K 132532

DEC - 9 2013

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

I. GENERAL INFORMATION

Establishment:

- Address: Siemens AG, Medical Solutions
  Henkestrasse 127
  D-91052 Erlangen
  Germany
- Registration Number: 3002808157
- Contact Person: Viktoria Benz
  Regulatory Affairs Manager
  Telephone: +49 (9131) 84-4483
  Telefax: +49 (9131) 84-8691

Device Name and Classification:

- Trade Name: *syngo*.plaza VB10A
- Classification Name: Picture Archiving and Communications System
- Classification Panel: Radiology
- CFR Section: 21 CFR §892.2050
- Device Class: Class II
- Product Code: LLZ

II. SAFETY AND EFFECTIVENESS INFORMATION SUPPORTING THE SUBSTANTIAL EQUIVALENCE DETERMINATION

Device Description and Intended Use:
syngo.plaza is a Picture Archiving and Communication System intended to display, process, read, report, communicate, distribute, store, and archive digital medical images, including mammographic images.
It supports the physician in diagnosis and treatment planning.

For primary image diagnosis in Mammography only uncompressed or non-lossy compressed images and only preprocessed DICOM "For Presentation" images must be used. Also monitors (displays) and printers which received FDA clearance for Mammography must be used.
syngo.plaza also supports DICOM Structured Reports.

In a comprehensive imaging suite, *syngo*.plaza integrates Hospital / Radiology Information Systems (HIS / RIS) to enable customer specific workflows.
syngo.plaza optionally uses a variety of advanced postprocessing applications.

Note:
Web-based image distribution is not intended for reporting.

Technological Characteristics:

syngo.plaza is a "software only"-system, which will be delivered on DVD to be installed on common IT hardware, matching the *syngo*.plaza hardware requirements.

syngo.plaza will be installed by Siemens implementation engineers.

The integration into customer specific IT environments is offered based on professional services. Updates / upgrades are offered based on service contracts and fulfilled by trained service technicians.

This is also applicable for the predicate device *syngo*.plaza VA20A (K101666).

The following matrix compares the functionality of the *syngo*.plaza VB10A to the predicate device *syngo*.plaza VA20A:

Functionality	*syngo*.plaza VB10A	*syngo*.plaza VA20A
Manufacturer	Siemens AG Medical Solutions	Siemens AG Medical Solutions
Intended Use	*syngo*.plaza is a Picture Archiving and Communication System intended to display, process, read, report, communicate, distribute, store, and archive digital medical images, including mammographic images. It supports the physician in diagnosis and treatment planning. For primary image diagnosis in Mammography only uncompressed or non-lossy compressed images and only preprocessed DICOM "For Presentation" images must be used. Also monitors (displays) and printers which received FDA clearance for Mammography must be used. *syngo*.plaza also supports DICOM Structured Reports. In a comprehensive imaging suite, *syngo*.plaza integrates Hospital / Radiological Information Systems (HIS / RIS) to enable customer specific workflows. *syngo*.plaza optionally uses a variety of advanced postprocessing applications. Note: Web-based image distribution is not intended for	*syngo*.plaza is a Picture Archiving and Communication System intended to display, process, read, report, communicate, distribute, store, and archive digital medical images, including mammographic images. It supports the physician in diagnosis and treatment planning. For primary image diagnosis in Mammography only uncompressed or non-lossy compressed images and only preprocessed DICOM "For Presentation" images must be used. Also monitors (displays) and printers which received FDA clearance for Mammography must be used. *syngo*.plaza also supports DICOM Structured Reports. In a comprehensive imaging suite, *syngo*.plaza integrates Hospital / Radiological Information Systems (HIS / RIS) to enable customer specific workflows. *syngo*.plaza optionally uses a variety of advanced postprocessing applications. Note: Web-based image distribution is not intended for

