



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

Hologic, Inc.  
% Ms. Sarah Fairfield  
Principal Regulatory Affairs Specialist  
36 Apple Ridge Road  
DANBURY CT 06810

April 1, 2016

Re: K153486  
Trade/Device Name: Affirm Prone Biopsy System  
Regulation Number: 21 CFR 892.1710  
Regulation Name: Mammographic x-ray system  
Regulatory Class: II  
Product Code: IZH  
Dated: March 9, 2016  
Received: March 10, 2016

Dear Ms. Fairfield:

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 in a cursive style and is positioned above the typed name and title.

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

## Indications for Use

510(k) Number (if known)

K153486

Device Name

Affirm Prone Biopsy System

Indications for Use (Describe)

The Affirm Prone Biopsy System combines the function of a standard x-ray mammography unit with that of a lesion localization system to produce a device that has specific application in first accurately localizing lesions in the breast in two and/or three dimensions, and then providing guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices) for lesions determined to be suspicious through prior mammographic examination.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**7. 510(k) SUMMARY****1. Submitter:**

Hologic, Inc.  
36 Apple Ridge Rd.  
Danbury, CT 06810 USA  
Telephone: 508.263.8857

Contact: Sarah Fairfield, Principal Regulatory Affairs Specialist

Date Prepared: December, 4 2015

**2. Device:**

Trade Name: Affirm Prone Biopsy System  
Common Name: Mammographic x-ray system  
Classification Name: Mammographic x-ray system  
Regulation number: 21 CFR 892.1710  
Product Code: IZH  
Class: II

**3. Predicate Device:**

Multicare Platinum Prone Breast Biopsy Table (K030666)  
Affirm Breast Biopsy Guidance System (K122836)

**4. Device Description:**

The Affirm Prone Biopsy Table is a mammographic x-ray system intended for lesion location while the patient is in the prone position. The subject device will be capable of both 2D and 3D imaging methods to calculate the target location. The system localizes suspicious lesions, as determined through prior mammographic examinations, using either stereotactic or tomosynthesis techniques. The system then affords a physician the capacity of performing vacuum assisted or needle core biopsy, or wire localization of the lesion.

Localization can be accomplished either via conventional 2D stereotactic imaging, or by use of a 3D data set. With the 3D data set, the image plane or "slice" most fully containing the suspected lesion is chosen by the physician from the data set to compute the lesion depth within the breast.

Safety features include:

- Automatic Detection of mounting, latching and connection of biopsy guidance module.
- C-arm motion is disabled if biopsy module is not locked in place
- Automatic compression release is disabled when biopsy guidance module is installed

- Motorized movement of biopsy device only occurs under user control
- Audible alert if biopsy motion could result in mechanical interference.

**5. Intended Use:**

It is intended for lesion location for biopsy while the patient is in the prone position to provide guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices).

The Affirm Prone Biopsy System combines the function of a standard x-ray mammography unit with that of a lesion localization system to produce a device that has specific application in first accurately localizing lesions in the breast in two and/or three dimensions, and then providing guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices) for lesions determined to be suspicious through prior mammographic examination.

**6. Comparison of Characteristics:**

The Affirm Prone Breast Biopsy System's design, operation, basic construction and materials used are substantially equivalent to the cleared Multicare Platinum System. The software enables use of either lesion localization in two and/or three dimensions for biopsy and is substantially equivalent to the cleared Affirm Breast Biopsy System (K122836). The Affirm Prone Biopsy System is substantially equivalent to and as safe and effective as the cleared the Multicare Platinum System (K030666) and the Affirm Breast Biopsy Guidance System (K122836), and poses no additional risks or hazards.

**7. Performance Testing:**

The Affirm Prone Biopsy 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.

**8. Conclusion:**

Based on the intended use, descriptive information and performance testing provided in this submission, the Affirm Prone Biopsy Table has been shown to be equivalent in technology, method of operation, functional performance and intended use to the predicates, Multicare Platinum Prone Breast Biopsy Table (K030666) and Affirm Breast Biopsy Guidance System (K122836).