CompAI Healthcare (Shenzhen) Co., Ltd.
% Wang Yan
QARA Manager
8B, Huangting Building, No.355, Fuhua Road,
Futian Street, Futian District
Shenzhen, Guangdong 518026
CHINA

November 18, 2020

Re: K202713
Trade/Device Name: TrueView 100 Pro Specimen Radiography System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MWP
Dated: September 8, 2020
Received: September 16, 2020

Dear Wang Yan:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K202713

Device Name
TrueView 100 Pro Specimen Radiography System

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 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.

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

TrueView 100 Pro
Specimen Radiography System

510(k) Summary

K202713

Date Prepared:	August 18, 2020
Manufacturer:	CompAI Healthcare (Shenzhen) Co.,ltd 8B,Huangting Building, No.355, Fuhua Road,Futian Street,Futian District, Shenzhen, P.R.China
Contact Person:	Wang Yan QARA Manager CompAI Healthcare (Shenzhen) Co.,ltd +86 512 67236750 yan.wang@comp-ai.com

Identification of the Device:

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

Identification of the Legally Marketed Predicate Device:

Trade Name:	Trident® HD 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:	Hologic, Inc.
Clearance:	K182727 (cleared January 10, 2019)

Device Description:

The TrueView 100 Pro is a self-contained, direct digital imaging system for imaging surgical and biopsy specimens. The TrueView 100 Pro includes the following major components: a system monitor, touch-screen display, a touchpad, and an imaging cabinet.

The system is self-contained. Shielding is incorporated within the cabinet chamber system design, eliminating the need for separate shielding. The unit is mounted on casters to allow for easy transportation.

Dedicated specimen radiography systems are intended for use in the following environments:

• The surgical suite
• The stereotactic biopsy suite
• The pathology lab

Specimen radiography units are utilized to confirm removal of the intended tissue, lesion, or site marker in surgical and core biopsy specimens from various anatomical regions. By generating a high-resolution X-ray of the specimen, the presence of a lesion or calcification in the extracted sample can be confirmed by the user reviewing the digital image.

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 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.

Standards:

- IEC 61010-1:2010 – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 1: General Requirements
- IEC 61010-2-091:2012 – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use, Part 2-091: Particular Requirements for Cabinet X-ray Systems
- IEC6101-2-101:2018 – Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
- EN 61326-1:2013 – Electrical Equipment for Measurement, Control, and Laboratory Use – EMC Requirements, General Requirements
- EN 61326-2-6:2013 – Electrical Equipment for Measurement, Control, and Laboratory Use – Part 2-6: Particular requirements for in vitro diagnostic (IVD) medical equipment
- EN 55011 (Class A) – Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment – Electromagnetic Disturbance Characteristics – Limits and Methods of Measurement

- ISO 14971: 2019 – Medical devices – Application of Risk Management to Medical Devices
- IEC 62366-1:2015 – Medical devices - Part 1: Application of usability engineering to medical devices
- IEC 62304:2006/AMD1:2015 – Medical device software - Software life cycle processes

FDA Guidance Documents:

- "Applying Human Factors and Usability Engineering to Medical Devices," issued on February 3, 2016
- "Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices," issued on September 1, 2016
- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," issued on May 11, 2005
- "Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software," issued on January 14, 2005
- "Off-the-Shelf Software Use in Medical Devices," issued on September 9, 2019
- "Compliance Guide for Cabinet X-Ray Systems" issued on September 19, 2007
- Format for Traditional and Abbreviated 510(k)s Guidance for Industry and Food and Drug Administration Staff

Comparison with Predicate Device:

The TrueView 100 Pro and its predicate device, the Trident® HD Specimen Radiography System, have the same intended use, general configuration, principles of operation, and operating parameters.

