510(k) Summary, Device Modification, K140683

JUN 0 3 2014

1. Submitter:
Arcoma AB
Annavagen 1
SE-352 46 Vaxjo
Sweden
Phone: +46 470 70 69 00
Contact/Prepared by: Mikael Larsson, CEO.
Date prepared: 17 February 2014

2. Identification of the Device: 0180 Intuition & 0072 Precision Stationary Digital X-Ray Systems
Classification Name: Stationary x-ray system
Common/Usual Name: Stationary digital x-ray system
Regulation Number: 21 CFR 892.1680
Product Codes: KPR and MQB

3. Predicate Device: Arcoma Intuition, K073632

4. Modification Summary: (1) Newer versions of Canon digital panels will be supplied. (2) A different brand of high frequency generator will be supplied. (3) The overhead tube crane has been motorized. (4) The wall stand now has motorized vertical movement.

5. A description of the device: This is a complete stationary diagnostic x-ray system employing digital x-ray panels coupled with image acquisition software. The key features are:

   a. Ceiling Tube Suspension
   b. Motorized Movements, Auto-Positioning
   c. Tube Mounted 10" Touch Screen
   d. Elevating 6 Way Table Patient Load: 550lbs
   e. Single User Interface
   f. High Frequency Generator

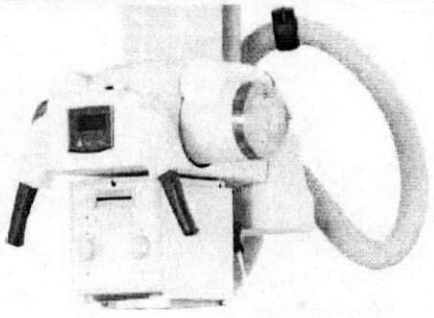
   This ergonomic design incorporates automatic motorized positioning, creating an efficient workflow increasing the patient throughput. Precision offers automatic stitching enhancing the workflow further. Tube, vertical wall stand and table have extended range of motion for easy patient positioning. The acquisition software is installed on a Windows compatible workstation. The high frequency generator is available in different power ratings. All components are either 510(k) exempt or previously cleared. Generators are available in 50, 65, 80 kW (High Frequency) models.

6. Indications for use: These are stationary x-ray systems intended for obtaining radiographic images of various portions of the human body in a clinical environment.
They are not intended for mammography.

7. The 0180 Intuition & 0072 Precision Stationary Digital X-Ray Systems have essentially the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device Arcoma Intuition, K073632. See the comparison table below. There are really only a few main differences: The digital panels, x-ray generator, and tube stands have been modified but have functionally identical capabilities. The proposed new digital x-ray panels each have their own 510(k) clearances.

K140683
Page 2 of 2

Comparison Table

Characteristic	Arcoma Intuition, K073632	0180 Intuition 0072 Precision
Indications	The 0170 Intuition is a stationary x-ray system intended for obtaining radiographic images of various portions of the human body in a clinical environment. The 0170 Intuition is not intended for mammography	The 0180 Intuition and 0072 Precision are stationary digital x-ray systems intended for obtaining radiographic images of various portions of the human body in a clinical environment. They are not intended for mammography
Digital Receptor Panel	Canon 40C/G K031633 and and Canon 50G K031447	Canon 401C K103591 and Canon 70C wireless K102012
Panel Resolution	Canon 40C/G Imaging area 43 x 43 cm Pixel Pitch 160 µm Image matrix size 2,688 x 2,688 pixels Canon 50G Imaging area 35 x 43 cm. Pixel Pitch 160 µm Image matrix size 2,208 x 2,688 pixels	Canon 70C Imaging area 35 X 43 cm Pixel Pitch: 125 µm Image matrix size: 2,800 x 3,408 Pixels Canon 401C Effective imaging area: 41.5 × 42.6 cm Pixel pitch: 125 µm Image matrix size: 3320 × 3408 pixels
Panel Connection	Wired	Wired or Wireless (WiFi)
DICOM	Yes	Yes
Tube Stand	Ceiling Mount	Same
Collimator	Siemens or Ralco	Siemens
Generator	EMD EPS 50, 65, 80 kW (High Frequency)	CPI, CMP 200 50, 65, 80 kW (High Frequency)
Safety	UL Listings and IEC Standards IEC 60601-1 and IEC 60601-1-2, US Performance Standards	UL/CSA Listings and IEC Standards IEC 60601-1 and IEC 60601-1-2, US Performance Standards
Photo		

8. Description of non-clinical tests. The modified unit has undergone individual and system performance tests, electrical safety and electromagnetic compatibility testing, as well as software integration validation and risk analysis. The unit meets IEC safety and EMC standards.

9. Description of clinical tests. Clinical images were obtained in accordance with the FDA Guidance Document on Solid State Imaging Devices. They were evaluated by professional radiologist and found to be of good diagnostic quality.

10. Conclusions drawn: The nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph 3, above.

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

June 3, 2014

Arcoma AB
% Daniel Kamm, P.E.
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K140683
Trade/Device Name: 0180 Intuition and 0072 Precision Stationary Digital X-Ray Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: April 29, 2014
Received: May 05, 2014

Dear Mr. Kamm:

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.

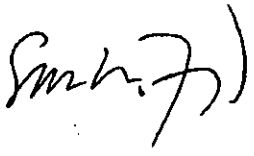
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 Industry and Consumer Education 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 Industry and Consumer Education 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

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 on last page.

510(k) Number *(if known)*
K140683

Device Name
0180 Intuition and 0072 Precision Digital Radiography Systems

Indications for Use *(Describe)*
These are stationary x-ray systems intended for obtaining radiographic images of various portions of the human body in a clinical environment. The devices are not intended for mammography

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*