Functionality	*syngo*.plaza VB10A	*syngo*.plaza VA20A
	reporting.	reporting.
Image communication	Standard network protocols like TCP / IP and standard communication protocol DICOM. Additional fast image transfer protocol for use inside *syngo*.plaza VB10A	Standard network protocols like TCP / IP and standard communication protocol DICOM. Additional fast image transfer protocol for use inside *syngo*.plaza VA20A.
Image data compression	JPEG lossless with compression factor 2 to 3 on storage (RAID) and before archiving (e.g. on NAS) - Uncompressed – lossless JPEG - Lossless JPEG – lossless JPEG - Lossless JPEG 2000 – lossless JPEG 2000 - Lossy JPEG – displayed as received - RLE – displayed as received - MPEG-II support	JPEG lossless with compression factor 2 to 3 on storage (RAID) and before archiving (e.g. on NAS) - Uncompressed – lossless JPEG - Lossless JPEG – lossless JPEG - Lossless JPEG 2000 – lossless JPEG 2000 - Lossy JPEG – displayed as received - RLE – displayed as received - MPEG-II support
Image Short Term storage	Internal and External online storage on configurable RAID systems. Industrial standards apply.	Internal and External online storage on configurable RAID systems. Industrial standards apply.
Image Long Term storage	External archiving on external (not inside *syngo*.plaza) archiving to either NAS storage systems or to any external DICOM Long Term Archive. Industrial standards apply.	External archiving on external (not inside *syngo*.plaza) archiving devices (e.g. NAS and DVD-RAM). Industrial standards apply.
User administration	Centralized user administration	Centralized user administration

Functionality	*syngo*.plaza VB10A	*syngo*.plaza VA20A
OEM Interface	*syngo*.via[20]	EndoMap Expert-i *syngo*.x *syngo* MammoReport
User Interface	UI is one of the *syngo*.plaza VB10A workstation deployments.	UI is one of the *syngo*.plaza VA20A workstation deployments.
RIS com-munication	Via standards HL7 and DICOM, aligned to IHE Framework Rev.1.	Via standards HL7 and DICOM, aligned to IHE Framework Rev.9.
Hardware	Windows based, manufacturer independent Workstations	Windows based, manufacturer independent Workstations: PC based with Windows XP or Windows Vista;
Client Installation	*New*: Introduction of a client software distribution for syngo.plaza Reporting Clients	manual installation using MSI packages
Application package / workplace function-	*syngo* 3D Basic *syngo* 3D Advanced 3D VesselMetrix	*syngo* 3D Basic *syngo* 3D Advanced 3D VesselMetrix

[20] Via internal reorganization *syngo*.x was renamed to *syngo*.via.

Functionality	*syngo*.plaza VB10A	*syngo*.plaza VA20A
nality	Filming Teleradiology Patient Media Creation Workflow Support for Mammography Spine Labeling / Cross Reference Cardio Thoracic Ratio (CTR[10]) DSA Viewer New: Token view New: Smart Read feature New: Angle on Stack" functionality New: Patient ID	Filming Teleradiology Scanner Patient Media Creation *Workflow Support for Mammography* Spine Labeling / Triangulations Cardio Thoracic Ratio (CTR[10]) DSA Viewer
Image Processing features	Filming 3D Reconstruction 3D Vessel Metrix Rendering Workflow Support for mammography Spine Labeling / Cross Reference Cardio Thoracic Ratio (CTR[10]) DSA Viewer	Filming 3D Reconstruction 3D Vessel Metrix Rendering Workflow Support for mammography Spine Labeling / Triangulations Cardio Thoracic Ratio (CTR[10]) DSA Viewer

Functionality	*syngo*.plaza VB10A	*syngo*.plaza VA20A
Image Processing Algorithms	**Quantitative Algorithm** *In syngo.plaza 2D Image processing Library* Region Calculation (Mammography) (**calculated**: Minimum bounding Rect co-ordinates of the tissue area in an image based on pixel intensity) 3D Projection (Cross-Reference) (**calculated**: Co-ordinates of the projected points from one plane on other orthogonal planes) Statistical Algorithms for calculation of Average, Std Deviation, Minimum or Maximum pixel values (**calculated**: Statistical values based on image pixel intensity in a given ROI) Affine Transformation (Zoom/Pan/Rotate/Flip) (**calculated**: New position of the given point (x,y) of image in displayed window after performing any of the affine operation) *In syngo.plaza 2D Image processing Library* Region Calculation (Mammography) (**calculated**: Minimum bounding Rect co-ordinates of the tissue area in an image based on pixel intensity) 3D Projection (Cross-Reference) (**calculated**: Co-ordinates of the projected points from one plane on other orthogonal planes) Statistical Algorithms for calculation of Average, Std Deviation, Minimum or Maximum pixel values (**calculated**: Statistical values based on image pixel intensity in a given ROI) Affine Transformation (Zoom/Pan/Rotate/Flip) (**calculated**: New position of the given point (x,y) of	**Quantitative Algorithm** *In syngo.plaza 2D Image processing Library* Region Calculation (Mammography) (**calculated**: Minimum bounding Rect co-ordinates of the tissue area in an image based on pixel intensity) 3D Projection (Cross-Reference) (**calculated**: Co-ordinates of the projected points from one plane on other orthogonal planes) Statistical Algorithms for calculation of Average, Std Deviation, Minimum or Maximum pixel values (**calculated**: Statistical values based on image pixel intensity in a given ROI) Affine Transformation (Zoom/Pan/Rotate/Flip) (**calculated**: New position of the given point (x,y) of image in displayed window after performing any of the affine operation) *In syngo.plaza 2D Image processing Library* Region Calculation (Mammography) (**calculated**: Minimum bounding Rect co-ordinates of the tissue area in an image based on pixel intensity) 3D Projection (Cross-Reference) (**calculated**: Co-ordinates of the projected points from one plane on other orthogonal planes) Statistical Algorithms for calculation of Average, Std Deviation, Minimum or Maximum pixel values (**calculated**: Statistical values based on image pixel intensity in a given ROI) Affine Transformation (Zoom/Pan/Rotate/Flip) (**calculated**: New position of the given point (x,y) of

