"K183474 510(k) Summary"

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Date Summary Prepared:	January 15, 2019
Device Trade Name:	Carestream DRX-1 System with DRX Core Detectors
Device Common Name:	Flat Panel Digital Imager
Classification Name:	Stationary x-ray system
Device Class:	Class II
Device Code:	MQB
Regulation Number:	21 CFR 892.1680
Predicate Device:	Carestream DRX-1 System with DRX Plus 3543 Detectors Manufactured by: Carestream Health, Inc. 510(k) No.: K150766 (June 24, 2015) Classification Regulation: 21 CFR 892.1680 Classification Name: Stationary x-ray system Primary Product Code: MQB

Device Description:

Carestream Health, Inc. is submitting this Special 510(k) premarket notification for a modification to the cleared Carestream DRX-1 System with DRX Plus 3543 Detectors (K150766). The product will be marketed as the Carestream DRX-1 System with DRX Core Detectors.

Consistent with the original system, the Carestream DRX-1 System with DRX Core 3543 Detectors are flat panel digital imagers utilizing a stationary digital radiography (DR) x-ray system.

Indications for Use
"The device is intended to capture for display radiographic images of human anatomy including both pediatric and adult patients. The device is intended for use in general projection radiographic applications wherever conventional screen-film systems or CR systems may be used. Excluded from the indications for use are mammography, fluoroscopy, and angiography applications."

The Indications for Use for the subject device is the same as for the predicate device and the intended use remains unchanged. Any variation in features or technical specifications have been identified and addressed through testing (described below) to support a substantial equivalence determination.

Intended Use
The intended use for this device, as determined by descriptions and the proposed labeling contained in this submission, is similar to the Indications for Use statement provided above. We believe that the Carestream DRX-1 System with DRX Core Detectors and the predicate device have the same intended use.

Comparison of Technological Characteristics:

Based upon information provided within this submission, we believe that the Carestream DRX-1 System with DRX Core Detectors is substantially equivalent to the legally marketed Carestream DRX-1 System with the DRX Plus 3543 Detectors (predicate device) (K150766). Both the currently marketed DRX Plus 3543 Detectors and the new DRX Core Detectors are used in combination with the image processing software (Eclipse II; K180809) and user interface resident on the DRX-1 System Console component of the Carestream DRX-1 System.

The system is used to directly capture conventional projected x-rays to generate digital images, regardless of which detector is being used. An image can be displayed on a preview monitor for viewing with any of the detectors. The system can transmit diagnostic images through a digital network for diagnostic viewing and printing regardless of which detector is used.

The Carestream DRX Core 3543C, DRX Core 4343C and DRX Core 4343FC Detectors (investigational devices) are similar to the FDA cleared DRX Plus 3543 Detector (predicate device) except for the scintillator (new supplier change for the CsI scintillator) and same or larger size, with all other aspects of the design remaining the same.

Based upon information provided within this submission, we believe that the Carestream DRX-1 System with DRX Core Detectors is substantially equivalent to the legally marketed Carestream DRX-1 System with DRX Plus 3543 Detectors (K150766).

Discussion of Testing

Bench Testing
The performance characteristics and operation / usability of the Carestream DRX-1 System with DRX Core Detectors were evaluated in non-clinical (bench) testing. These studies have

demonstrated the intended workflow, related performance, overall function, shipping performance, verification and validation of requirements for intended use, and reliability of the system including both software and hardware requirements. Non-clinical test results have demonstrated that the device conforms to its specifications. Predefined acceptance criteria were met and demonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.

In addition to the bench testing described above, the performance of the Carestream DRX-1 System with DRX Core 3543C Detector (investigational) was evaluated against the predicate device in a phantom imaging study. The purpose of this study was to compare the image quality between the investigational and predicate devices using anthropomorphic phantoms.

Because detector performance was well characterized by laboratory data, the following information was not necessary to demonstrate substantial equivalence but provides additional support that the device works as intended:
A set of anthropomorphic phantoms (adult and pediatric) were used to perform paired acquisitions using the investigational and predicate devices. Thirty image pairs were obtained using a DRX-Evolution stationary x-ray system. The Beam Detect feature was used in half of the acquisitions for both predicate and investigational detectors. Due to intrinsic differences in the efficiencies of the scintillator materials, the GOS (predicate) panel was operated at 30% higher exposure than the CsI panel to facilitate an appropriate image quality comparison. The improved imaging performance of the CsI panel was verified based on a comparison of DQE and MTF to the predicate.

Exam types included adult and pediatric chest, shoulder, clavicle, upper and lower extremities, and adult skull. The exams were acquired according to the phantom imaging protocol developed for this study. Three expert observers (former radiographic technologists with extensive experience in resolving image quality related service issues) evaluated images in a blinded pair-wise study on a PACS system. Image quality attributes of detail contrast, sharpness and noise were evaluated using a 5 point preference scale.

Any artifacts present in the resultant images were evaluated as part of the image comparison and no unique artifacts associated with either detector were evident. Dust or debris was observed in several exams on both the predicate and investigational images suggesting that dirt or contamination was under or on the phantom during acquisition. Since it was common in images from both detectors, such artifacts were deemed inconsequential.

Conclusion
The average preference for all image quality attributes (detail contrast, sharpness and noise) demonstrates that the image quality of the investigational device (exposed with 30% less exposure) is the same as that of the predicate device. The two-sample equivalence tests confirm that the beam detect mode has no effect on preference.

Summary
The statistical test results and graphical summaries generated by the phantom study results demonstrate that the DRX Core 3543C Detector (investigational device) delivers images that are equivalent in quality when compared with images obtained using the commercially available DRX Plus 3543 Detector (predicate device).

Results of the Phantom Reader Study indicated that the image quality of the modified Carestream DRX-1 System with DRX Core 3543C Detector is statistically equivalent to or better than that of the DRX Plus 3543 Detector (predicate device).

IEC Consensus Standards and FDA Guidance Documents

The Carestream DRX-1 System with 3543C Core Detector was tested and found compliant to the following consensus standards:

IEC 60601-1: Medical electrical equipment—Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 62321: Electrotechnical products – Determination of levels of six regulated substances (lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, polybrominated diphenyl ethers)

The following FDA Guidance Documents were followed in preparation of this 510(k) submission:

"Guidance for the Submission of 510(k)s for Solid State Imaging Devices"
"Pediatric Information for X-ray Imaging Device Premarket Notifications"