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

July 11, 2019

Re: K190694
Trade/Device Name: Unifi™ Workspace v1.0.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 6, 2019
Received: June 18, 2019

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/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)*
K190694

Device Name
Unifi™ Workspace v1.0.0

Indications for Use *(Describe)*

Unifi Workspace is a software application that is intended for use in receiving, processing, manipulating, displaying, printing, and archiving mammography images as well as other medical images and data (e.g. US and MR). Images and data can be stored, communicated, and displayed within the system or across computer systems. Unifi Workspace provides various image processing and measurement tools to facilitate the interpretation of mammography X-ray, breast tomosynthesis, and other multimodality DICOM medical images and enable diagnosis. Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared monitor that meets technical specifications reviewed and accepted by the FDA.

Unifi Workspace is typically used by trained professionals, including radiologists, oncologists, surgeons, technologists, and clinicians and may provide information to be used for screening and diagnostic procedures.

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."

Traditional 510(k) Summary

K190694

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

Date Prepared: July 9, 2019

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:	Unifi™ Workspace v1.0.0
Classification Name:	Picture archiving and communication system
Regulatory Number:	21 CFR 892.2050
Product Code:	LLZ
Device Class:	Class II
Review Panel:	Radiology

Identification of the Legally Marketed Predicate Device:

Trade Name:	Prima
Classification Name:	Picture archiving and communication system
Regulatory Number:	21 CFR 892.2050
Product Code:	LLZ
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	Hologic, Inc.
Clearance:	K140960 (cleared June 13, 2014)

The legally marketed predicate device, Prima, has not been subject to a design-related recall.

Identification of the Legally Marketed Reference Devices:

Trade Name:	SecurView DX
Classification Name:	Picture archiving and communication system
Regulatory Number:	21 CFR 892.2050
Produce Code:	LLZ
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	Hologic, Inc.
Clearance:	K103385 (cleared February 2, 2011)

Trade Name:	MultiView
Classification Name:	Picture archiving and communication system
Regulatory Number:	21 CFR 892.2050
Produce Code:	LLZ
Device Class:	Class II

Review Panel:	Radiology
Submitter/510(k) Holder:	Hologic, Inc.
Clearance:	K132316 (cleared October 30, 2013)

The legally marketed reference device, SecurView DX, was subject to a design-related recall in 2012. The software of the reference device is independent of the proposed device, and the software defects noted in the recall do not impact the safety or effectiveness of the subject device. The other legally marketed reference device, MultiView, has not been subject to a design-related recall.

Device Description:
Unifi™ Workspace is a multi-modality software application that can be used for processing and displaying mammography x-ray, breast tomosynthesis, and other multimodality DICOM medical images for reference and diagnostic use by physicians and medical professionals.

Indications for Use:
Unifi™ Workspace is a software application that is intended for use in receiving, processing, manipulating, displaying, printing, and archiving mammography images as well as other medical images and data (e.g. US and MR). Images and data can be stored, communicated, and displayed within the system or across computer systems. Unifi Workspace provides various image processing and measurement tools to facilitate the interpretation of mammography x-ray, breast tomosynthesis, and other multimodality DICOM medical images and enable diagnosis. Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared monitor that meets technical specifications reviewed and accepted by the FDA.

Unifi™ Workspace is typically used by trained professionals, including radiologists, oncologists, surgeons, technologists, and clinicians and may provide information to be used for screening and diagnostic procedures.

Standards:
- IEC 62304: 2006 – Medical device software – Software Life Cycle Processes
- ISO 14971: 2012 – Medical devices – Application of Risk Management to Medical Devices

FDA Guidance Documents:
- "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," issued on July 28, 2014
- "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
- "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," issued on October 2, 2014
- "Applying Human Factors and Usability Engineering to Medical Devices," issued on February 3, 2016
- "Off-the-Shelf Software Use in Medical Devices," issued on September 9, 1999
- "Design Considerations and Pre-Market Submission Recommendations for Interoperable Medical Devices," issued on September 6, 2017

Comparison with Predicate Device:
The Unifi™ Workspace and its predicate device, Prima, have the same intended use. The proposed device has similar technological characteristics, application features, and operational use as the predicate device and reference devices, as noted in the comparison matrix below.

Substantial Equivalence:

	Prima Predicate (K140960)	SecurView DX Reference (K103385)	MultiView Reference (K132316)	Unifi™ Workspace Proposed	Comparison
Indications for Use	Prima is a software application that is intended for use in receiving, processing, manipulating, displaying, printing, and archiving mammography images as well as other medical images and data (e.g. US and MR). Images and data can be stored, communicated, and displayed within the system or across computer systems. Unifi Workspace provides various image processing and measurement tools to facilitate the interpretation of mammography x-ray, breast tomosynthesis, and other multimodality DICOM medical images and enable diagnosis. Lossy	The Hologic SecurView DX is intended for selection, display, manipulation, filming and media interchange of multi-modality images from a variety of different modality systems. It also interfaces to various image storage and printing devices using DICOM or similar interface standards. The device may be used by a trained physician for display, manipulation and interpretation of lossless compressed or non-compressed mammographic images using FDA cleared displays for screening and diagnostic mammography, as well as any other	MultiView is a software application that is intended for use in processing, manipulating, and displaying magnetic resonance imaging (MRI) images as well as other multi-modality DICOM medical images and data that it receives from various sources (e.g. CT, US, secondary capture devices, scanners, imaging sources, and imaging gateways). MultiView provides various image processing and measurement tools to facilitate the interpretation of breast MRI images and enable diagnosis. These computer-aided and/or user-defined processing functions	Unifi Workspace is a software application that is intended for use in receiving, processing, manipulating, displaying, printing, and archiving mammography images as well as other medical images and data (e.g. US and MR). Images and data can be stored, communicated, and displayed within the system or across computer systems. Unifi Workspace provides various image processing and measurement tools to facilitate the interpretation of mammography x-ray, breast tomosynthesis, and other multimodality DICOM medical images and enable	Same as predicate.

	compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared monitor that meets technical specifications reviewed and accepted by the FDA. Prima is typically used by trained professionals, including radiologists, oncologists, surgeons, technologists, and clinicians and may provide information to be used for screening and diagnostic procedures.	DICOM multi-modality image. The SecurView DX software is typically used by trained professionals, including, but not limited to physicians, radiologists, nurses, medical technicians and assistants.	include artifact minimization, image subtractions, multi-planar reformats, and maximum intensity projections. It also includes the following automatic functions: physiological analysis tools, diffusions analysis, and segmenting of lesions. MultiView also provides tools for automated targeting for breast interventional procedures. Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared monitor that meets technical specifications reviewed and accepted by the FDA.	diagnosis. Lossy compressed mammographic images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA cleared monitor that meets technical specifications reviewed and accepted by the FDA. Unifi Workspace is typically used by trained professionals, including radiologists, oncologists, surgeons, technologists, and clinicians and may provide information to be used for screening and diagnostic procedures.	

			MultiView is typically used by trained professionals, including radiologists, technologists and clinicians and may provide information to be used for screening, diagnostic and interventional procedures. Patient management decisions should not be made solely on the results of MultiView analysis.		
Level of Concern	Moderate	Moderate	Moderate	Moderate	Same
Method of Use	Multi-modality workstation that provides various image processing and measurement tools to facilitate diagnostic and non-diagnostic viewing capabilities.	Breast imaging workstation that provides various image processing and measurement tools to facilitate diagnostic and non-diagnostic viewing capabilities.	Multi-modality workstation that provides various image processing and measurement tools to facilitate diagnostic and non-diagnostic viewing capabilities.	Multi-modality workstation that provides various image processing and measurement tools to facilitate diagnostic and non-diagnostic viewing capabilities.	Same as predicate
Mechanism of Action	Viewing, patient management, study data management	Viewing, patient management, study data management	Viewing, patient management, study data management	Viewing, patient management, study data management	Same
Operating System	Windows 7	Windows 7	Windows 7	Windows 10	Similar; both the predicate and proposed devices use Windows OS
System Access	Web-based, hosted	Local application	Local application, or web-based	Local application	Proposed software removed web-based capabilities compared to the predicate

Support for image display on mobile devices	Yes	No	Yes	No	Proposed software does not support display on mobile devices as compared to the predicate
Modalities supported on display	US, MR, MG, BTO, DR, CR, SC, CT, and other DICOM formats	US, MR, MG, BTO, DR, CR, SC, CT and other DICOM formats (with Multi-Modality Viewer add-on)	MR, CT, US, SC, and other DICOM formats	US, MR, MG, BTO, DR, CR, SC, CT, and other DICOM formats	Same as predicate
DICOM Input for Medical Images	Accept and display any valid DICOM-standard object	Accept and display any valid DICOM-standard object	Accept and display any valid DICOM-standard object	Accept and display any valid DICOM-standard object	Same as predicate
Tomosynthesis image display	Support for all available BTO images	Support for all available BTO images	N/A	Support for all available BTO images	Same as predicate
CAD support	No	Yes	No	Yes	Proposed device accepts Mammography CAD SR objects produced by ImageChecker CAD (P970058) or other applications; same as SecurView (K103385).
Image viewing and manipulation tools	Window/Level, Pan, Zoom, Invert, Flip, Rotate, View/Create Annotations, Scrolling, Cine, Measurement, Magnify, Link data sets	Window/Level, Pan, Zoom, Invert, Magnify, View/Create Annotations, Scrolling, Cine, Measurement, Toggle Study/Patient Overlays, MIP, Intelligent Roaming	Window/Level, Pan, Zoom, Invert, Flip, Rotate, Create Annotations, Show/Hide Text Overlay, Probe Tool, Set, Cine, Stack, Radial Stacking, Rotate, Link data sets, Measurement,	Window/Level, Pan, Zoom, Invert, Flip, Rotate, View/Create Annotations, Scrolling, Cine, Measurement, Magnify, Link data sets, Sizing mode control, Toggle Study/Patient Overlays, Reset,	Similar: the standard features for image review of the proposed device are similar to tools available in the predicate and reference devices.

			Scrolling, Identify ROI, MIP	Display text overlays, MIP, Intelligent Roaming	
MR Image Processing	Features not included	N/A	Motion Correction DCE Semi-Quantitative Colorization	Motion Correction DCE Semi-Quantitative Colorization	Image processing tools of the MR Module for proposed device are the same features present in the reference device, MultiView (K132316).
Application Synchronization Support	Yes	Yes	Yes	Yes	Same

Summary of Testing:
Hologic, Inc. successfully performed system design control verification and validation tests for the proposed Unifi Workspace device, 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.

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 Unifi™ Workspace. The comparative and other performance testing showed that the overall system demonstrated equivalent performance and equivalent safety and effectiveness as the predicate (Prima K140960), as well as reference devices (SecurView DX (K103385) and MultiView (K132316)) for specific application features.

Conclusion:
Based on the information submitted in this premarket notification, Unifi™ Workspace is substantially equivalent to the predicate, Prima (K140960). The intended use, technological characteristics, and operational use are substantially equivalent to the predicate device.