Functionality	*syngo*.plaza VB10A	*syngo*.plaza VA20A
	image in displayed window after performing any of the affine operation) Distance : Line Measurement between 2 points, calculation based on image pixel spacing value and the length of the line between start and end points Angle : The angle between the two lines measured in anti-clockwise direction Area: The calculation of area of Circle, Ellipse, Rectangle Perimeter: The calculation of perimeter for Circle, Rectangle: Average, Minimum and Maximum pixel value and Standard Deviation calculation for the pixels inside Circle, Ellipse and Distance line. Volume: no volume measurements in syngo.plaza **Rendering Algorithm** *In 3D application by Voxar* Multiplanar Reconstruction (**calculated**: Images in one plane are used to reconstruct images of other orthogonal planes) Maximum and Minimum Intensity Projection (**calculated**: Visualization of Maximum and minimum voxel values that are visible projected to parallel plane) Volume Rendering Technique (**calculated**: Visualization of 3D volume) Shaded Surface Display (**calculated**: Visualization of Surface rendered 3D volume) *In syngo.plaza 2D Image processing Library*	image in displayed window after performing any of the affine operation) Distance : Line Measurement between 2 points, calculation based on image pixel spacing value and the length of the line between start and end points Angle : The angle between the two lines measured in anti-clockwise direction Area: The calculation of area of Circle, Ellipse, Rectangle Perimeter: The calculation of perimeter for Circle, Rectangle: Average, Minimum and Maximum pixel value and Standard Deviation calculation for the pixels inside Circle, Ellipse and Distance line. Volume: no volume measurements in syngo.plaza **Rendering Algorithm** *In 3D application by Voxar* Multiplanar Reconstruction (**calculated**: Images in one plane are used to reconstruct images of other orthogonal planes) Maximum and Minimum Intensity Projection (**calculated**: Visualization of Maximum and minimum voxel values that are visible projected to parallel plane) Volume Rendering Technique (**calculated**: Visualization of 3D volume) Shaded Surface Display (**calculated**: Visualization of Surface rendered 3D volume) *In syngo.plaza 2D Image processing Library*

