Hologic, Inc
% Ms. Kate Brown
Sr. Specialist, Regulatory Affairs
36 Apple Ridge Road
DANBURY CT 06810

October 5, 2020

Re: K202294
Trade/Device Name: Affirm® Contrast Biopsy
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: Class II
Product Code: IZH
Dated: September 21, 2020
Received: September 22, 2020

Dear Ms. Brown:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202294

Device Name
Affirm® Contrast Biopsy

Indications for Use *(Describe)*

Affirm® Contrast Biopsy is indicated as an optional accessory for the Selenia Dimensions 2D Full Field Digital Mammography System and 3Dimensions system. It is designed to allow 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).
Contrast Enhanced Digital Mammography (CEDM) is an extension of the existing indication for diagnostic mammography with the Selenia Dimensions system and 3Dimensions system. Biopsy targeting can be done on captured contrast enhanced images (scout and stereo pair). The CEDM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and/or ultrasound exams to localize a known or suspected lesion. Affirm® Contrast Biopsy is intended for patients recommended for biopsy who have had a suspicious finding on previous contrast enhanced imaging or have lesions that may be occult under other modalities.

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.

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Section 006 – 510(k) Summary

K202294

Please see the next page for the 510(k) Summary.

Special 510(k) Summary

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

Date Prepared:	October 1, 2020
Manufacturer:	Hologic, Inc. 36 Apple Ridge Road Danbury, CT 06810 USA
Establishment Registration #:	1220984
Contact Person:	Kate Brown Sr. Regulatory Affairs Specialist P: 203.702.7819

Identification of the Device:

Proprietary/Trade Name:	Affirm® Contrast Biopsy
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
Classification Name:	Mammographic X-ray System
Regulatory Number:	21 CFR 892.1710
Product Code:	IZH
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	Hologic, Inc.
Clearance:	K103512 (cleared January 07, 2011)

Identification of the Legally Marketed Reference Device:

Trade Name:	Contrast Enhanced Digital Mammography
Classification Name:	Full Field Digital, System, X-Ray, Mammographic
Regulatory Number:	21 CFR 892.1715
Product Code:	MUE
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	Hologic, Inc.
Clearance:	K123873 (cleared January 29, 2013)

Device Description

The proposed Affirm® Contrast Biopsy is a licensable software feature for the Selenia Dimensions and 3Dimensions system platforms (P010025 and P080003, respectively). The proposed software option will be used with the Affirm® Breast Biopsy Guidance System (K103512). The proposed software is a stereotactic lesion localization system option for the Dimensions and 3Dimensions systems. It allows clinicians to perform biopsy targeting on captured contrast enhanced images. Affirm® Contrast Biopsy uses the same workflow as stereotactic biopsy, substituting standard scout and stereo pair views with contrast enhanced views captured at the associated angles. The proposed device is compatible with the standard vertical biopsy approach as well as the right or left lateral approach.

Affirm® Contrast Biopsy introduces new software and labeling. There are no changes to the Dimensions platform and Affirm® Breast Biopsy Guidance System hardware, platform software architecture, or stereotactic function as a result of the proposed software.

Indications for Use

The Affirm® Contrast Biopsy is indicated as an optional accessory for the Selenia Dimensions 2D Full Field Digital Mammography System and 3Dimensions system. It is designed to allow 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). Contrast Enhanced Digital Mammography (CEDM) is an extension of the existing indication for diagnostic mammography with the Selenia Dimensions system and 3Dimensions system. Biopsy targeting can be done on captured contrast enhanced images (scout and stereo pair). The CEDM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and/or ultrasound exams to localize a known or suspected lesion. Affirm® Contrast Biopsy is intended for patients recommended for biopsy who have had a suspicious finding on previous contrast enhanced imaging or have lesions that may be occult under other modalities.

