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

August 14, 2015

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

Re: K150169
Trade/Device Name: Sertera Biopsy Device
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: July 16, 2015
Received: July 17, 2015

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.

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" (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 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,

David Krause -S

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

Hologic, Inc.
510(k) Submission for Sertera
January 2015

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): N/A

Device Name: Sertera Biopsy Device

Indications For Use: The Sertera Biopsy Device is intended to obtain percutaneous core biopsy samples from soft tissue and tumors of the breast. When used for breast biopsy, the product is for diagnosis only. It is not intended for use in bone.

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 Device Evaluation (ODE)

6.0 510(k) Summary

6.1 Date: January 19, 2015

6.2 510(k) Submitter:

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752
Attn: Brenda M. Geary
P: 508.263.8819
F: 508.263.8872

6.3 Establishment Registration Number: 1222780

6.4 Trade Name: Sertera Biopsy Device

6.5 Common/Usual Name: Biopsy Instrument, 21.CFR.Reg 876.1075 Product Code: KNW

6.6 Classification: Class II

6.7 Panel: Gastroenterology/Urology

6.8 PREDICATE DEVICES

6.8.1 **Tradename:** Achieve Programmable Automatic Biopsy Needle
Submitter / 510(k) Holder: (Bauer Medical) CareFusion (Cardinal Health)
510(k) #: K960064 Classification code: KNW and Regulation: 21.CFR.876.1075.

6.8.2 **Tradename:** Monopty Disposable Core Biopsy Instrument
Submitter / 510(k) Holder: C.R. Bard, Inc.
510(k) #: K922939 Classification code: KNW and Regulation: 21.CFR.876.1075.

6.9 DEVICE DESCRIPTION

The Hologic Sertera Biopsy Device is a spring-loaded core biopsy device to be used primarily in ultrasound-guided breast biopsies. The Sertera Biopsy Device is a disposable, hand-held spring-loaded core biopsy device that is fully operable with one hand. The Sertera Biopsy Device consists of a hand piece, which advances an inner needle with a side aperture to penetrate into the tissue, and a sharpened outer cutting cannula that extends over the aperture with sufficient force to slice the tissue. The Sertera Biopsy Device is available with 12 and 14 gauge needles.

Hologic, Inc.
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January 2015

6.10 INTENDED USE:

The Sertera Biopsy Device is intended to obtain percutaneous core biopsy samples from soft tissue, and tumors of the breast. When used for breast biopsy, the product is for diagnosis only. It is not intended for use in bone.

6.11 Comparison to Predicate Devices:

	ACHIEVE (K960064)	**MONOPTY** (K922939)	**Sertera Biopsy Device (SUBJECT DEVICE)**	**COMPARISON TO PREDICATES**
Intended Use	Intended for use in obtaining core biopsy samples from soft tissue such as breast, kidney, liver, prostate and various soft tissue masses. Not intended for use in bone.	The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.	The Sertera Biopsy Device is intended to obtain percutaneous core biopsy samples from soft tissue, and tumors of the breast. When used for breast biopsy, the product is for diagnosis only. It is not intended for use in bone.	SUBJECT DEVICE is substantially equivalent to both predicate devices
Method of Use	Minimally-invasive excision of breast tissue. After local anesthetic is applied and incision is made, biopsy needle is introduced to breast. Physician targets area of interest and collects tissue.	Minimally-invasive excision of breast tissue. After local anesthetic is applied and incision is made, biopsy needle is introduced to breast. Physician targets area of interest and collects tissue.	Minimally-invasive excision of breast tissue. After local anesthetic is applied and incision is made, biopsy needle is introduced to breast. Physician targets area of interest and collects tissue.	SUBJECT DEVICE is substantially equivalent to predicate devices
Mechanism of Action	Collection of specimens into needle aperture, and inner cannula excision of specimen.	Collection of specimens into needle aperture, and inner cannula excision of specimen.	Collection of specimens into needle aperture, and inner cannula excision of specimen.	SUBJECT DEVICE is substantially equivalent to predicate devices.
Mode of Operation	Handheld biopsy device	Handheld biopsy device	Handheld biopsy device	SUBJECT DEVICE is substantially equivalent to predicate devices.

6.12 Performance Testing

Bench testing of the Sertera Biopsy Device demonstrated equivalent performance to the predicate devices, and met all acceptance criteria.

6.13 CONCLUSION

The Sertera Biopsy Device met all acceptance criteria for design verification and validation, as specified by applicable standards, guidance, test protocols and/or customer inputs. The Sertera Biopsy Device is substantially equivalent to the legally marketed predicate devices (Care Fusion Achieve Programmable Automatic Biopsy Needle and C.R. Bard Inc.'s Monopty Disposable Core Biopsy Instrument).