Carestream Health, Inc.
% Ms. Victoria Wheeler
Sr. Regulatory Affairs Manager
150 Verona Street
ROCHESTER NY 14608

February 5, 2018

Re: K173924
Trade/Device Name: DRX-Revolution Nano Mobile X-ray System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: December 27, 2017
Received: December 28, 2017

Dear Ms. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Robert 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173924

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:	January 24, 2018
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 Nano Mobile X-ray System Manufactured by: Carestream Health, Inc. 510(k) No.: K170755 (June 21, 2012) Classification Regulation: 21 CFR 892.1720 Classification Name: Mobile x-ray system Primary Product Code: IZL

Device Description:

Carestream Health, Inc. is submitting this Traditional 510(k) premarket notification for a modification to the cleared DRX-Revolution Nano Mobile X-ray System (K170755). The product will continue to be marketed as the DRX-Revolution Nano Mobile X-ray System.

Consistent with the original system, the modified DRX-Revolution Nano Mobile X-ray System (also referred to throughout this document as the Nano system) 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 modified Nano system can also be used to expose Computed Radiography (CR) storage phosphor or film cassettes.

Modifications have been made to the design of the system's x-ray tube and its operational characteristics for the purpose of improving the x-ray tube reliability and life span. This required modifications to the embedded software to accommodate these tube design changes.

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

Comparison of Technological Characteristics:

Modifications have been made to the design of the x-ray tube and its operational characteristics for the purpose of improving the x-ray tube reliability and life span.

The technical characteristics of the modified device are not different from the predicate device except for minor adjustments to tungsten thickness (on the anode), focal spot size, and maximum exposure current. These adjustments led to a reduction in generator power from 6.5 kW to 5.3 kW.

Based upon information provided within this submission, we believe that the modified DRX-Revolution Nano Mobile X-ray System is substantially equivalent to the legally marketed DRX-Revolution Nano X-ray System (K170755).

Discussion of Non-clinical Testing:

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

Discussion of Clinical Testing (using Phantoms):

The diagnostic imaging performance of the modified DRX-Revolution Nano system was evaluated by executing a phantom imaging study.

Anthropomorphic Phantoms

The phantoms used for the imaging study were purchased commercial products intended for x-ray imaging tests. The phantoms represent different sections of the human anatomy and are anthropomorphic both in appearance, size, and x-ray attenuation characteristics. For example, the adult chest phantom ("Lungman") was manufactured by Kyoto Kagaku and it is widely accepted in the scientific community for x-ray imaging quality assessment. The particular phantom used contains actual human bone and simulated lung tissues.

Similarly, the adult pelvis phantom, also used in this study, contains actual human bones. As both the chest and the pelvis phantom only mimic a medium sized adult patient, larger sized patients were simulated by adding additional PMMA (acrylic glass) plates each of 2.5 cm in thickness to the two phantoms. For example, images were taken with no additional PMMA on the phantoms, one PMMA plate in the front of the phantoms, and one PMMA plate in both the front and the back of the phantoms (two PMMA plates in total). In summary, these two phantoms cover the anatomical regions of the lung, mediastinum, diaphragm, ribs, clavicles, shoulder, inferior c-spine, t-spine, l-spine, pelvis, and superior femur.

The other two anthropomorphic phantoms used in the clinical study were an upper limb and a lower limb representing anatomical size and structure of a typical five year old child. These phantoms were recently manufactured by CIRS Inc (Model number 715-A-L-FX and 715-L-R). They contain simulated human bone skeletons and also simulated soft tissue/muscle/fat around the skeletons. These phantoms are intended for imaging at both diagnostic and therapy x-ray energy ranges. These two phantoms cover the anatomical regions of the interior femur, knee, tibia/fibula (lower leg), ankle, foot, inferior humerus, elbow, ulna/radius (forearm), ankle, and hand.

The standard Gammex 610 neonatal chest phantom manufactured by Supertech, was used for the neonate imaging. It is designed for routine quality assurance monitoring of computed and digital radiography systems. This phantom replicates both the anatomic structure and the tissue attenuation characteristics of an actual human neonate.

In summary, we believe the anthropomorphic phantoms used in this study adequately represent the device's broad range of intended uses.

The study objective was to evaluate the imaging performance (diagnostic image quality) of the modified DRX-Revolution Nano Mobile X-ray System using a radiologist reader rating scale (RadLex Rating) that is applicable to projection radiography. Three (3) board certified radiologists with extensive reading experience (Table 1) rated the images using the RadLex scale for diagnostic quality. The radiologists provided image quality ratings from 1.0 to 4.0 using a graduated RadLex rating scale (to one decimal place) to account for ratings between the absolute values (e.g. 3.1, 3.5, or 3.9).

For each reading session, the radiologists were given work lists of image cases to review on the CARESTREAM PACS Workstation. Images were randomized and displayed following a single stimulus format. In addition, the image work lists were randomized for the radiologists to avoid bias due to study learning curve or reader fatigue. The radiologists were allowed to pan, adjust window/level, and magnify on the PACS workstation while evaluating image quality.

Summary of Statistical Analysis Methodology

The statistical analysis is performed using Minitab® statistical software and Microsoft Excel for generating charts. Diagnostic quality ratings (RadLex Scale) are treated as a continuous variable for the descriptive statistics and hypothesis tests. The inferential tests are performed at the 5% level of significance.

Descriptive statistics including mean, standard error of the mean, median, standard deviation, and sample size are presented in Table 1 for all RadLex rating data.

Statistic	Investigational RadLex Rating
Mean	3.595
Standard Error	0.028
Median	3.6
Standard Deviation	0.220
Observation Count	60

Table 1 – RadLex Rating Descriptive Statistics

Applying the one-sample t-test to the mean RadLex rating we find statistical significance. At a 95% significance level the mean of the DRX-Revolution Nano RadLex rating data is greater than the mid-value (3.5) of the Diagnostic (3) quality image rating scale. There is no significant difference in ratings across Readers. The ANOVA yields a p-value greater than alpha (0.05) which fails to reject the null hypothesis "All means are equal" (referring to the RadLex rating means of each Reader). In summary, the three different Readers are similar in their evaluation of the images.

Conclusion

The mean RadLex rating for the 60 responses is 3.6. 100% of the image ratings were Diagnostic (3) quality. Approximately 78 % of the total number of rating responses falls in the mid to upper end of the Diagnostic (3) RadLex Rating scale between Diagnostic and Exemplary. The one- sample t-test yields statistical significance at the 95% significance level. This result implies quality ratings equal to or better than a Diagnostic (3) quality rating. There is no significant difference in ratings across Readers.

Summary

The statistical test results and graphical summaries demonstrate the DRX-Revolution Nano Mobile X-ray System Study using Phantoms delivers quality imaging performance that is rated Diagnostic.

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