510(k) Summary

JAN 1 1 2013

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

Product Name: Affirm Breast Biopsy Guidance System

Product Classification Name: Mammographic X-Ray System

Product Classification Code: 90 IZH **CFR Section:** 892.1710

Classification Panel: Radiology **Class** II

Manufacturer: Hologic, Inc.
36-37 Apple Ridge Road
Danbury, CT 06810 USA

Contact Person: Gail Yaeker-Daunis
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Date Prepared: August 14, 2012

Predicate Device: Affirm Breast Biopsy Guidance System, K103512

Device Description:

The Affirm Breast Biopsy Guidance System is used with Selenia Dimensions 2D or with Selenia Dimensions 3D tomosynthesis. Lesion location can be obtained from either 2D stereotactic or 3D tomosynthesis image acquisition.

Both stereotactic and 3D localization calculate a three dimensional location for percutaneous placement for biopsy, pre-surgical localization or treatment devices.

Safety Features include:

- Automatic detection of mounting, latching, and connection of biopsy guidance module
- C-arm motion disabled if biopsy guidance module is not locked in place
- Automatic compression release disabled when biopsy guidance module installed
- Motorized movement of biopsy device only under user control
- Audible alert if biopsy device motion could result in mechanical interference

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).

Comparison with Predicate Devices:

The modified Affirm Breast Biopsy Guidance System is substantially equivalent to Affirm Breast Biopsy Guidance System which was cleared as K103512 for use with the Selenia Dimensions 2D Mammography system to provide localization of areas of concern for performance of breast biopsies. The intended use is the same using either stereotactic or 3D tomosynthesis lesion localization for biopsy with Selenia Dimensions Mammography System.

Summary of Testing:

The Affirm Breast Biopsy Guidance System meets IEC 60601-2-45 Medical Electrical Equipment – Safety of Mammographic X-ray Equipment and Mammographic Stereotactic Devices. Hologic successfully performed design control verification and validation tests in accordance with 21 CFR Part 820.

Conclusion:

The Affirm Breast Biopsy Guidance System's design, operation, construction and materials are unchanged from the cleared Affirm Breast Biopsy Guidance System. A software change enables use of either stereotactic or 3D tomosynthesis calculations for lesion localization for biopsy when the Affirm is used with a Selenia Dimensions 3D system . There is no change to the device when used with the Selenia Dimensions 2D system. Accuracy can be verified during the biopsy process. The 3D tomosynthesis lesion location is substantially equivalent to and as safe and effective as the cleared Affirm Breast Biopsy Guidance System and poses no additional risks or hazards.

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

January 11, 2013

Ms. Gail Yaeker-Daunis
Senior Regulatory Specialist
Hologic, Inc.
36 Apple Ridge Road
DANBURY CT 06810

Re: K122836
Trade/Device Name: Affirm Breast Biopsy Guidance System
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: December 14, 2012
Received: December 17, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 1-800- 638-2041 or 301-796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sean M. Boyd -S 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): **K122836**

Device Name: **Affirm Breast Biopsy Guidance System**

Indications for Use:

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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 CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K122836