality and usability data has been provided.

- Technical and acceptance testing was completed on the DR 800 with DSA in order to confirm the medical device functions and performs as intended. All deviations or variances are documented in a defect database and addressed in the CRD documentation and verified. All mitigations have been tested and passed. All design input requirements have been tested and passed. All planned verification activities have been successfully completed.
- Performance functionality and usability evaluations were conducted with qualified experts. The results of these tests fell within the acceptance criteria for the DR 800 with DSA; therefore, the DR 800 supports GenRad, Full Leg/ Full Spine (FLFS), roadmapping and Digital Subtraction Angiography (DSA) workflow.

- Clinical image validation was conducted using anthropomorphic phantoms and evaluated by qualified experts. The radiographers evaluated the DSA image quality on the DR 800 by comparing overall image quality with the primary predicate A device (K190373). Diagnostic confidence for DSA image quality and roadmapping on the DR 800 was between good and excellent.

Clinical image quality evaluation is not essential in establishing substantial equivalence for the DR 800 with DSA. Adequate Bench Testing results should be sufficient to determine device safety and effectiveness.

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.

DSA software verification testing for NX 23 was completed in scope of the DR 800 with DSA X-Ray System. Software testing of MUSICA image processing included digital subtraction angiography (DSA). HERDE defects were identified; however, they were solved between test execution and the completion of the final report and will be part of the next maintenance software release.

Additional validation testing for NX 23 was completed and data provided in the premarket 510(k) notification for the DX-D Imaging Package – XD Detectors which is currently pending 510(k) clearance (K211790). Refer to this submission for all verification and validation documentation for NX 23 GenRad software applications and the XD Detector workflow.

For the NX 23 (NX Orion) software there are a total of 535 risks in the broadly acceptable region and 37 risks in the ALARP region with only four 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 with DSA.

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 with DSA and NX 23 has been determined to be moderate.

Electrical Safety and Electromagnetic Compatibility (EMC) Testing:

- IEC 60601-1: 2005 Medical Electrical Equipment: General Requirements for Safety and Essential Performance.
- IEC 60601-1-2: 2014 Medical Electrical Equipment – Part 1-2: General Requirements for Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- IEC 60601-1-3: 2013 Medical Electrical Equipment – Part 1-3: General Requirements for the Basic Safety and Essential Performance – Collateral Standard Radiation Protection in Diagnostic X-Ray Equipment
- IEC 60601-2-54:2019 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 is compliant to FDA Subchapter J mandated performance standards 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 13485:2015 Medical Devices - Quality Management Systems
- ISO 14971:2012 Application of Risk Management to Medical Devices
- ACR/NEMA PS3.1-3.20: 2011 Digital Imaging and Communications in Medicine (DICOM)
- IEC 62366-1:2015 Medical Devices – Part 1: Application of Usability Engineering to Medical Devices

- IEC 62304:2006 Medical Device Software – Software Lifecycle Processes [Including Amendment 1 (2016)]

Guidance Documents

Agfa utilized the following guidance documents in the development of the DR 800 with DSA:

- 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 (Jan 2005)
- Off-the-Shelf Software Use in Medical Devices (September 2019)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (Oct 2018)
- Guidance for Pediatric Information for X-ray Imaging Device Premarket Notifications (Nov 2017)

Summary

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

VIII. CONCLUSIONS

Agfa's DR 800 with DSA has indications for use that is consistent with that of the legally marketed predicate devices (K190373 & K183275). Intended uses are the same. Laboratory tests conclude that the device is substantially equivalent to the predicate. Differences in devices do not alter the intended diagnostic effect nor do they impact the safety and effectiveness of the device.

The new device and the SONIALVISION G4 primary predicate device A (K190373) and predicate device B, DR 800 with Tomosynthesis (K183275) are fluoroscopic x-ray systems, Product Code JAA. Agfa's DR 800 with DSA device is substantially equivalent to both the primary predicate device A (K190373) and predicate device B (K183275) in that it uses the same basic 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.