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 7, 2015

Quantum Medical Imaging Division of Carestream
% Pamela Papineau, RAC
President
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
AYER MA 01432

Re: K151924
Trade Name: Q-Rad Radiographic System with Auto-Tracker Option
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: July 8, 2015
Received: July 13, 2015

Dear Ms. Papineau:

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" (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.

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

Robert Ochs, Ph.D.
Acting 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)*

K151924

Device Name

Q-Rad Radiographic System with Auto-Tracker Option

Indications for Use *(Describe)*

The Q-Rad Radiographic System is indicated for use in obtaining diagnostic quality radiographic images to aid the physician with diagnosis. The system can be used to perform radiographic imaging of various portions of the human body, including the skull, spinal column, extremities, chest, abdomen and other body parts. The Q-Rad System is not indicated for use in 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5 – Special 510(k) Summary

General Information

Date Prepared:	July 8, 2015
Owner's Name:	Quantum Medical Imaging Division of Carestream
Address:	2002-B Orville Drive North Ronkonkoma, NY 11779
Telephone Number:	631-737-7237
Fax Number:	613-567-5074
Contact Person:	Mark Camirand
Subject Device Name:	Q-Rad Radiographic System with Auto-Tracker Option
Trade Name:	Q-Rad Radiographic System with Auto-Tracker Option
Common/Usual Name:	X-Ray System
Product Code:	KPR
Classification Name:	Stationary X-Ray System 21 CFR 892.1680; Class II
Predicate Device Name:	Q-Rad Radiographic System
Trade Name:	Q-Rad Radiographic System
Common/Usual Name:	X-Ray System
Product Code:	KPR
Classification Name:	Stationary X-Ray System 21 CFR 892.1680; Class II
Premarket Notification:	K011486; Quantum Medical Imaging Q-Rad Radiographic System (SE date June 20, 2001)

Predicate Device Description

The Q-Rad Radiographic System is general-purpose radiographic (X-ray) system used for acquiring radiographic images of various portions of the human body. The Q-Rad System consists of a combination of several components including various models of X-ray generators and control panels or workstation computers, various models of patient support tables with integrated image receptor(s), wall-mounted image receptor/detector units for upright imaging, tube supports (ceiling-suspended or floor-mounted), and an X-ray source and collimator (beam-limiting device). The Q-Rad System is available with conventional analog (film cassette), digital radiography (DR) and computed radiography (CR) receptors; systems equipped with DR or CR modalities can also be configured to include a workstation computer that is fully integrated with the X-ray generator to allow

communication of information such as image exposure factors directly from a connected RIS/PACS (radiology information system / picture archiving and communications system). The currently marketed Q-Rad System requires manual motion control for 3-axis alignment of the X-ray source (tube) and the image receptor/detector located in the patient table or wall stand.

Indications for Use

The Q-Rad Radiographic System is indicated for use in obtaining diagnostic quality radiographic images to aid the physician with diagnosis. The system can be used to perform radiographic imaging of various portions of the human body, including the skull, spinal column, extremities, chest, abdomen and other body parts. The Q-Rad System is not indicated for use in mammography. The indications for use of the modified Q-Rad Radiographic System with Auto-Tracker option remain identical to those of the currently marketed "standard" Q-Rad System.

Device Modifications

This Special 510(k): Device Modification is for the introduction of optional Auto-Tracker functionality to improve the ergonomics of the user – device interface of the currently marketed Q-Rad Radiographic System. The Auto-Tracker function provides optional automated, motorized vertical tracking of the X-ray tube to the image receptor. Q-Rad Systems with the Auto-Tracker option will have a motor added to the X-ray tube support, and position sensors incorporated into the image receptors/detectors located in the patient table and/or in the wall-mounted image receptor unit. The motor and image receptors are linked via a CANbus communication interface, which allows the X-ray tube to automatically align with the vertical position of the image receptor, which is still manually positioned by the operator. The automated tracking feature applies only to vertical positioning; the operator must still manually align the X-ray tube with the image receptor in the X- and Y-axes (longitudinal and lateral/transverse positioning). The addition of a motor to the X-ray tube support also enabled the addition of optional motorized vertical positioning of the X-ray tube using a "tube-up" or "tube-down" switch; this option is independent of the auto-tracking capability, and is offered as a convenience to the operator as an alternative to the fully manual tube up/down positioning on standard (non-Auto-Tracker) Q-Rad Systems. The standard Q-Rad System without Auto-Tracker option will still be available, and the operator will have the option of disabling the Auto-Tracker function at any time if fully manual tube positioning is preferred.

The changes described in this Special 510(k) are limited to the addition of the optional Auto-Tracker functionality and motorized vertical X-ray tube positioning. There are no other changes to the device specifications and performance. The intended use and

indications for use remain unchanged. The same fundamental scientific technology for X-ray imaging is present in the "standard" Q-Rad System cleared in K011486 and in the Q-Rad Systems with optional Auto-Tracker functionality.

Risk Management

Risk management for the modified device has been performed and documented in accordance with ISO 14971:2007. Risk analysis has been performed for the modified device to identify any new risks associated with the new functionality. Any new risks have been thoroughly documented and appropriate risk reductions have been applied. Verification and validation testing has been performed to confirm that the device modifications have been thoroughly evaluated to ensure that design outputs meet design inputs, and that all risk mitigations are effective in achieving their intended effect. Risk-benefit analysis has been performed to establish that all residual risks for the modified device have been reduced as far as possible, and are outweighed by expected benefits. The outputs of the risk management process were utilized to ensure that appropriate performance testing and software V&V requirements have been identified to ensure that the modified device meets design specifications and is free from unacceptable risk.

Design Controls and Performance Testing

The proposed modification to add optional Auto-Tracker functionality to the currently marketed Q-Rad Radiographic System has been fully documented via a design control system that is compliant with 21 CFR 820.30. The modified design has been verified and validated in accordance with documented protocols and procedures which include predetermined acceptance criteria. Performance testing includes the following: electrical safety testing per IEC 60601-1, safety and performance evaluation for X-ray systems per IEC 60601-2-54, radiation protection for X-ray systems per IEC 60601-1-3, usability evaluation per IEC 60601-1-6 and IEC 62366, and EMC testing per IEC 60601-1-2. Software verification and validation testing was performed to confirm that the modified device performs as intended, and that no unintended errors or failure modes have been introduced. Testing has demonstrated that the Q-Rad Radiographic System with Auto-Tracker option meets all design requirements, performs as intended, and is capable of fulfilling its intended use.

Conclusion

The modified device (Quantum Medical Imaging Q-Rad Radiographic System with Auto-Tracker Option) is substantially equivalent to the predicate Quantum Medical Imaging Q-Rad Radiographic System cleared in K011486.