510(k) Summary
SecurView DX

FEB - 2 2011

Product Name: **SecurView DX**

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

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Date Prepared: January 5, 2011

Predicate Device: **K062107 SecurView DX, Hologic Inc.**

Predicate Device Description:

The Hologic SecurView DX 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.

The minimum computer requirements to run the SecurView DX software are:

- Windows Operating System
- Intel CPU with a clock rate of 2.0 GHz or greater
- 2.0 GB RAM or greater
- 140 GB Hard drive or greater, operating at 160 Mb/s or greater
- CD-ROM/R
- 10/100 Base -T Network Interface

Intended Use:

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 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.

Comparison with Predicate Device:

The modified SecurView DX is substantially equivalent to the SecurView DX previously cleared as **K062107** as described above and has the same indications and intended use.

The comparison table below shows that the modified SecurView DX is substantially equivalent to the predicate with the exception of the following features:

- Ability to run on both Windows XP or Windows 7 or higher Operating System
- Ability to display information or images calculated by separate medical devices cleared by FDA, such as: AIE Region of Interest Image Enhancement for Digital Mammography software, cleared as K062059.

COMPARISON TABLE

Hardware	SecurView DX K062107	**Modified Device**
Processor	Dual Processor Intel CPU with clock rate of 2.0 GHz or higher	**Same**
Memory	2.0 GB RAM	**Same** or greater
Hard Disks	140 GB total	**Same** or greater
Display	Multiple display systems (display with graphics controller) which has been FDA cleared for mammography specific medical diagnostic applications & Optional Color High Contrast Display for multimodality image review other than mammography	**Same** Multiple display systems (displays and graphics controllers) which have been FDA cleared for mammography specific medical diagnostic applications and optional additional displays for multimodality image review other than mammography
Networking	Network Interface Card (NIC) 10/100 Base-T	**Same** or greater
Removable Media	CD-ROM/R	**Same** or greater
Keypad	Custom keypad single click access to commonly used features	**Same**
Operating System	Windows XP	**Same** (Windows XP) or higher, Windows 7
Memory	2.0 GB RAM	**Same** or greater
Hard Disks	140 GB total	**Same** or greater

Software	SecurView DX K062107	Modified SecurView DX
Administrative functions	A menu exists for administrator use which includes access to functions such as: • User account administration • Setting system wide defaults • Patient List administration	**Same**
Service functions	A menu exists for a service user which includes access to functions such as: • DICOM settings • License administration	**Same**
User Preference selection	A menu exists for radiologist users which includes access to functions such as: • Setting individual preferences • Setting personal workflow and Reportflows (series of configurable hanging snapshots created as user preferences and associated with different types of studies	**Same**
Receiving Exams	Images are transmitted to the SecurView DX software according to the DICOM standard. Modalities supported include: MG, MR, US, CT, SC, CR, PET, DR, and multiframe mammography images After an exam has been received by the software, an entry is added to the patient list.	**Same**
Viewing Exams	All exams which are stored on the system appear in a patient list. The user selects exams from this list for viewing.	**Same**
Printing	Images can be printed on DICOM printers.	**Same**

PACS Archive Connectivity	The system can perform a Query/Retrieve operation on a DICOM archive to retrieve studies of interest	**Same**
Image viewing tools	The software provides tools for image viewing and manipulation such as: • Window / Level • Magnification Window • Display at variable resolutions • Image Pan • Rotation • Mirroring • Image inversion • Display of CAD results • Display of patient demographic information Multimodality Viewer has cine mode tools for multiframe images, breast MR CAD analysis tools and breast MR motion correction	**Same** with addition of ability to display information or images calculated by separate medical devices cleared by FDA, such as: • AIE Region of Interest Image Enhancement for Digital Mammography software, cleared as K062059
Annotation and Measurement tools	The software provides tools for: • Free hand drawing • Ellipse drawing • Ability to add textual annotations • Ability to measure features	**Same**
Send GSPS or SC images to other DICOM nodes	The system can send grayscale softcopy presentation state (GSPS) objects or secondary capture DICOM images to other DICOM nodes	**Same**
Export Image	Capable of export to local storage in TIFF format de-identified such that image file content contains no patient identifying information Capable of exporting DICOM format images.	**Same**
Application Synchronization and Data Exchange	Provides synchronization interface to synchronize patient and patient data with external applications such as RIS, data tracking systems, dictation systems, etc.	**Same**

Safety and Effectiveness - Performance Standards:

The SecurView DX software is specified, validated and tested by Hologic, Inc., under a registered ISO 13485 and 21 CFR Part 820 Quality System.

The SecurView DX software conforms to the ACR/NEMA Digital Imaging Communications in Medicine PS 3 (DICOM) Standard. Hologic publishes a DICOM Conformance Statement.

A comprehensive Operator's Manual is provided with each system, to facilitate intended operation.

Conclusion:

The modified SecurView DX software is substantially equivalent to the predicate software in terms of intended use, indications of use and conformance to the DICOM standard. The SecurView DX software changes were specified, validated and tested by Hologic, Inc., under an ISO 13485 and 21 CFR Part 820 Quality System. The following quality assurance measures were applied to the device software modification:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- System Verification
- System Validation

The modified software has successfully undergone bench testing designed to simulate clinical factors.

Based on the information supplied in this 510(k), Hologic concludes that the modified device is substantially equivalent to the predicate device and is safe and effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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FEB - 2 2011

Re: K103385
Trade/Device Name: SecurView DX
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 10, 2011
Received: January 12, 2011

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary Pastel, ScD.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications For Use

Premarket Notification: SecurView DX

510(k) No. K103385

Device Name: **SecurView DX**

Indications For Use

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510K Number K103385