December 27, 2019

Clarix Imaging
% Xiao Han, Ph.D.
CEO
2242 West Harrison Street, Suite 201
CHICAGO IL 60612

Re: K192939
Trade/Device Name: Volumetric Specimen Imager
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MWP
Dated: October 16, 2019
Received: October 18, 2019

Dear Dr. Han:

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)*

K192939

Device Name
Volumetric Specimen Imager

Indications for Use *(Describe)*

The Volumetric Specimen Imager is a Cabinet x-ray system that is used to provide two and three dimensional digital x-ray images of harvested specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure. Doing the verification directly in the same room or nearby enables cases to be completed faster, thus limiting the time the patient needs to be under examination. Specimen radiography can potentially limit the number of patient recalls.

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.

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510(k) Summary: K192939
(As required by 21 CFR 807.92)

Date Summary Prepared:	October 16, 2019	
Company Name: As required by 807.92(a)(1)	Clarix Imaging Corporation	
	Xiao Han CEO, Clarix Imaging 2242 West Harrison Street Suite 201 Chicago, IL 60612 (872) 760-3788 xiao.han@clarixiimaging.com	
Device Name: As required by 807.92(a)(2)	Device/Trade Name:	Volumetric Specimen Imager
	Device Common Name:	Specimen X-ray System/ Cabinet X-ray System
	Regulation Number:	21 CFR 892.1680
	Regulation Name:	Stationary X-ray System
	Class:	II
	Product Code:	MWP
Predicate Device(s): As required by 807.92(a)(3)	Faxitron VisionCT, K173309	
Device Description: As required by 807.92(a)(4)	The Clarix Imaging Volumetric Specimen Imager (VSI) is a portable, fully shielded cabinet X-ray system that provides high resolution 2D and 3D radiographic images of surgically excised specimens. The VSI system consists of an image-acquisition device and software for image reconstruction, visualization, and archival. Enabled by optimized imaging geometry and iterative image reconstruction algorithm, VSI provides superior spatial and contrast resolution for visualizing specimens with soft tissues or boney structures. VSI is designed to comply with 21 CFR 1020.40 and DICOM standards.	
Statement of Intended Use: As required by 807.92(a)(5)	The Volumetric Specimen Imager is a Cabinet x-ray system that is used to provide two and three dimensional digital x-ray images of harvested specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the biopsy procedure. Doing the verification directly in the same room or nearby enables	

cases to be completed faster, thus limiting the time the patient needs to be under examination. Specimen radiography can potentially limit the number of patient recalls.

Comparison of Technological Characteristics with Predicate Devices:
As required by 807.92(a)(6)

Device	Proposed Device Volumetric Specimen Imager	Predicate Device Faxitron VisionCT, K173309
Detector • Array Size • Pixel Size • Resolution	 • 1488 x 1148 • 99 x 99 µm • 5 lp/mm	 • 1548 x 1548 • 99 x 99 µm • 5 lp/mm
X-ray Tube • Voltage Range • Current • Target Material	 • 4-60 kV • Up to 1.0 mA • Tungsten	 • 15-50 kV • Up to 1.0 mA • Tungsten
Exposure • Time Range	 • Up to 300 seconds	 • 0 to 900 seconds

The proposed and predicate device only differ in minor technological details sourced from the devices using different x-ray tubes and detectors. Overall both the proposed and predicate devices have the specifications necessary to deliver imaging safely and effectively.

Non-clinical Performance Data:
As required by 807.92(b)(1)

Non-clinical performance testing was performed to verify substantial equivalence to predicate device, Faxitron VisionCT (K173309). Testing included:

- Electrical safety: IEC 61010-1, IEC 61010-2-091, IEC 61010-2-101
- Electromagnetic compatibility: IEC 61326-1, IEC 61326-2-6
- Compliance with 21 CFR 1020.40
- Compliance with DICOM Standards
- Phantom imaging
- User testing
- Tissue Verification

Assessment of Clinical Data:
As required by 807.92(b)(2)

Clinical data was not required to demonstrate substantial equivalence to predicate device.

Overall Conclusions:
As required by 807.92(b)(3)

Based on the indications for use, technological characteristics, and performance results, the Volumetric Specimen Imager has been shown to be substantially equivalent to the predicate and is safe and effective for its intended use.