December 13, 2019

Cirdan Imaging Limited
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite #510k
SAINT PAUL MN 55114

Re: K193317
Trade/Device Name: CoreLite
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MWP
Dated: November 27, 2019
Received: November 29, 2019

Dear Prithul Bom:

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)*
K193317

Device Name
Corelite

Indications for Use *(Describe)*

The CoreLite device is a cabinet X-ray system used to provide digital X-ray images of specimens from various anatomical regions in order to allow rapid verification that the correct tissue has been excised during the biopsy procedure.

Performing the verification in the same room as the procedure or nearby improves workflow, thus reducing the time the patient needs to be under examination.

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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Section 5. 510(K) Summary

Premarket Notification 510 (k) Summary, as required by 21 CFR 807.92

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807.92

Date Prepared: 11th October 2019

Identification of the Device:

Trade Name:	CoreLite
Classification Name:	Stationary X-Ray System
Classification Regulation:	21 CFR 892.1680
Product Code (Precode):	MWP
Device Class:	Class II
Panel:	Radiologic Devices Panel
Manufacturer:	Cirdan Imaging Ltd 8 Enterprise Crescent, Ballinderry Road, Lisburn, BT28 2BP, County Antrim, Northern Ireland, United Kingdom
Contact**:**	Jenna McGarry QARA Phone +44 (0)2892 660880

Legally Marketed Predicate Device

Trade Name:	Faxitron CoreVision Digital Specimen Radiography (DSR) System
Classification Name:	Cabinet X-Ray System
Classification Regulation:	21 CFR 892.1680
Product Code (Precode):	MWP
Device Class:	Class II
Panel:	Radiologic Devices Panel
Submitter/510K Holder:	Faxitron Bioptics Inc.
Clearance	K082432 (Cleared 21st November 2008)

DEVICE DESCRIPTION - as required by 21 CFR 807.92(a)(4)

The CoreLite Specimen Radiography System is a self-contained digital imaging system for verification of breast biopsy specimens at the point of care which enables the procedure to be completed faster.
The system is comprised of the x-ray cabinet and the PC with DICOM compliant software which provides the user interface, means to enter patient details (either directly or from a DICOM Modality Worklist, if available) and the means to acquire, review and save or transmit DICOM images to the Picture Archiving and Communication System (PACS).
The cabinet incorporates shielding and interlock circuits to meet regulatory requirements.

INDICATIONS FOR USE – as required by 807.92(a)(5)

The CoreLite device is a cabinet X-ray system used to provide digital X-ray images of specimens from various anatomical regions in order to allow rapid verification that the correct tissue has been excised during the biopsy procedure.
Performing the verification in the same room as the procedure or nearby improves workflow, thus reducing the time the patient needs to be under examination.

DEVICE CLAIMS – as required by 807.92(a)

The CoreLite X-ray Specimen Cabinet has been designed to comply with the following standards and regulations:

- IEC 61010-1:2010. Ed.3
- IEC 61010-2-091:2012. Ed.1
- IEC 61010-2-101:2015. Ed.2
- IEC 61326-1:2012. Ed.2
- 21 CFR 1020.40,
- 47 CFR 15.107, 15.109

CoreLite Software supports the DICOM Store and Modality Worklist services.

TECHNOLOGICAL CHARACTERISTICS SUMMARY- as required by 807.92(a)(6)

The CoreLite X-ray Specimen Cabinet has the same indications for use, general configuration, and principles of operation as the predicate devices listed above. The technological characteristics of the CoreLite X-ray Specimen Cabinet have been compared to the predicate device cited and is covered in detail in the Substantial Equivalence section of this submission.

COMPARISON WITH PREDICATE DEVICE.

Use Description.	CoreVision (Predicate)	CoreLite
Environment of Use	Hospital/Healthcare Facility (Radiology/mammography Clinic)	Hospital/Healthcare Facility (Radiology/mammography Clinic)
Integrated shielding	Yes	Yes
Anode material	Tungsten	Tungsten
Focal Spot	50 um nominal	50 um nominal
Window Filtration	Beryllium	Beryllium
Detection technology	Indirect	indirect
Sensor Technology	CMOS	CMOS
Imaging Area (mm)	26 X 75 mm	42 X 67 mm
Software Level of Concern	Moderate	Moderate
DICOM Modality Worklist	YES	YES
PACS connectivity	YES	YES
UI	Traditional Windows UI (toolbar, dropdown menus etc.)	Streamlined touch driven UI

PERFORMANCE DATA TESTING AND REVIEW- as required by 807.92(b)(1)

The CoreLite system successfully performed design control verification tests and validation tests.

The CoreLite complies with applicable IEC-61010 standards (general electrical safety including mechanical hazards plus particular standards for cabinet x-ray systems and in-vitro products) and international EMC standards/regulations including FCC.
Compliance was demonstrated by the third-party test house, a member of the NRTL scheme.

Non-Clinical Testing included image quality tests with accredited phantom test objects and High Contrast resolution targets. Additionally, the device was benchmarked against the predicate in a clinical setting: the results were judged to be equivalent to the predicate.

Results of these performance tests, combined with design and comparison with the predicate device, support substantial equivalence.

SUBSTANTIAL EQUIVALENCE SUMMARY

The CoreLite X-ray Specimen Cabinet has the same indications for use as the predicate device cited. The technical characteristics of the CoreLite X-ray Specimen Cabinet are the same or similar to the predicate device and do not raise any new questions on the safety and effectiveness of the proposed device.

CONCLUSIONS - as required 807.92(b)(3)

We conclude that the documentation and testing included in this submission indicates that the CoreLite X-ray Specimen Cabinet is safe and effective and substantially equivalent to the predicate device cited.