DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Carestream Health, Inc.
Victoria Wheeler
Seinor Regulatory Affairs Manager, Regulatory & Quality Systems
150 Verona Street
Rochester, New York 14608

June 21, 2017

Re: K170755
Trade/Device Name: DRX-Revolution Nano Mobile X-ray System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: May 26, 2017
Received: May 30, 2017

Dear Ms. Victoria Wheeler:

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,

For

Robert A. Ochs, Ph.D.
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)*
K170755

Device Name
DRX-Revolution Nano Mobile X-ray System

Indications for Use *(Describe)*
The device is designed to perform radiographic x-ray examinations on pediatric and adult patients, in all patient treatment areas.

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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Carestream

"510(k) Summary"

510(k) Owner Name:	Carestream Health, Inc.
510(k) Owner Address:	150 Verona Street Rochester, New York 14608
510(k) Owner Phone:	585-627-8706
510(k) Owner Fax:	585-627-8802
Contact Person & Info:	Victoria Wheeler Senior Regulatory Affairs Manager victoria.wheeler@carestream.com 585-627-8706
Date Summary Prepared:	May 26, 2017
Device Trade Name:	DRX-Revolution Nano Mobile X-ray System
Device Common Name:	Mobile x-ray system
Classification Name:	Mobile x-ray system
Device Class:	Class II
Device Code:	IZL
Regulation Number:	21 CFR 892.1720
Predicate Device:	DRX- Revolution Mobile X-ray System Manufactured by: Carestream Health, Inc. 510(k) No.: K120062 (April 13, 2012) Classification Regulation: 21 CFR 892.1720 Classification Name: Mobile x-ray system Primary Product Code: IZL

Device Description:

Device Description

The DRX-Revolution Nano Mobile X-ray System (also referred to as the DRX-Revolution Nano) is a diagnostic mobile x-ray system utilizing digital radiography (DR) technology. The system consists of a self contained x-ray generator, image receptor(s), imaging display and software for acquiring medical diagnostic images outside of a standard stationary x-ray room. The DRX-Revolution Nano system can also be used to expose CR storage phosphor screen or film cassettes.

The DRX-Revolution Nano system is designed to be used with the following legally marketed solid state imaging devices (referred to throughout this document as "detectors"):

- Carestream DRX-1 Detector (K090318);
- Carestream DRX-1C Detector (K120062)
- DRX Plus 3543 Detector and DRX Plus 3543C Detector (K150766)
- DRX Plus 4343 Detector and DRX Plus 4343C Detector (K153142)
- DRX Core 3543 Detector (Relabeled version of the DRX Plus 3543 Detector)
- DRX Core 3543C Detector (Relabeled version of DRX Plus 3543C Detector)
- DRX Core 4343 Detector (Relabeled version of the DRX Plus 4343 Detector)
- DRX Core 4343C Detector (Relabeled version of the DRX Plus 4343C Detector
- DRX 2530C Detector (K130464)

These detectors are commercially available for use with other Carestream products or as standalone devices. Image acquisition software for the detectors is integrated with the mobile x-ray system's user interface.

The DRX-Revolution Nano contains several wireless components that facilitate its use. Specifically, the Carestream detectors communicate to the console wirelessly, eliminating the need for cables that can hinder efficient workflow. The detector is also capable of communicating to the console via a wired ("tethered") connection if desired. Other peripheral wireless components include a badge reader for employee sign-in, an optional 2D barcode reader (for patient ID), and wireless communication capability with the hospital network.

Indications for Use

The Indications for Use for the device, as described in its labeling, are:
"The device is designed to perform radiographic x-ray examinations on pediatric and adult patients, in all patient treatment areas."

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. The DRX-Revolution Nano is a mobile system used to generate and control x-rays for diagnostic procedures. We believe that the DRX-Revolution Nano and the predicate device have the same intended use.

Comparison of Technological Characteristics:

Based upon information provided within this submission, we believe that the DRX-Revolution Nano Mobile X-ray System is substantially equivalent to the legally marketed DRX-Revolution Mobile X-ray System. At a high level, the subject device and predicate devices are based on the same technological elements as listed below:

- X-ray generator
- X-ray tube
- Collimator
- Graphical user interface
- Operator console with Touchscreen Display
- Battery powered mobile cart
- Flat panel detector and
- System software with image processing capability
- Optional IR remote

The following technological characteristics in the subject device are different from those of the predicate device:

- Stationary anode X-ray tube
- Lower powered generator
- Collimator has lower projection radiography range
- Elimination of auxiliary Touchscreen Display on the tube head
- Use of different battery technology
- Smaller sized cart
- Manually driven
- Use of articulating arm with increased rotation

The DRX-Revolution Nano Mobile X-ray System (Nano) and the DRX-Revolution Mobile X-ray System both consist of an x-ray generator, x-ray tube, collimator, optional Infrared remote and graphical user interface on an operator console with touch screen monitor. These components are mounted on a mobile cart to enable the device to be moved from location to location. Both systems utilize a digital flat panel detector for image capture and can also be used to expose CR storage phosphor screen or film cassettes. Both systems have an operator console with the same image processing software. The Intended Use is the same for both devices.

