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

May 20, 2021

Re: K210257
Trade/Device Name: Xoran Workstation, Model 10050
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: April 23, 2021
Received: April 26, 2021

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,

For

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)*
K210257

Device Name
Xoran Workstation, Model 10050

Indications for Use *(Describe)*
Xoran Workstation is an image processing and viewing software. The Xoran Workstation software provides tools for patient data management, image processing, viewing, interpretation, annotation, clinical review, analysis, distribution, archival, printing, and administrative reporting by healthcare professionals.

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.

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

Date Prepared: April 19, 2021

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:	Xoran Workstation, Model 10050
Classification Name:	Computed Tomography X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1750
Device Class:	Class II
Product Code:	OAS

Predicate Devices:

Trade Name:	MiniCAT
510(k) number:	K113421 cleared 07/11/2012
Manufacturer:	Xoran Technologies, LLC
Classification Name:	Computed Tomography X-Ray System
Classification Panel:	Radiology
Classification Regulation:	21 CFR 892.1750
Device Class:	Class II
Product Code:	JAK

Device Description:

Xoran Workstation is an image processing and viewing software for use with imported Xoran MiniCAT IQ, MiniCAT 2020, xCAT XL, and xCAT IQ patient image data. The Xoran Workstation runs on a Windows OS based PC with the following Minimum requirements:

- Laptop or desktop computer
    - Windows 10 64-bit Professional or Enterprise

- 4GB of RAM or more
- Intel i5 or better
- USB Type A port

Indications for Use:

Xoran Workstation is an image processing and viewing software. The Xoran Workstation software provides tools for patient data management, image processing, viewing, interpretation, annotation, clinical review, analysis, distribution, archival, printing, and administrative reporting by healthcare professionals.

Substantial Equivalence:

Comparable Properties	Predicate Device: MiniCAT	Xoran Workstation	Comparison Result
Intended Use	The MiniCAT is an X-ray imaging device that constructs a three-dimensional model of the head and neck from images taken during a rotational X-ray sequence. The MiniCAT is optimized for the imaging of the maxillofacial complex, temporal bone, sinuses and for neuro-angiography.	Xoran Workstation is an image processing and viewing software. The Xoran Workstation software provides tools for patient data management, image processing, viewing, interpretation, annotation, clinical review, analysis, distribution, archival, printing, and administrative reporting by healthcare professionals.	Software: Functionally Equivalent Hardware: There is no scanning hardware for Xoran Workstation
Environment of Use	ENT, Allergy, and dental Offices	ENT, Allergy and dental Offices	Functionally Equivalent
Basic Technology	PC Based SW	PC Based SW	Functionally Equivalent
Principles of Operations	Browsing images by Patient, Date, Ordering physician, Protocol	Browsing images by Patient, Date, Ordering physician, Protocol	Equivalent
	Viewing Images	Viewing Images	Equivalent
	3D reconstruction of images taken by the MiniCAT	Xoran Workstation can import raw 2D images acquired with MiniCAT or xCAT devices for 3D reconstruction and viewing. It can also import 3D images from any MiniCAT	Equivalent

Comparable Properties	Predicate Device: MiniCAT	Xoran Workstation	Comparison Result
		or xCAT device for viewing	
	Annotation tools: distance, circle, rectangle, text, label	Annotation tools: distance, circle, rectangle, text, label	Equivalent
	Annotations are automatically saved with image planning file	Annotations are automatically saved with image planning file	Equivalent
	Annotation tools: distance, circle, rectangle, text, label	Annotation tools: distance, circle, rectangle, text, label	Equivalent
	Viewing tools: zoom and pan	Viewing tools: zoom and pan	Equivalent
	Continuous rotation up to +/- 45 degrees	Continuous rotation up to +/- 45 degrees	Equivalent
	Viewing tools: Window/Level adjustment	Viewing tools: Window/Level adjustment	Equivalent
	Viewing tools: Window/Level adjustment	Viewing tools: Window/Level adjustment	Equivalent
	Annotation tools: distance	Annotation tools: distance	Equivalent
	Viewing tools: zoom, slice thickness	Viewing tools: zoom, slice thickness	Equivalent
	3D Reconstruction of acquired images	Xoran Workstation can import raw 2D images acquired with MiniCAT or xCAT devices for 3D reconstruction	Equivalent
Administration	User login	User login	Equivalent
	User New/Edit/Delete/Active	User New/Edit/Delete/Active	Equivalent
	Service mode for administration	Service mode for administration	Equivalent

Comparison Summary:

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 the Xoran Workstation are listed below:

- Predicate device has both Hardware (for X-ray scanning and imaging) and Software for reconstructing those images.
- Subject device is Software Based on a PC that meets minimum Hardware requirements equivalent to those of the predicate device. While the Hardware components are for x-ray scanning are not included with Xoran Workstation, the Software reconstruction algorithms and viewing functionality are the equivalent to the Predicate device. Therefore, both are functionally equivalent and do not raise any Safety and Effectiveness questions.

Performance Testing:

Xoran Workstation has undergone Verification, Software 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.

During the design process, risk analysis tools were used to identify hazards and risks, which have been mitigated by traceable requirements, tested during verification and validation.

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 Software validation tests were performed by qualified personnel, familiar with the function and use of Xoran Workstation, but not directly responsible for its design. Product validation evaluations were performed by qualified physicians, who have anatomical and/or surgical expertise related to Xoran Workstation's intended use.
- The evaluation of the results and of the overall verification or validation result was discussed in the Test Report document.

Xoran Workstation meets all the evaluation criteria for Verification, Software Validation and Product Validation tests.

Refer to section 018 Performance Testing Bench for more details.

Conclusion:

The Xoran Workstation is intended for the same use as the predicate device with the exception that it is not an imaging device. It uses the same reconstruction software algorithms and viewing functionality as the MiniCAT. It is Xoran Technologies LLC's opinion that the Xoran Workstation is substantially equivalent to the cleared predicate device, the MiniCAT.