JUN 13 2014

K 140960
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510(k) Summary

Trade Name: Prima

Product Classification Name: Picture archiving and communication system

Product Classification Code: LLZ **CFR Section:** 892.2050

Classification Panel: Radiology **Class** II

Manufacturer: Hologic, Inc.
35 Crosby Drive
Bedford, MA 01730 USA

Contact Person: Gail Yaeker-Daunis
Telephone Number: (203) 731-8337
Fax Number: (203) 731-8440

Date Prepared: April 14, 2014

Predicate Devices: SecurView DX K103385
ASTRA K111694

Predicate Device Description:

The **SecurView DX** cleared as K103385 is mainly a software product. It is used for visualization and manipulation of digital radiology images. The SecurView DX is a multi-modality review workstation software focused on mammographic applications. The software can drive high-resolution displays (FDA cleared for Mammography), a PC mouse, a keyboard, optional lower resolution monitors and dedicated workflow keypad. The software accepts standard or multi-frame mammography images that have been created according to the "FOR PRESENTATION" specification of the DICOM Standard with no compression or using lossless compression. Image processing is external to the SecurView DX software. The software accepts standard or multi-frame multimodality images of US, MR, DR, CR, SC, CT, PET, and other DICOM formats for display and manipulation on high resolution displays (FDA cleared for mammography) or on other lower resolution color displays in 2-D or 3-D view. The SecurView DX software can be used in a single or in a multi-workstation configuration.

ASTRA cleared as K111694 is a web-enabled software application that provides image processing and viewing tools and access to studies and reports from a Local Area Network, Wide Area Network, remote workstation, personal computer, or an iPhone, or iPad via a Virtual Private Network connection. Diagnosis is not performed by the software but by Radiologists, Clinicians or referring Physicians. The software application conforms

to the DICOM 3.0 standard to allow interoperability with other DICOM compliant systems.

Comparison with Predicate Devices:

Prima software application is similar to SecurView DX (K103385) as both devices are software and share the same technological characteristics. Both devices process and display DICOM mammography and multimodality images for reference and diagnostic use by medical professionals and physicians.

Prima like ASTRA (K111694) can be used in a web-environment where the software application provides image processing, viewing tools and access to studies and reports over a Local Area Network or Wide Area Network, to a remote workstation, personal computer, or other web capable device.

Intended 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. Prima 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.

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.

Technological Characteristics:

The device is a software application similar to the predicate devices and does not contact the patient. The Prima software runs on a Windows Operating System as does SecurView DX and ASTRA. Images and information are stored, transferred and viewed on a variety of image storage and viewing hardware, i.e., PACS Systems, RIS, and softcopy workstations as does SecurView DX. Prima images and data can also be accessed by personal computers and other devices through internet access which is similar to ASTRA

Safety and Effectiveness Concerns:

Prima is designed and manufactured in accordance with the following standards:

- ISO 13845 Medical Devices – Quality management Systems
- ISO 14971 Medical Devices – Application of Risk Management

- IEC 62304 Medical Device Software Life Cycle Process
- 21 CFR Part 820 – Quality System Regulations

The performance of the software was tested in accordance with Hologic's design control procedures to demonstrate intended performance. Potential hazards are controlled via risk management processes and verification and validation testing. Testing was successfully conducted and demonstrates that Prima meets all of its functional requirements and specifications. Instructions for use are provided to facilitate intended operation.

Conclusion:

The Prima software application and the predicate devices share similar intended use, technical characteristics and performance standards. Potential hazards have been studied and controlled by a Risk Management Plan. Based on the information supplied in this 510(k), Prima is safe, effective and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 13, 2014

Hologic, Inc.
% Ms. Gail Yaeker-Daunis
Sr. Regulatory Affairs Specialist
35 Crosby Drive
BEDFORD MA 01730

Re: K140960
Trade/Device Name: Prima
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 16, 2014
Received: April 17, 2014

Dear Ms. Yaeker-Daunis:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K140960

Device Name
Prima

Indications for Use *(Describe)*
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. Prima 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.

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*