January 10, 2019

Hologic, Inc.
% Meghan Wakeford
Regulatory Affairs Specialist
36 Apple Ridge Road
DANBURY CT 06810

Re: K182727
Trade/Device Name: Trident HD Specimen Radiography System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: MWP
Dated: December 11, 2018
Received: December 13, 2018

Dear Ms. Wakeford:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

Device Name
Trident HD 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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Traditional 510(k) Summary

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

Date Prepared: December 11, 2018

Manufacturer: Hologic, Inc.
36 Apple Ridge Road
Danbury, CT 06810 USA

Establishment Registration #: 1220984

Contact Person: Meghan Wakeford
Regulatory Affairs Specialist
P: 203.702.7819

Identification of the Device:

Proprietary/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

Identification of the Legally Marketed Predicate Device:

Trade Name:	Trident® 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:	K111508 (cleared August 19, 2011)

Device Description:

The Trident® HD Specimen Radiography System is a self-contained, direct digital imaging system for imaging surgical and biopsy specimens. The Trident® HD system includes the following major components: an image display monitor, touch-screen control display, 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:
- UL 61010-1:2012 – Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use; Part 1: General Requirements
- 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
- EN 61326-1:2013 – Electrical Equipment for Measurement, Control, and Laboratory Use – EMC Requirements, General Requirements
- EN 55011 and CISPR 11 (Class A) – Industrial, Scientific and Medical (ISM) Radio-Frequency Equipment – Electromagnetic Disturbance Characteristics – Limits and Methods of Measurement
- ISO 14971: 2012 – Medical devices – Application of Risk Management to Medical Devices

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
- "Radio Frequency Wireless Technology in Medical Devices," issued on August 14, 2013
- "Off-the-Shelf Software Use in Medical Devices," issued on September 9, 1999

Comparison with Predicate Device:
The Trident® HD System and its predicate device, the Trident® Specimen Radiography System, have the same intended use, general configuration, principles of operation, and operating parameters.

Substantial Equivalence:

	Trident® Specimen Radiography System Predicate (K111508)	Trident® HD Specimen Radiography System Proposed	Comparison
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.	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.	Same
Level of Concern	Moderate	Moderate	Same
Method of Use	Cabinet X-ray system used for imaging small to medium biopsy and surgical specimens	Cabinet X-ray system used for imaging small to large biopsy and surgical specimens	Expanded specimen size capabilities with larger detector
Mechanism of Action	Sample verification: obtain correct margins, specimen of interest, etc.	Sample verification: obtain correct margins, specimen of interest, etc.	Same
Physical			
Construction	Shielded cabinet on moveable cart	Fully integrated system with movable base casters	Similar; redesigned for ease of use and transportation
Size (W x D x H) (in.)	26.5 x 37.5 x 68.3	24 x 26 x 66.5	Similar; reduced footprint for ease of use and transportation
Weight (lb.)	275 325 with UPS	278 (with MFD) 291 (with HDT)	Similar; minor weight changes due to design change
Digital Image Receptor			
Detector Technology	TFT-based direct capture technology	TFT-based direct capture technology	Same
X-ray Absorption Material	Amorphous selenium	Amorphous selenium	Same
Active Imaging Area Size	12 cm x 14 cm	12 cm x 14 cm (MFD) 20 cm x 20 cm (HDT)	Trident® HD is available with two

			detectors for variety in image size and preference
Digital Detector	Detector used on predicate, K111508, was approved for use with the Selenia FFDM system, in P010025.	MFD used on the Affirm Prone Biopsy System, cleared under K153486. HDT used on the Selenia Dimensions systems, approved in P010025/S013 and P080003.	Both the predicate and the proposed devices use detectors cleared/approved for use with Hologic digital mammography and biopsy systems.
Pixel Size	70 µm pixels	70 µm pixels	Same
Limiting Spatial Resolution	7.1 lp/mm	7.1 lp/mm	Same
Output Image	14-bit image data	14-bit image data	Same
Image Enhancement	Enhanced visualization adjustment for image sharpness	Enhanced visualization adjustment for image sharpness	Same
Acquisition Workstation			
Display Monitor	2.3 MP color LCD display	2 MP High luminescence diagnostic monitor	Similar
Operating System	Windows 7	Windows 10	Similar; both the predicate and proposed devices use Windows OS
DICOM Services	Worklist, print, storage	Worklist, print, storage, query retrieve	Similar; increased DICOM capabilities through ability to pull priors
User Interface	Keyboard, mouse	Integrated touch screen, track pad	Improved for ease of use
X-ray Source			
Energy Range	20-35 kV	20-50 kV	Expanded upper range to support larger detector and imaging area
Anode Type	Tungsten	Tungsten	Same
Tube Current	1 mA	1 mA	Same
Exposure	Up to 10 mAs	Up to 20 mAs	Increase to support thicker specimen samples
Focal Spot Size	50 µm	50 µm	Same
Filtration	125 µm beryllium	200 µm beryllium	Larger target angle; larger image area
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	30 Seconds	< 60 seconds	Increased cycle time to support thicker specimen samples
Cabinet			
Safety Features	Door interlock, key switch, fully shielded	Door interlock, passcode key, fully shielded	Similar
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, auto-sensed	Specimen tray positions at 1.5x and 2.0x, auto-sensed	Same

Summary of Testing:
The Trident® HD system 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 Trident® HD system complies with IEC 61010 standards, as performed by the third-party test house, UL. No clinical studies have been performed. Substantial equivalence has been demonstrated by non-clinical testing. Additional bench testing, including functional testing and usability testing, was also performed on the Trident® HD system. The comparative and other performance testing showed that the overall system demonstrated equivalent performance and equivalent safety and effectiveness as the predicate Trident® Specimen Radiography System (K111508).

Conclusion:
Based on the information submitted in this premarket notification, The Trident® HD system is substantially equivalent to the Trident® system (K111508). The design, operation, basic construction and materials used are substantially equivalent to the predicate device.