November 20, 2020

Xoran Technologies LLC
% Mr. Mark McGarrow
VP of Quality and Operations
5210 South State Road
ANN ARBOR MI 48108

Re: K201825
Trade/Device Name: MiniCAT 2D
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR
Dated: October 16, 2020
Received: October 19, 2020

Dear Mr. McGarrow:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*
K201825

Device Name
MiniCAT 2D

Indications for Use *(Describe)*
The MiniCAT 2D is a diagnostic x-ray system for general radiographic x-ray imaging of the head and neck for use in hospitals, clinics, medical imaging centers, and medical practices.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K201825

This 510(k) summary of the Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

Date Prepared: June 1, 2020

Submitter:
Xoran Technologies LLC
5210 S. State Road
Ann Arbor, MI 48108

Contact Person:
Mark McGarrow
Vice President of Quality and Operations
Phone: 734-418-5125
Email: mark.mcgarrow@xorantech.com

Device Name and Classification:

Trade Name:	MiniCAT 2D
510(k) number:	K201825
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1680
Device Class:	Class II
Product Code:	KPR

Predicate Devices:

Trade Name:	Carestream DRX-Evolution
510(k) number:	K141837 cleared 03/11/2015
Manufacturer:	Carestream Health, Inc.
Classification Name:	Stationary X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1680
Device Class:	Class II
Product Code:	KPR

Device Description:
The MiniCAT 2D is a dedicated X-ray imaging device that acquires a 360º rotational X-ray

sequence and produces two dimensional views. MiniCAT 2D provide immediate access to images at the patient's point-of-care resulting in faster diagnosis and treatment.

The MiniCAT 2D system consists of a high voltage x-ray generator, 360-degree rotational overhead gantry, x-ray tube assembly, x-ray controller, fixed detector panel, and x-ray controls containing a "power distribution unit and operator PC (user interface)."

Indications for Use:
The MiniCAT 2D is a diagnostic x-ray system for general radiographic x-ray imaging of the head and neck for use in hospitals, clinics, medical imaging centers, and medical practices.

Substantial Equivalence:

Table 1

Comparable Properties	**Predicate Device: DRX-Evolution**	**MiniCAT 2D**	**Comparison Result**
Intended Use	The device is a permanently installed diagnostic x-ray system for general radiographic x-ray imaging including tomography. The tomography feature is not to be used for imaging of pediatric patients.	The MiniCAT 2D is a diagnostic x-ray system for general radiographic x-ray imaging of the head and neck for use in hospitals, clinics, medical imaging centers, and medical practices.	Equivalent
Patient Support	Table: contains Bucky with detector	Chair, max patient weight 350 lbs (159 kg), motorized adjustable height	Functionally Equivalent
Wall stand	Wall stand contains Bucky with detector	No wall stand	Not applicable
Overhead	Overhead tube crane with manual and automated x-ray tube assembly movement	Motorized overhead, 360 degree rotation of x-ray tube and detector around patient.	Functional Equivalent

Comparable Properties	Predicate Device: DRX-Evolution	MiniCAT 2D	Comparison Result
		Forward/backwards motion for sinus/ear scan positioning	
X-Ray Tube & power supply	Varian x-ray Tube (RAD-60 with B-130 housing) / Alternate: Toshiba E7254GX with XH-157 Housing	Source-Ray Inc. x-ray tube model SXR-130-15-0.5 125 kVp; 0.5 mm focal spot	Equivalent
X-Ray generator	Communication Power Industries CMP200DR x-ray generator Alternative optional generator	Source-Ray Inc., Model XRS-125-7K	Equivalent
X-ray controller	Power Distribution Unit (provides power distribution & generator interface): Optional APC 1500 VA UPS	Xoran designed x-ray controller board 20240. Fixed KVp, mA, pulse width settings. Interfaces with XRS-125-7K generator	Equivalent
Collimator	Ralco R302 DACS/A	Xoran designed beam limiter board 15006	Functional Equivalent
Fixed Detector	Compatible with Carestream DRX-1 Digital Detector, DRX-1C, and DRC 2530C	Varex 2520DX receptor panel	Equivalent
Operator Console	PC	PC	Equivalent

Comparison of Technological Characteristics:

The differences between the subject device and the predicate device, the reason they do not impact the indications of use, or the safe and effective use of MiniCAT 2D are listed below:

- Patient support. MiniCAT 2D intended use is x-ray imaging of the head and neck. Patient position for such exams is sitting position for comfort and ergonomics. MiniCAT 2D chair is designed to accommodate up to 350lbs and 6.5 ft height patients. The MiniCAT 2D chair is functionally equivalent to the predicate device
- Wall stand and overhead. MiniCAT 2D intended use is x-ray imaging of the head and neck. The overhead contains the x-ray tube and x-ray detector panel. It's motorized to

rotate 360 degrees around the patient's head. It also has a motorized forward/backward motion optimize positioning for imaging the sinus or ear. MiniCAT 2D does not have a wallstand to image other parts of the anatomy. The MiniCAT 2D overhead is functionally equivalent to the predicate device

- Collimator: The Beam limiter board 15006 in MiniCAT 2D is designed to collimate the x-ray beam for a fixed detector size and fixed SID. The user cannot modify SID, detector position or detector size in MiniCAT 2D. The collimation is adjusted to the field of view (FOV) by the system depending on the imaging protocol selected by the user. The MiniCAT 2D collimator is functionally equivalent to the predicate device

The rest of the MiniCAT 2D system components are equivalent to the predicate device, and do not affect the safety or effectiveness of the device.

The properties of the subject device (MiniCAT 2D) presented in the comparison table above (see Table 1) and described throughout this submission do not differ significantly from the legally marketed predicate (Carestream DRX Evolution) device with regards to fundamental scientific technology, nor do they reflect a significant change in the indications for use. The differences between the subject device and the legally marketed predicate device have been assessed using Risk Management and through third-party evaluation using FDA-recognized consensus standards. The results of these efforts demonstrate that the device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness than the predicate.

Performance Testing:

- MiniCAT 2D has undergone Verification, SW Validation and Product Validation testing to demonstrate its safety, effectiveness, and conformance to its user needs intended use, as required by 21 CFR 820.30 Design controls – (f) Design Verification, and (g) Design Validation. In addition, the MiniCAT 2D conforms to IEC standard 60601-2-63 and FDA performance standards, 21 CFR 1020.30 and 21 CFR 1020.31.

- Each Verification or Validation has followed the same process and it has been documented in the manner listed below:

  - The test plan and test instructions were laid out in the Test Protocol and Test Cases documents, where information such as test configurations, test sample sizes and test result evaluation criteria, is established.

  - The testing was performed, and the results captured in the Test Results document.

  - The testing was performed on production equivalent units. Verification and SW validation tests were performed by qualified Xoran personnel, familiar with the function and use of MiniCAT 2D, but not directly responsible for its design. Product validation evaluations were performed by qualified physicians, who have anatomical and/or surgical expertise related to MiniCAT 2D's intended use.

- The evaluation of the results and of the overall verification or validation result was discussed in the Test Report document.

- Both the Design Verification and the Product Validation had all identified hazards and risks tested and successfully mitigated by traceable requirements.

- MiniCAT 2D meets all the evaluation criteria for Verification, SW Validation and Product Validation tests.

Conclusion:

The MiniCAT 2D is intended for the same use as the DRX-Evolution. It uses components similar to those in the DRX-Evolution (e.g. x-ray tube, collimator, x-ray generator, operator console). It is Xoran Technology, LLC's opinion that the MiniCAT 2D is substantially equivalent to the cleared predicate device, the DRX-Evolution.