Technological Characteristics

The Affirm® Contrast Biopsy uses the same technological principles as that of the cleared Affirm® Breast Biopsy Guidance System; however, Contrast Enhanced Digital Mammography (K123873) images are utilized instead of standard scout and standard stereo pair images. In the proposed device the lesion will be localized by 2D stereotactic image acquisition based on visualization of the lesion enhancement after an IV injection of an iodinated contrast agent. Stereo pair images are captured at plus and minus 15-degree angles using Dual Energy Contrast Enhanced Digital Mammography (CEDM). Low energy, and subtracted images can be displayed on the Acquisition Workstation monitor and are used for targeting purposes. The user then positions on-screen cursors to identify the position of the target lesion in the projected image pairs. Utilizing the target lesion location information from these acquired images, the software uses trigonometric calculations to determine the Cartesian coordinates (X, Y, and Z) of the targeted lesion within the breast. The calculated coordinates of the targeted lesion are sent to the Affirm biopsy control module mounted on the Selenia Dimensions or 3Dimensions Gantry C-Arm, which positions the biopsy device under user guidance in preparation of the biopsy procedure.

Comparison with Predicate Devices

The Affirm® Contrast Biopsy and its predicate device, Affirm® Breast Biopsy Guidance System (K103512) and reference device, Contrast Enhanced Digital Mammography (K123873), have the same or similar intended use, technological characteristics, and operational use.

Summary of Substantial Equivalence

Features and Characteristics	Affirm® Breast Biopsy Guidance System Primary Predicate (K103512)	I-View™/ Contrast Enhanced Digital Mammography (CEDM) Reference Device (K123873)	Affirm® Contrast Biopsy Proposed	Comparison
Indications for Use	The Affirm® Breast Biopsy Guidance System is an optional accessory for the Selenia Dimensions 2D Full Field Digital Mammography System. It is designed to allow 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).	Contrast Enhanced Digital Mammography (CEDM) is an extension of the existing indication for diagnostic mammography with the Selenia Dimensions system. The CEDM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and/or ultrasound exams to localize a known or suspected lesion.	Affirm® Contrast Biopsy is indicated as an optional accessory for the Selenia Dimensions 2D Full Field Digital Mammography System and 3Dimensions system. It is designed to allow 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). Contrast Enhanced Digital Mammography (CEDM) is an extension of the existing indication for diagnostic mammography with the Selenia Dimensions system and 3Dimensions system. Biopsy targeting can be done on captured	Similar. The proposed device's indications for use will be a combination of the primary predicate and reference device's indications for use statement. The addition of "3Dimensions system" was added to the proposed indications for use statement. The 3Dimensions system does not differ technologically from that of the Selenia Dimensions system.

			contrast enhanced images (scout and stereo pair). The CEDM application shall enable contrast enhanced breast imaging using a dual energy technique. This imaging technique can be used as an adjunct following mammography and/or ultrasound exams to localize a known or suspected lesion. Affirm® Contrast Biopsy is intended for patients recommended for biopsy who have had a suspicious finding on previous contrast enhanced imaging or have lesions that may be occult under other modalities.	
X-Ray Image Device	Selenia Dimensions 2D FFDM	Selenia Dimensions 2D FFDM	Selenia Dimensions and 3Dimensions	Similar. Selenia Dimensions and 3Dimensions are both capable of 2D FFDM which is utilized for the proposed device's lesion localization.
Coordinate Determination	Cartesian Coordinates determined from Dimensions Stereotactic software	Not applicable to CEDM	Cartesian Coordinates determined from Dimensions Stereotactic software	Same as primary predicate, Affirm® Breast Biopsy Guidance System
Movement Method	X: Motorized Y: Motorized Z: Manual	Not applicable to CEDM	X: Motorized Y: Motorized Z: Manual	Same as primary predicate, Affirm® Breast Biopsy Guidance System

