510(K) SUMMARY
Agfa Computed Radiography (CR) Systems with CR 12-X Digitizer

Common Name: Computed Radiography System
Classification Name: Solid State X-Ray System
Regulatory Classification: 21 CFR 892.1680
Product Code: MQB
Proprietary Name: Computed Radiography (CR) Systems with CR 12-X Digitizer
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Koen Vervoort, Prepared: May 15, 2013
Telephone: +32-34444-7368

AUG 2 9 2013

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's Computed Radiography (CR) System with CR 12-X Digitizer, a solid state x-ray imaging device. It is substantially equivalent to systems with Agfa's CR 10-X Digitizer (K121948) and 3Disc America's Fire CR+ Digitizer (K102619).

B. DEVICE DESCRIPTION

Agfa's Computed Radiography (CR) Systems with CR 12-X Digitizer is a solid state x-ray imaging device. Principles of operation and technological characteristics of the new and predicate devices are largely the same as other computed radiography systems:

Phosphor coated imaging plates and cassettes for image capture.
Laser digitizer for generating the electronic image.
NX workstation for image previewing, processing and routing.

C. INTENDED USE

Agfa's Computed Radiography (CR) System with CR 12-X Digitizer is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy. The system may be used wherever conventional screen-film systems are used.

Agfa's Computed Radiography (CR) System With CR 12-X Digitizer is not indicated for use in mammography.

The intended use has not changed as a result of any labeling modifications.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's Computed Radiography (CR) System with CR 12-X Digitizer has an Indications For Use statement identical to the statement for the predicate devices, K121948 and K102619. Intended uses are the same. The devices have the same technological characteristics. Descriptive characteristics and performance data are adequate to ensure equivalence.

Differences in devices do not alter the intended therapeutic/diagnostic effect.

PRODUCT COMPARISON TABLE			
	Systems with CR 12-X Digitizer (New Device)	**Systems with CR 10-X Digitizer (PREDICATE-K121948)**	**3Disc: FireCR+ Digitizer (PREDICATE-K102619)**
Communications	Same as both predicates	DICOM	DICOM
Cassette and Image Plates			
Cassettes and Image Plate Sizes	Same as CR 10-X	35x43 cm	35x43 cm & 24x30 cm
Image Plate Phosphors	Same as both predicates	BaSrFBrI:Eu	BaSrFBrI:Eu
Digitizer			
Scanning technology	Same as both predicates	Point at-a-time	Point at-a-time
Light collection	Same as CR 10-X	Solid, high efficiency	Unavailable
Scanning resolution	100µm, 150µm, 200µm	100µm	100µm and 200µm
Active matrix	Same as CR 10-X	3420 x 4218	Unavailable
Dynamic range (acquisition)	Same as both predicates	16 bit, sq. root compressed	16 bit, sq. root compressed
Throughput (35x43 cm plates/hr.)	60 @ 200µm 72 @ 150µm 90 @ 100µm	34 @ 100µm	20 @ 200µm 70 @ 100µm
Power Supply	Same as CR 10-X	100 – 240V 50/60 Hz	110-240V 50/60 Hz
Mobile installations	Same as CR 10-X	Mobile mounting option	Solid Transport case
Image stitching	Same as CR 10-X	Full Leg Full Spine	N/A
Workstation			
Image processing	Same as CR 10-X	MUSICA, MUSICA^2	QuantorMed+ Imaging Software
Dynamic range (display)	Same as CR 10-X	12 bit	32 bit & 64 bit
Operating system	Same as both predicates	Windows 7	Windows 7
Power Supply	Same as CR 10-X	100 – 240V 50/60 Hz	110-240V 50/60 Hz
Display System	Same as CR 10-X	Standard PC display or separately cleared medical display	1,280x900 pixel, DVI interface

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's Computed Radiography (CR) Systems with CR 12-X Digitizer is a solid state x-ray imaging device. It uses phosphor coated imaging plates to capture an x-ray exposure. Upon scanning of the image plates by the CR-12-X digitizer, the x-ray image is read and transmitted to the NX workstation where the image can be previewed, processed and transmitted to other devices for viewing, printing or storage.

The CR 12-X digitizer is identical to the CR 10-X with the exception of the following:

60 plates/hr with scanning resolution of 200µm
72 plates/hr with added scanning resolution of 150µm
Increase to 90 plates/hr with scanning resolution of 100µm

Agfa CR 12-X and 3Disc America's FireCR+ (K102619) both enable selection of resolution options. The remaining differences would not be expected to impact safety and effectiveness.

