



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Hologic, Inc.  
% Ms. Debbie Peacock  
Senior Manager, Regulatory Affairs  
36 Apple Ridge Road  
DANBURY CT 06810

August 10, 2016

Re: K161575  
Trade/Device Name: Affirm Lateral Arm Upright Biopsy Accessory  
Regulation Number: 21 CFR 892.1710  
Regulation Name: Mammography x-ray system  
Regulatory Class: II  
Product Code: IZH  
Dated: June 8, 2016  
Received: June 9, 2016

Dear Ms. Peacock:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written over a large, semi-transparent watermark of the FDA logo.

For

Robert 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

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

**Indications for Use**

510(k) Number (if known)

K161575

Device Name

Affirm Lateral Arm Upright Biopsy Accessory

Indications for Use (Describe)

The Affirm Breast Biopsy Guidance System is an optional accessory for the Selenia Dimensions Mammography System. It is designed to allow the accurate localization of lesions in the breast in three dimensions. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).

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

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

**Date Prepared:** June 6, 2016

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

**Est. Registration #:** 1220984

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

**Est. Registration #:** 1225717

**Contact Person:** Debbie Peacock  
Sr. Manager, Regulatory Affairs  
Phone: (203) 702-7794

## **Identification of the Device:**

Proprietary/Trade Name Affirm™ Lateral Arm Upright Biopsy Accessory  
Classification Name: Mammographic X-Ray System  
Regulatory Number: 21 CFR 892.1710  
Product Code: IZH  
Device Class: Class II  
Review Panel: Radiology

## **Identification of the Legally Marketed Predicate Device:**

**Trade name:** Affirm Breast Biopsy Guidance System  
**General name:** Mammographic X-ray system  
**Submitter / 510(k) Holder:** HOLOGIC, Inc.  
**510(k) #'s:** K122836, cleared on 01/11/13  
**Product Code:** IZH  
**Regulation Number:** 892.1710

## **Identification of the Legally Marketed Reference Device:**

**Trade name:** GE Senographe  
**General name:** Mammographic X-ray system  
**Submitter / 510(k) Holder:** General Electric, Inc.  
**510(k) #'s:** K040125, cleared on 04/19/04  
**Product Code:** IZH  
**Regulation Number:** 892.1710

**Device Description:**

This submission introduces the optional Affirm Lateral Arm Upright Biopsy Accessory which attaches to the Affirm Breast Biopsy Guidance System used with the Selenia Dimensions 2D/3D Mammography System, software version 1.8.4 and higher.

The optional Affirm Lateral Arm Upright Biopsy Accessory attaches to the Affirm Biopsy Guidance Module (BGM) to enable lateral needle approach procedures. The Lateral Arm can only be used when the Selenia Dimensions C-arm is positioned at 0 degrees. When using the Lateral Arm, the X- Y- and Z-axis movement is the same as for the Affirm standard (upright) needle approach. For the lateral approach, the biopsy needle is manually advanced into the breast along its own X-axis, referred to as “Lat X”.

When performing lateral approach biopsies, the biopsy device is installed onto the lateral arm in the same manner as when performing standard (upright biopsies).

New components used with the Affirm Lateral Arm Upright Biopsy Accessory include: lateral biopsy paddle, lateral arm stand, case, and QC phantom specifically to be used for Lateral approach biopsies.

The Indications for Use is unchanged from the predicate Affirm Breast Biopsy Guidance System as shown below.

**Indications for Use:**

The Affirm Breast Biopsy Guidance System is an optional accessory for the Selenia Dimensions Mammography System. It is designed to allow the accurate localization of lesions in the breast in three dimensions. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).

**Substantial Equivalence:**

The (optional) Affirm Lateral Arm Upright Biopsy Accessory is substantially equivalent to the predicate Affirm Breast Biopsy Guidance System (K122836) and to the lateral arm attachment used as a reference device, cleared in GE’s Senographe Stereo System, (K040125). Substantial equivalence is based on design, technology, Indications for Use, labeling, operation, basic constructions and materials used. The addition of the optional Lateral Arm Accessory to the cleared Affirm Biopsy Guidance System poses no additional hazards and is substantially equivalent to our predicate and reference devices listed below.

	<b>Affirm Lateral Arm Upright Biopsy Accessory (Proposed)</b>	<b>Predicate Device Affirm Breast Biopsy Guidance System (K122836)</b>	<b>Reference Device GE Senographe Stereo (K040125); (lateral arm)</b>
<b>Indications for Use</b>	The Affirm Breast Biopsy Guidance System is an optional accessory for the Selenia Dimensions Mammography System. It	The Affirm Breast Biopsy Guidance System is an optional accessory for the Selenia Dimensions Mammography System. It is	Senographe Stereo is an optional accessory for the Senographe DS full field digital system. It is designed to allow