Stereotactic Angle	+/- 15°	Not applicable to CEDM	+/- 15°	Same as primary predicate, Affirm® Breast Biopsy Guidance System
Method of Use	Lesion localization is obtained from 2D stereotactic image acquisition.	Lesion localization is obtained from contrast enhanced 2D breast imaging using a dual energy technique.	Lesion localization is obtained from 2D contrast enhanced image acquisition from low energy and subtracted image pairs.	Similar. Lesion localization is obtained utilizing the primary predicate and reference device's method of use.
Mechanism of Action	Guidance for breast biopsy: -Standard (vertical) approach	Not applicable to CEDM	Guidance for breast biopsy: -Standard (vertical) approach -Right or left lateral approach	Similar. The addition of the lateral approach was cleared via K161575 and is compatible with the proposed device.
Workflow	Stereotactic biopsy workflow	Dual energy imaging technique workflow	Stereotactic biopsy workflow	Similar. The proposed device's workflow is similar to the primary predicate device's workflow. The only difference are the additional steps on the AWS GUI which allow the user to choose Contrast Enhanced Digital Mammography images instead of 2D images before performing the stereotactic biopsy. The proposed device Affirm® Contrast Biopsy workflow differs from the reference device CEDM workflow as it is specific to biopsy.

Summary of Testing

Non-clinical bench testing demonstrates the Affirm® Contrast Biopsy is substantially equivalent to the predicate and reference device with regards to the indication for use, software, technology, and performance. Design verification testing demonstrates the proposed device complies with design specifications. The proposed device was developed under Hologic's Quality Management System which adheres to 21 CFR Part 820 and ISO 13485:2016. Risk management activities, in accordance with ISO 14971:2019, demonstrate that the risks associated with the use of the Affirm® Contrast Biopsy software are mitigated as far as possible. Analyses of these activities indicate the benefits associated with the use of the Affirm® Contrast Biopsy outweigh the residual risks.

The software, and performance showed that the overall system demonstrated equivalent performance and equivalent safety and effectiveness as the predicate Affirm® Breast Biopsy Guidance System (K103512) and reference Contrast Enhanced Digital Mammography (K123873).

Benefit-Risk Analysis
The benefit of the device is to allow visualization and biopsy of suspicious lesions that may otherwise be occult or difficult to confidently target using other modalities. The main risks are the additional radiation dose and exposure to contrast agents.

The radiation dose is approximately 25% greater than performing FFDM stereotactic biopsy, and per exposure would be about the same as the reference device operating in 2D contrast enhanced imaging mode.

The exposure of the patient to the iodinated contrast agent presents another risk. Although the probability of occurrence is remote, the most significant additional risk to a patient during a contrast enhanced biopsy procedure relative to a stereotactic biopsy is an allergic reaction to the injected contrast agent which could potentially result in a life threatening aphylactic reaction. Recent estimates suggest that the rate of acute adverse events for low-osmolar contrast agents is approximately 0.2%–0.7%, with a severe acute reactions being approximately 0.04%. This risk is mitigated via procedural guidelines set up in hospitals which cover training, pre-screening of patients' kidney function (i.e.; glomerular filtration rate or GFR), and appropriate acute care readiness (e.g., "crash carts"), as may be expected to be in place for the reference device as well. Furthermore, if the patient has had previous exposure to iodinated contrast agents safely with no adverse reaction, such as a contrast-enhanced digital mammography exam, then this risk will be additionally reduced. These additional radiation and contrast agent risks are therefore likely outweighed by the benefits of the device for patients recommended for biopsy who have had a suspicious finding on previous contrast enhanced imaging or have lesions that may be occult under other modalities.

Conclusion
The Affirm® Contrast Biopsy is substantially equivalent to the legally marketed predicate device, Affirm Breast Biopsy Guidance System cleared on January 08, 2011 via K103512, and the legally marketed reference device, Contrast Enhanced Digital Mammography, cleared on January 29, 2013 via K123873. The indications for use and fundamental scientific technology of the proposed device are the same or similar to that of the Affirm® Breast Biopsy Guidance System and Contrast Enhanced Digital Mammography.