F. TESTING

The device has completed verification and validation testing to confirm it meets specifications and operates as planned. Tests included image quality tests with internal and external experts comparing the CR 12-X to the CR 10-X predicate. Clinical Images were unnecessary to evaluate modifications from the predicate device; therefore, phantom images were used to evaluate substantial equivalence with the CR 10-X predicate device (K121948).

The change in the design of the CR 10-X to include the image processing was verified and validated per the following:

Exhibit 3-2, Software Design Input Output Verification (DIOV) Report - Arcus Digitizer..
Exhibit 5-1, Verification Plan - Consolidated Requirement & Testing (incl. SW), Arcus Solution.
Exhibit 5-2, Verification Report - Consolidated Requirement & Testing (incl. SW), Arcus Solution.
Exhibit 5-3, Validation Test Plan - Arcus Solution
Exhibit 5-4, Design Validation Report – Arcus Solution
Exhibit 5-5, Validation Test Report - Arcus Solution
Exhibit 5-6, Final Design Review for the CR 12-X Digitizer.
Exhibit 5-7, Design Complete Acceptance for the CR 12-X Digitizer
Exhibit 5-8, CRB (Change Review Board) Arcus Software Version ARC_1404 (This is the maintenance release for digitizer software version ARC_1404).

The product, manufacturing and development processes have been shown to conform to product safety, radiology, and imaging standards including:

PRODUCT STANDARDS

IEC 60601-1: 2005 Medical Electrical Equipment - Part 1: General Requirements for Safety

IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests

ACR/NEMA PS3.1-3.20: 2011 Digital Imaging and Communications in Medicine (DICOM)

MANAGEMENT STANDARDS

ISO 14971:2007 Application of Risk Management to Medical Devices

ISO 13485:2003 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

G. RISK ASSESSMENT AND MANAGEMENT SUMMARY

During the final risk analysis meeting, the risk management team concluded that the medical risk is not higher than previous released system to the field.

After review of these risks with the risk analysis team, it was decided that this risk could not be further mitigated and that for this risk, the benefits of the system outweigh the risks.

There are a total of 22 risks in the broadly acceptable region and 2 riskd in the ALARP region. Zero risks were identified in the not acceptable region.

The residual risk of the device is acceptable.

- the risk control measures are effective
- usability acceptance criteria for safety-related functions have been met (IEC 62366)
- no residual risk is situated in the intolerable region
- the residual risks are controlled as far as reasonably practicable

Of the 72 identified medical risks, 7 are in the ALARP region. The residual risks cannot be reduced any further with reasonable effort. Therefore the device is assumed to be safe, the benefits of the device are assumed to outweigh the residual risk.

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 device has been determined to be moderate.

Refer to **Section 16 Software**, for more information regarding risk management.

H. CONCLUSIONS

Agfa's Computed Radiography (CR) System with CR 12-X Digitizer has an Indications For Use statement is identical to the statement for the predicate devices, K121948 and K102619. Intended uses are the same. The devices have the same technological characteristics in that they use the same imaging phosphor and the same laser diode for stimulation light operating with the same spot size as both predicates. Descriptive characteristics and performance data are adequate to ensure equivalence.

Agfa's Computed Radiography (CR) System with CR 12-X Digitizer is substantially equivalent to its CR 10-X System (K121948) in that it uses the same technology to capture and transmit images, use the NX user workstation, use the same MD1.0 image plate and cassette with manual cassette insertion, includes the full leg full spine function, provides a mobile mounting option, and uses 100-240V 50/60 Hz power supply.

Agfa CR 12-X and 3Disc America's FireCR+ (K102619) both enable selection of resolution options from 100µm to 200µm.

The CR 12-X is equivalent to the predicate devices in regards to the plate speed.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 29, 2013

AGFA HealthCare N.V.
% Ms. ShaeAnn Cavanagh
Regulatory Affairs Specialist NA
AGFA HealthCare
10 South Academy Street
GREENVILLE SC 29601

Re: K131408
Trade/Device Name: CR 12-X Digitizer
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 1, 2013
Received: August 7, 2013

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
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): K131408

Device Name: CR 12-X Digitizer

Indications For Use:

Agfa's Computed Radiography (CR) System with CR 12-X Digitizer is indicated for use in general projection radiographic applications to capture for display diagnostic quality radiographic images of human anatomy. The system may be used wherever conventional screen-film systems are used.

Agfa's Computed Radiography (CR) System With CR 12-X Digitizer is not indicated for use in mammography.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)