April 10, 2018

Hologic, Inc
Ms. Brenda Geary
Regulatory Affairs Specialist
250 Campus Drive
Marlborough, Massachusetts 01752

Re: K180233
Trade/Device Name: Eviva Stereotactic Guided Breast Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: February 8, 2018
Received: February 9, 2018

Dear Ms. Geary:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180233

Device Name
Eviva Stereotactic Guided Breast Biopsy System

Indications for Use *(Describe)*
The Eviva Stereotactic Guided Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities under stereotactic breast biopsy guidance. The Eviva device is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedure.

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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HOLOGIC, Inc.
Premarket Notification Eviva Stereotactic Guided Breast Biopsy System

6.0 510(k) Summary

January 11, 2018

6.1 510(k) Submitter

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
Attn: Brenda Geary
P: 508.263.8819
F: 844.223.4956

6.2 Establishment Registration Number: 1222780

6.3 Trade Name: Eviva Stereotactic Guided Breast Biopsy System

6.4 Common/Usual Name: Biopsy Instrument, 21CFR.876.1075

6.5 Product Code: KNW

6.6 Classification: Class II

6.7 Panel: Gastroenterology/Urology

6.8 Predicate Device

Tradename:	ATEC Breast Biopsy System
Submitter / 510(k) Holder:	Hologic, Inc.
510(k) #:	K042290
Classification code:	KNW
Regulation:	21.CFR.876.1075

6.9 Device Description

The Eviva Stereotactic Guided Breast Biopsy System is a hand-held biopsy device that is marketed for guidance with stereotactic imaging. The Eviva device is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedure.

6.10 Intended Use:

The Eviva Stereotactic Guided Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities under stereotactic breast biopsy guidance. The Eviva device is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedure.

6.11 Comparison to Predicate Device:

Attribute	Predicate Device ATEC Breast Biopsy System (K042290)	Subject Device Eviva Stereotactic Breast Biopsy System	Status
Intended Use	The ATEC Breast Biopsy System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of the histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of the removal of the imaged evidence of an abnormality does not predict the extent of removal of histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedure.	The Eviva Stereotactic Guided Breast Biopsy System is indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities under stereotactic breast biopsy guidance. The Eviva device is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedure.	Subject device is substantially equivalent to predicate device
Method of Use	Vacuum-assisted device to remove breast tissue in a minimally invasive manner. For use with Ultrasound, Stereotactic or MRI. Requires additional Introducer accessory for marker.	Vacuum-assisted device to remove breast tissue in a minimally invasive manner. For use only in Stereotactic. Integrated Introducer for marker.	Subject device is substantially equivalent to predicate device
Mechanism for Action	Manually fired. Rotate all device to acquire tissue 360°. Tissue retrieval part of device.	Pneumatic firing mechanism. Rotate using thumbwheel and using “clock position” window. Remote tissue retrieval.	Subject device is substantially equivalent to predicate device

Attribute	Predicate Device ATEC Breast Biopsy System (K042290)	Subject Device Eviva Stereotactic Breast Biopsy System	Status
Mode of Operation	Tissue acquisition, press down footswitch and hold. Pressure and Vacuum from Console activate internal mechanism to cut and acquire tissue.	Tissue acquisition, press down footswitch and hold. Pressure and Vacuum from Console activate internal mechanism to cut and acquire tissue.	Subject device is substantially equivalent to predicate device

6.12 Performance Testing:

Bench testing of the Eviva Stereotactic Guided Breast Biopsy System including functional testing, biocompatibility, sterilization and package testing demonstrated equivalent performance, and showed to be as safe and effective as the predicate device, and met all acceptance criteria.

6.13 Conclusion:

The Eviva Stereotactic Guided Breast Biopsy System met all acceptance criteria for design verification and validation, as specified by applicable standards, guidance, test protocols and/or customer inputs. The Eviva Stereotactic Guided Breast Biopsy System is substantially equivalent to the legally marketed predicate device (Hologic's ATEC Breast Biopsy System K042290).