Both systems have operator console software that is based on the DirectView platform, but specific user interface screens and software components are specific to the DRX-Revolution Nano device. These screens were developed to control and manage the DRX-Revolution Nano's hardware subsystems including its X-ray generator. All of the embedded software and subsystem firmware of the DRX-Revolution Nano was developed specifically for the new (Nano) hardware system.

The DRX-Revolution Nano offers hardware features (such as an articulating arm) that are different from the predicate device. These features are designed to aid the user in achieving an efficient workflow but do not result in additional indications for use (i.e., there is no change to the intended diagnostic effect) for the new device as compared to the predicate.

Performance Testing:

The DRX-Revolution Nano conforms to the following standards:

- ISO 14971:2012 Medical device – application of risk management to medical device
- Digital Imaging and Communication in Medicine (DICOM)
- IEC 60601-1-2 Edition 3: Medical electrical equipment, Part 1-2: General requirements for basic safety and essential performance
- IEC 60601-2-54: Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.

Discussion of Testing

The performance characteristics and operation / usability of the DRX-Revolution Nano Mobile X-ray System 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 test results havedemonstrated that the device is as safe, as effective, and performs as well as or better than the predicate device.

The following performance data were provided in support of the substantial equivalence determination:

- **Electrical safety and electromagnetic compatibility (EMC)**

  Electrical safety and EMC testing were conducted on the DRX-Revolution Nano Mobile X-ray System in compliance to IEC 60601-1-2:2007 – Medical electrical equipment Part 1-2, Electromagnetic Compatibility.

- **Software Verification and Validation Testing**

  Software verification and validation testing was conducted and documentation has been provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in

Medical Devices." The software for this device is considered to present a "moderate" level of concern. This is based on the fact that a malfunction of or latent design flaw in the software component could lead to an erroneous diagnosis, or to a delay in delivery of appropriate medical care that may lead to a minor injury.

Clinical Studies

A Clinical Study was performed to investigate the imaging performance of the DRX-Revolution Nano Mobile X-ray System ((investigational device) as compared to the currently marketed DRX-Revolution Mobile X-ray System (K120062), (predicate device). Both devices were paired with the the DRX Plus 3543 detector (K150766) for execution of the clinical study.

As compared to the predicate device, the DRX-Revolution Nano is a smaller, manually driven and operated mobile x-ray system. The Nano has a collapsible arm assembly that pivots rather than the predicate's telescoping column. The image acquisition module and image processing software are unchanged from the predicate. The DRX-Revolution Nano can interface with various Carestream digital detectors including the DRX 2530C, DRX-1, DRX Plus, and DRX Core detectors, as can the predicate.

Adult cadavers were used to perform pair-wise investigational vs. predicate acquisitions using similar radiographic techniques and body positioning for 2D imaging. The images acquired included targeting various exam types such as the chest, abdomen, skull, C-Spine, L-Spine, pelvis, hip, nasal bones, shoulder, and extremity radiographs. In addition, eight pediatric phantom images were acquired on both the investigational and predicate devices in the laboratory at Carestream Health, Inc. The images were assembled and reviewed in a single stimulus random format in order to perform a Comparative Evaluation to statistically confirm the findings of this evaluation.

Results of the Reader Study demonstrated that the diagnostic capability of the DRX-Revolution Nano Mobile X-ray System is statistically equivalent to or better than that of the predicate device.

Conclusions

Since the predicate device was cleared based in part on the results of clinical studies, clinical testing was required to support substantial equivalence in terms of diagnostic capability. Non-clinical test results support the safety and effectiveness of the device and demonstrate that the DRX-Revolution Nano Mobile X-ray System performs as intended in the specified conditions. Results of both non-clinical and clinical tests demonstrate that the DRX-Revolution Nano Mobile X-ray System is as safe and as effective as the predicate device that is currently marketed for the same intended use.