April 24, 2023

CompAI Healthcare (Suzhou) Co.,ltd
℅ Xueqiao Wang
Q&R Director
Room 3A05, Building 2, No.8 Changting Road, High-tech Zone
Suzhou, Jiangsu 215151
CHINA

Re: K230140
Trade/Device Name: TrueView Core 100Pro-US Core Specimen Radiography System (TrueView Core 100Pro-US)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MWP
Dated: January 17, 2023
Received: March 24, 2023

Dear Xueqiao Wang:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230140

Device Name

TrueView Core 100Pro-US Core Specimen Radiography System (TrueView Core 100Pro-US)

Indications for Use *(Describe)*

A cabinet X-ray system used to provide digital X-ray images of surgical and core biopsy specimens from various anatomical regions in order to allow rapid verification that the correct tissue has been excised during the procedure.
Doing the verification in the same room as the procedure or nearby improves workflow, thus reducing the overall operative time.

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 K230140

TrueView Core 100Pro-US
Core Specimen Radiography System

510(k) Summary K230140

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:	January 17, 2023
Manufacturer:	CompAI Healthcare (Suzhou) Co.,ltd Room 3A05, Building 2, No.8 Changting Road, High-tech Zone, Suzhou, Jiangsu, P.R. China
Contact Person:	Xueqiao Wang Q&R Director CompAI Healthcare (Suzhou) Co.,ltd +86 512 67236750 xueqiao.wang@comp-ai.com

Identification of the Device:

Proprietary/Trade Name:	TrueView Core 100Pro-US Core Specimen Radiography System (TrueView Core 100Pro-US)
Classification Name:	Cabinet X-Ray System
Regulatory Number: Product Code:	21 CFR 892.1680 MWP
Device Class:	Class II
Review Panel:	Radiology

Identification of the Legally Marketed Predicate Device:

Trade Name:	TrueView 100 Pro Specimen Radiography System
Classification Name:	Cabinet X-Ray System
Regulatory Number:	21 CFR 892.1680
Product Code:	MWP
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	CompAI Healthcare (Shenzhen) Co., Ltd
Clearance:	K202713

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

The TrueView Core 100Pro-US Core Specimen Radiography System (CSRS) is a Cabinet X-ray System intended to provide the detailed radiographic imaging of small surgical excised or biopsy specimens and to further provide rapid verification that correct tissue has been excised.

The TrueView Core 100Pro-US includes the following major components: touch-screen control display, and an imaging cabinet.

This all-in-one system includes shielding that is incorporated within the cabinet chamber system design, eliminating the need for separate shielding.

This system is intended to use in the following environments:

- Surgical suites
- Biopsy suites
- Pathology labs

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

A cabinet X-ray system used to provide digital X-ray images of surgical and core biopsy specimens from various anatomical regions in order to allow rapid verification that the correct tissue has been excised during the procedure.

Doing the verification in the same room as the procedure or nearby improves workflow, thus reducing the overall operative time.

DEVICE CLAIMS – as required by 807.92(a)

The TrueView Core 100Pro-US has been designed to comply with the following standards and regulations:

- ANSI UL 61010-1 3rd Ed, dated May 12, 2012 with revision through July 19, 2019
- IEC 61010-2-091:2019
- IEC 61010-2-101:2018
- IEC 61326-1 Edition 3.0 2020-10
- IEC 61326-2-6 Edition 3.0 2020-10
- ISTA 3B-2017
- 21 CFR 1020.40

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

The TrueView Core 100Pro-US has the same indications for use and principles of operation, similar general configuration and operating parameters

to the predicate device cited. The technological characteristics of the TrueView Core 100Pro-US 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

	TrueView Core 100Pro-US Core Specimen Radiography System	TrueView 100 Pro Specimen Radiography System （K202713）
Indications for Use	A cabinet X-ray system used to provide digital X-ray images of surgical and core biopsy specimens from various anatomical regions in order to allow rapid verification that the correct tissue has been excised during the procedure. Doing the verification in the same room as the procedure or nearby improves workflow, thus reducing the overall operative time.	A cabinet X-ray system used to provide digital X-ray images of surgical and core biopsy specimens from various anatomical regions in order to allow rapid verification that the correct tissue has been excised during the biopsy procedure. Doing the verification in the same room as the procedure or nearby improves workflow, thus reducing the time the patient needs to be under examination.
principle of operation	X-ray imaging principle	X-ray imaging principle
Level of Concern	Moderate	Moderate
Method of Use	Cabinet X-ray system used for imaging biopsy and surgical specimens	Cabinet X-ray system used for imaging biopsy and surgical specimens
Mechanism of Action	Sample verification: obtain correct margins, specimen of interest, etc.	Sample verification: obtain correct margins, specimen of interest, etc.
Construction	Fully integrated system with Under-Chassis	Fully integrated system with movable base casters
Size (W x D x H) (in.)	18.3 x 15 x 20.8	23.6 x 28.3 x 64.9
Detector	Active-pixel CMOS	Active-pixel CMOS

Technology		
Active Imaging Area Size	5.7cm×6.4cm	11.4 cm x 14.6 cm
Pixel Size	49.5 μm pixels	49.5 μm pixels
Limiting Spatial Resolution	10 lp/mm	10 lp/mm
Output Image	14-bit image data	14-bit image data
Display Monitor	2.1Mp High luminescence diagnostic monitor	2.3 MP High luminescence diagnostic monitor
Operating System	Windows 10	Windows10
User Interface	Integrated touch screen	Integrated touch screen, track pad
Energy Range	10-30 kV	20-50 kV
Anode Type	Tungsten	Tungsten
Tube Current	1 mA	1 mA
Exposure	Up to 20 mAs	Up to 20 mAs
Focal Spot Size	50 μm	50 μm
Manual	User selects kV and mAs	User selects kV and mAs
Auto	System determines optimum kV and mAs	System determines optimum kV and mAs
Time to Preview	< 20 seconds	< 20 seconds
Cycle Time	< 60 seconds	< 60 seconds
Safety Features	Door interlock, passcode key, fully shielded	Door interlock, passcode key, fully shielded
Indicators	Power, door open, ready, X-ray ON	Power, door open, ready, X-ray ON
Magnification	Specimen tray positions at 1.0x and 1.5x, autosensed	Specimen tray positions at 1.0x,1.5x and 2.0x, autosensed

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

The TrueView Core 100Pro-US successfully performed design control verification tests and validation tests.

The TrueView Core 100Pro-US complies with applicable IEC-61010 standards (general electrical safety including mechanical hazards plus particular standards for cabinet x-ray systems) and international EMC standards.

Compliance to IEC 61010 standards was demonstrated by a third-party test house, Intertek.

Additional bench testing, including functional testing and usability testing, was also performed on the TrueView Core 100Pro-US Core Specimen Radiography System.

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

SUBSTANTIAL EQUIVALENCE SUMMARY

The TrueView Core 100Pro-US has the same indications for use and principles of operation, similar general configuration and operating parameters to the predicate device cited. The technical characteristics of the TrueView Core 100Pro-US 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 TrueView Core 100Pro-US is safe and effective and substantially equivalent to the predicate device cited.