Substantial Equivalence:

The TrueView 100 Pro Specimen Radiography System employs the same fundamental scientific technology as its predicate devices, as below table:

	Trident® HD Specimen Radiography System Predicate (K182727)	TrueView 100 Pro Specimen Radiography System Proposed	Comparison
Indications for Use	A cabinet X-ray system used to provide digital X-ray	A cabinet X-ray system used to provide digital X-ray	Same

	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.	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	Same
Level of Concern	Moderate	Moderate	Same
Method of Use	Cabinet X-ray system used for imaging small to large biopsy and surgical specimens	Cabinet X-ray system used for imaging small to large biopsy and surgical specimens	Same
Mechanism of Action	Sample verification: obtain correct margins, specimen of interest, etc.	Sample verification: obtain correct margins, specimen of interest, etc.	Same
Physical			
Construction	Fully integrated system with movable base casters	Fully integrated system with movable base casters	Similar; designed for ease of use and transportation
Size	24 x 26 x 66.5	23.6 x 28.3 x 64.9	Similar; slim

(W x D x H) (in.)			design for ease of use and transportation
Digital Image Receptor			
Detector Technology	TFT-based direct capture technology	Active-pixel CMOS	Different
Active Imaging Area Size	12 cm x 14 cm (MFD) 20 cm x 20 cm (HDT)	11.4 cm x 14.6 cm	Trident® HD is available with two detectors for variety in image size and preference
Pixel Size	70 µm pixels	49.5 µm pixels	Similar, TrueView 100 Pro pixel size is 29% smaller
Limiting Spatial Resolution	7.1 lp/mm	10 lp/mm	Similar, TrueView 100 Pro has 41% more line pairs per mm.
Output Image	14-bit image data	14-bit image data	Same
Acquisition Workstation			
Display Monitor	2 MP High luminescence diagnostic monitor	2.3 MP High luminescence diagnostic monitor	Similar, TrueView 100 Pro slightly improved resolution
Operating System	Windows 10	Windows10	Same
User Interface	Integrated touch screen, track pad	Integrated touch screen, track pad	Same
X-ray Source			
Energy Range	20-50 kV	20-50 kV	Same
Anode Type	Tungsten	Tungsten	Same
Tube Current	1 mA	1 mA	Same
Exposure	Up to 20 mAs	Up to 20 mAs	Same
Focal Spot Size	50 µm	50 µm	Same

Exposure Modes			
Manual	User selects kV and mAs	User selects kV and mAs	Same
Auto	System determines optimum kV and mAs	System determines optimum kV and mAs	Same
System Performance			
Time to Preview	< 20 seconds	< 20 seconds	Same
Cycle Time	< 60 seconds	< 60 seconds	Same
Cabinet			
Safety Features	Door interlock, passcode key, fully shielded	Door interlock, passcode key, fully shielded	Same
Indicators	Power, door open, ready, X-ray ON	Power, door open, ready, X-ray ON	Same
Magnification	Specimen tray positions at 1.5x and 2.0x, autosensed	Specimen tray positions at 1.5x and 2.0x, autosensed	Same

Summary of Testing:

Summary of Non-Clinical Tests:

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)
- Simulated use testing (Validation)

The TrueView 100 Pro successfully performed system design control verification and validation tests, which are summarized in accordance with FDA's Guidance for the Content of Premarket Submissions for Software

Contained in Medical Devices (issued May 11, 2005) based on a moderate level of concern.
The TrueView 100 Pro complies with IEC 61010 standards, as performed by the third-party test house, Intertek. No clinical studies have been performed. Substantial equivalence has been demonstrated by nonclinical testing. Additional bench testing, including functional testing and usability testing, was also performed on the TrueView 100 Pro Specimen Radiography System. The comparative and other performance testing showed that the overall system demonstrated equivalent performance and equivalent safety and effectiveness as the predicate Trident® HD system (K182727).

Summary of Clinical Tests:
The subject of this premarket submission, The TrueView 100 Pro, did not require clinical studies to support substantial equivalence.

Conclusion:
Based on the information submitted in this premarket notification, The TrueView 100 Pro is substantially equivalent to the Trident® HD system (K182727). The design, operation, basic construction, and materials used are substantially equivalent to the predicate device. CompAI Healthcare considers the TrueView 100 Pro to be as safe, as effective, and with performance substantially equivalent to the predicate device(s).