Functionality	*syngo*.plaza VB10A	*syngo*.plaza VA20A
	Nearest-Neighbour interpolation (Smoothing) (**calculated**: Estimated Pixel intensity based on nearest neighbour algorithm) Bilinear interpolation (Smoothing) (**calculated**: Estimated Pixel intensity based on bilinear algorithm) Bicubic interpolation (Smoothing) (**calculated**: Estimated Pixel intensity based on bicubic algorithm) 8-bit Greyscale image display using Windows GDI (**calculated**: Rendered pixel intensity on the screen co-ordinates) 24- bit colour Image display using Windows GDI (**calculated**: Rendered pixel intensity on the screen co-ordinates) Windowing and LUT Mapping (Windowing) (**calculated**: Pixel intensity transformation based on VOI LUT and Presentation LUT information and convert to raster format which can be rendered) Image subtraction (DSA) (**calculated**: Pixel intensity after subtracting the mask frame pixel intensity)	Nearest-Neighbour interpolation (Smoothing) (**calculated**: Estimated Pixel intensity based on nearest neighbour algorithm) Bilinear interpolation (Smoothing) (**calculated**: Estimated Pixel intensity based on bilinear algorithm) Bicubic interpolation (Smoothing) (**calculated**: Estimated Pixel intensity based on bicubic algorithm) 8-bit Greyscale image display using Windows GDI (**calculated**: Rendered pixel intensity on the screen co-ordinates) 24- bit colour Image display using Windows GDI (**calculated**: Rendered pixel intensity on the screen co-ordinates) Windowing and LUT Mapping (Windowing) (**calculated**: Pixel intensity transformation based on VOI LUT and Presentation LUT information and convert to raster format which can be rendered) Image subtraction (DSA) (**calculated**: Pixel intensity after subtracting the mask frame pixel intensity)
Introduction Warnings and Cautions	**WARNINGS** (Operator Manual) No warnings are applicable for the medical device *syngo*.plaza. The device is classified as Safety Class B according to IEC 62304. Therefore cautions are sufficient. The generic chapter in the introduction was	**WARNINGS** (Operator Manual) Warnings and cautions are specially marked in the documentation. The content of a Warning or a Caution is structured in three different sections: Cause, Consequence, Remedy. Warning indicates potential danger that could cause

Functionality	*syngo*.plaza VB10A	*syngo*.plaza VA20A
	adapted accordingly. There are no implications by the removing the warnings on the safe and proper use of the device. **CAUTIONS** The wording was improved for better understanding: Cautions are specially marked in the documentation. The content of a caution is structured in three different sections: Source of danger, Consequence, Countermeasure: CAUTION indicates potential risk that may result in minor physical injury or material damage. First, the source of danger is addressed! Then, possible consequences are described. Finally, measures are given to prevent a dangerous situation. To operate syngo.plaza safely, read the "Safety Advisory" chapters in the syngo.plaza Operator Manual - User Manual and in the syngo.plaza Operator Manual - Administrator Manual.	injury or death in extreme cases. First, the source of danger is addressed! **Then, possible consequences are described.** Finally, measures are given to prevent a dangerous situation. **CAUTIONS** Caution indicates potential (direct) danger that could cause minor injury or damage to the system First, the source of danger is addressed! **Then, possible consequences are described.** Finally, measures are given to prevent a dangerous situation. To operate syngo.plaza safely, read the "Safety Advisory" chapter in this document. In this chapter, you find a list of all relevant safety notices
User manual content Cautions	*Image Review* The wording was improved for better understanding: Use of Viewer setting 'Never save changes' on close Loss of findings when closing the study	*Image Review* The Viewer can be configured not to store image editing. Loss of data

Functionality	*syngo*.plaza VB10A	*syngo*.plaza VA20A
	• Make sure that the checkbox 'Never save changes to loaded images' is not selected in the Viewer Settings dialog box. - OR - • Click the Save Changes icon on the tool palette to save edited images despite the setting. *Receiving Images* n.a. anymore - removed for user manual as the related risk is mitigated per safe software design: See document Risk Analysis, RIM115291/mv300_risk_I-11.1: "The validation of the DICOM hierarchy is performed prior to storage when an image is received or imported." This risk mitigation performs a check if the received images are in a valid DICOM hierarchy (structure) with the software, it is not necessary any more that the user performs it. *Scanned Images* n.a. anymore - The scanner tab card has been removed from the VB10A application as the functionality is provided from other vendors. See VB10A User Manual statement "You can also import images in various formats (JPEG, BMP, TIFF) into your database, or scan hard copies with a connected scanner (digitizing)." *Write Lock* The wording was improved for better understanding:	• Make sure that the Never save changes to loaded images option is not activated in the Viewer settings. - OR - • Click the Save Changes icon in the tool palette to save edited images despite the setting. *Receiving Images* Incorrect structure generated in the image. Wrong diagnosis • Always perform a basic validation (syntactic and semantic check) when you receive images. *Scanned Images* Scanned images can be cropped before saving. Irreversible cropping of images • Before saving the images, make sure you will not need the original images. *Write Lock* Cancelling write lock on the server workplace manually. Loss of image modification data • Before cancelling the write lock, make sure that the client with write authorization is no longer editing the images. • You can find the name of the client with write authorization in the Host Name column in the Patient List.