	is designed to allow the accurate localization of lesions in the breast in two/and or three dimensions. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).	designed to allow the accurate localization of lesions in the breast in three dimensions. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).	the accurate location of lesions in the breast in three dimensions, using information extracted from stereotactic pairs of two-dimensional images. It is intended to provide guidance for interventional purposes (such as biopsy, pre-surgical localization, or treatment devices).
<b>X-ray Image Device</b>	Hologic Selenia Dimensions 2D/3D Mammography System	Same	GE Senographe DS 2D
<b>Software</b>	Selenia Dimensions V1.8.4 and higher)	Selenia Dimension V1.8.3 (current version)	Same description; version unknown.
<b>Method of Use</b>	Breast lesion localization and biopsy <ul style="list-style-type: none"> <li>• core biopsy</li> <li>• vacuum assisted biopsy</li> <li>• fine needle aspiration</li> <li>• hook wire localization exams.</li> </ul>	Breast lesion localization and biopsy <ul style="list-style-type: none"> <li>• core biopsy</li> <li>• vacuum assisted biopsy</li> <li>• fine needle aspiration</li> <li>• hook wire localization exams.</li> </ul>	Breast lesion localization and biopsy, such as: <ul style="list-style-type: none"> <li>• core biopsy</li> <li>• vacuum assisted biopsy</li> <li>• fine needle aspiration</li> <li>• hook wire localization exams.</li> </ul>
<b>Dedicated Breast Biopsy Positioner</b>	Yes	Yes	Yes
<b>Mechanism of Action</b>	Guidance for breast biopsy -Standard (vertical) approach, and -Right or left lateral approach.	Guidance for breast biopsy -Standard (vertical) approach	Guidance for breast biopsy -Standard (vertical), and right or left lateral approach.
<b>Technology</b>			
<b>Coordinate Determination</b>	Yes	Yes	Yes
<b>Needle Positioning</b>	Biopsy Positioning Module gets X, Y, Z coordinates of target area from AWS	Biopsy Positioning Module gets X, Y, Z coordinates of target area from AWS	Biopsy Positioning Module gets X, Y, Z coordinates of target area from AWS

<b>Stereotactic/ Tomographic Angle</b>	<b>Stereo:</b> +/- 15 ° <b>Tomo:</b> 15 degrees total (+/- 7.5 degrees)	<b>Stereo:</b> Same <b>Tomo:</b> Same	<b>Stereo:</b> +/- 15 ° <b>Tomo:</b> N/A
<b>Stated Accuracy</b>	+/- 1 mm in X, Y and Z Axis [overall targeting accuracy is equal to combined targeting accuracy of the Biopsy arm controller and the biopsy device (maximum deviation from target coordinate will not be more than 2 mm from either side)].	Same	+/- 1 mm in X, Y and Z Axis
<b>Compression Method</b>	Manual, automatic compression release is disabled automatically when the BGM is installed.	Same	Manual, compression range is 10-100 mm, with compression controlled manually.
<b>Compression Paddle</b>	Vertical approach w/window,  Lateral approach, no window	Vertical approach w/window	Vertical approach w/window,  Lateral approach, no window:
<b>Safety Features</b>	Same  Plus: When the system is in lateral approach biopsy mode, the system shall only allow exposures at C- arm position of 0 degrees.	Automatic detection of mounting, latching and connection of biopsy module  C-arm motion disabled if biopsy module is not locked in place.  Automatic compression release disabled when biopsy module installed  C-Arm Motion disabled when breast is under compression  Motorized movement of biopsy device only under user control.  Audible alert when biopsy device motion may result in	Unknown

		mechanical interference.	
<b>Materials (Short-term Skin Contracting)</b>			
<b>Breast Platform Material</b>	Carbon Fiber	Same	Same
<b>Biopsy Paddle Material</b>	Polycarbonate plastics	Same	Same

**Summary of Testing:**

The (optional) Affirm Lateral Arm Upright Biopsy Accessory 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 on May 11, 2005) based on a moderate level of concern.

In addition, the following test reports are included:

- Lateral Arm Targeting Accuracy Test
- Default Needle Parameter Validation Test Report

The Affirm CB test report was updated to include the optional Lateral Arm Accessory and the new lateral biopsy paddle. Third party testing was conducted on the tests listed below which were considered necessary to evaluate the noted changes:

- Tensile Safety Factor (IEC 60601-1, Clause 9.8.2)
- Strength of Compression Plates (IEC 60601-2-45, Subclause 203.8.5.4.102.5)
- Biopsy Needle Positioning Accuracy of Mammographic Stereotactic Devices \*IEC 60601-2-45, Subclause 201.9.2.1013 a,b,c)

No clinical studies were performed. Substantial equivalence has been demonstrated by non-clinical testing.

**Conclusion:**

The Affirm Lateral Arm Upright Biopsy Accessory is a modification to the predicate Affirm Breast Biopsy Guidance System (K122836) and is also substantially equivalent to the lateral arm component used in the reference GE Senographe Stereo System, (K040125). The design, operation, basic construction and materials used are substantially equivalent to the above predicate devices. Selenia Dimensions software V1.8.4 and higher enables use of either 2D or tomosynthesis-guided biopsy in a standard (vertical) or lateral approach. The addition of the (optional) Affirm Lateral Arm Upright Biopsy Accessory to the cleared Affirm Biopsy Guidance System is substantially equivalent to our predicate and reference devices listed above.