Functionality	*syngo*.plaza VB10A	*syngo*.plaza VA20A
	Removing write lock on a series or study level manually. Loss of image modification data • Before unlocking the series or study, make sure that the user/client with write authorization is no longer editing the images. • You will find the name/hostname of the user/client with write lock authorization in the "Reserved by" column in the Patient List. *Archive Media* n.a. anymore - Archival is only allowed on NAS systems; CD/DVD is not intended as archive media *Displayed Patient Data* n.a. anymore - removed for user manual, the related risk is mitigated per safe software design: See document Risk Analysis, RIM115372/plaza_risk_PatientIdentification-Truncation_CDR "Ensure in worklist that patient name and patient ID will not be cut out due to improper space or indicate to the user that the full information is not displayed. Ensure that user can access the complete information". This risk mitigation gives an indication if text was cut-off and gives the user the possibility to look at the whole text, therefore no need to adress this in the user manual any more.	*Archive Media* Improper handling of archive media can result in illegible media. Loss of data due to damaged archive media • Always comply with the instructions of the manufacturer when handling archive media. • Please only use "medical" quality CD/DVD media recommended by Siemens. *Displayed Patient Data* Text elements are too small. Patient information is cut off • Note that patient information may not be fully displayed.

Functionality	*syngo*.plaza VB10A	*syngo*.plaza VA20A
Standards	SMPTE – n.a. anymore, syngo.plaza itself does not comply to the SMPTE standard as the compliance to this standard lies within the responsibility to the customer. This is communicated via User Manual Chapter 2 on page 32 ("Approved calibrated monitors are required for diagnostic workstations") and ("Monitors that are used for medical reporting must be calibrated before use")	SMPTE (Society of Motion Picture and Television Engineers) Test Pattern [1995] – Intended to test CRT monitors and printers used to display medical images for acceptance and quality control purposes. The conformance to this standard is ensured by verification activities as the usage of SMPTE pattern is a software requirement.

Summary of Non-Clinical Testing:

The software verification and validation (Unit Test Level, Integration Test Level and System Test Level) was performed for all newly developed components and the complete system according the following standards:

- ISO 14971:2007[21]
- AIMI/ANSI ES 60601-1:2005/(R) 2012 + C1:2009/(R) 2012, clause 14
- IEC 62304:2006
- IEC 62366:2007
- DICOM Standard [2011]
- HL7 [2006]
- ISO / IEC 10918-1:1994 + TC 1:2005
- ISO / IEC 15444-1:2005+TC 1:2007
- ISO / IEC 13818:2009

After completion of the system test and comparison of the test results with the software release acceptance criteria, Siemens is of the opinion, that *syngo*.plaza is substantially equivalent to and performs as well as the predicate device.

General Safety and Effectiveness Concerns:

The device labeling contains instructions for use and any necessary cautions and warning, to provide for safe and effective use of the device.

Risk management is ensured via a risk analysis, which is used to identify potential hazards. These potential hazards are controlled via software development, verification and validation testing. To minimize hazards, Siemens adheres to recognized and established industry practice and standards.

syngo.plaza conforms to the applicable FDA recognized and international IEC, ISO, and NEMA standards with regards to performance and safety as recommended by the respective FDA Guidance Document.

Substantial Equivalence:

The *syngo*.plaza, addressed in this premarket notification, is substantially equivalent to the following commercially available device:

Manufacturer	*Predicate Device Name*	*FDA Clearance Number*
Siemens	*syngo*.plaza VA20A	K101666

The *syngo*.plaza described in this 510(k) has the same intended use and similar technical characteristics as the predicate device listed above in regard to the specific functionalities.

[21] The submitted MRS document shows DIN EN ISO 14971:2012 version of this standard which is already recognized in Germany.

In summary, Siemens is of the opinion that *syngo*.plaza VB10A does not introduce any new potential safety risks and is substantially equivalent to and performs as well as the predicate device.

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

December 9, 2013

Siemens AG Healthcare
% Mr. Olaf Teichert
Third Party Reviewer
Tuv Sud America, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112-1891

Re: K132532
Trade/Device Name: Syngo® plaza VB10A
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 06, 2013
Received: November 12, 2013

Dear Mr. Teichert:

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.

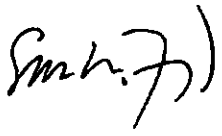
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/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

INDICATIONS FOR USE

510(k) Number (if known): K132532
Device Name: *syngo*®.plaza VB10A

Indications For Use:

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syngo.plaza optionally uses a variety of advanced postprocessing applications.

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

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

Concurrence of Center for Devices and Radiological Health (CDRH)

(Division Sign-Off)
Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health