May 6, 2020

Health Beacons, Inc.
% Felicia Hosey
Senior Principal Specialist
R&Q Solutions
2790 Mosside Blvd, Suite 800
Monroeville, Pennsylvania 15146

Re: K193189
Trade/Device Name: RFID Localization System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: April 4, 2020
Received: April 8, 2020

Dear Ms. Hosey:

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); 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,

Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193189

Device Name
RFID Localization System (RFLS)

Indications for Use *(Describe)*
The Tag of the RFLS is intended for percutaneous placement in the breast to mark (>30 days) a lesion intended for surgical removal. Using image guidance (such as ultrasound or radiography) or aided by non-imaging guidance (RFLS), the RFID Tag is located and surgically removed with the target tissue. The RFLS is intended only for the non-imaging detection and localization of the Tag that has been implanted in a lesion intended for surgical removal.

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.

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510(k) SUMMARY

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92 on May 5th, 2020.

I. Submitter

Submitter's Name:	Hologic, Inc.
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II. Application Correspondent

Contact's Name:	Regulatory and Quality Solutions, LLC.
Contact Person:	Mrs. Felicia Hosey, RAC Senior Principal Specialist
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Telephone:	(877) 652-0830 ext. 161
Email:	fhosey@rqteam.com

III. Device

Trade Name:	RFID Localization System (RFLS)
Common Name:	Marker, Radiographic, Implantable

Classification Name: Implantable clip.

Product Classification: Class II, §878.4300, Product Code NEU

IV. Predicate Device

- Health Beacons RFID Localization System
  - K190932 (Health Beacons Inc.), FDA cleared on 09/13/2019

V. Reference Devices

- JAMM Technologies Verichip Health Information Microtransponder And Pocket Reader
  - DEN040007/K033440 (Digital Angel Corporation), FDA cleared on 10/12/2004

- Cianna Medical SAVI Scout Reflector and SAVI Scout System
  - K181007 (Cianna Medical, Inc.), FDA cleared on 08/02/2018

VI. Device Description

The proposed RFID Localization System is a marker-with-detector localization device that employs miniature RFID tags as markers and a hand-held reader that can measure distance to the tag. The RFLS is comprised of a Tag, Tag Applicator/Tag Applicator S, LOCalizer Reader (Reader) and LOCalizer Surgical Probe (Surgical Probe). The Tag, when used in conjunction with the Reader and Surgical Probe, can be used as a guide for the surgeon to refer to in the excision of tissue. The RFLS is a prescription device meant only for use by trained professionals.

VII. Indications for Use

The Tag of the RFLS is intended for percutaneous placement in the breast to mark (>30 days) a lesion intended for surgical removal. Using image guidance (such as ultrasound or radiography) or aided by non-imaging guidance (RFLS), the RFID Tag is located and surgically removed with the target tissue. The RFLS is intended only for the non-imaging detection and localization of the Tag that has been implanted in a lesion intended for surgical removal.

VIII. Comparison of Technological Characteristics with the Predicate Devices

The proposed RFID Localization System (RFLS) has identical indications for use, principles of operation, fundamental scientific technology and materials as the predicate device Health Beacons RFID Localization System. The only differences between the subject and predicate devices are minor software updates and revision of the instructions for use to clarify the use of multiple tags in on operative site.

The following table (**Table 7-1**) provides an overview of general technological characteristics in comparison to the predicate device.

Table 7-1: General Technological Characteristics Comparison

Product Features	Proposed Device Health Beacons, Inc. RFID Localization System (RFLS)	Predicate Device Health Beacons RFID Localization System (K190932)
Indications for Use	The Tag of the RFLS is intended for percutaneous placement in the breast to mark (>30 days) a lesion intended for surgical removal. Using image guidance (such as ultrasound or radiography) or aided by non-imaging guidance (RFLS), the RFID Tag is located and surgically removed with the target tissue. The RFLS is intended only for the non-imaging detection and localization of the Tag that has been implanted in a lesion intended for surgical removal.	-same-
Classification	Class II	-same-
Product Code	NEU	-same-
Regulation Number	§878.4300	-same-
Regulation Name	Marker, Radiographic, Implantable	-same-
Anatomical Locations	Breast Tissue	-same-
Tissue Penetration /Delivery Device	Needle Implanter	-same-
Visibility	X-ray, Ultrasound and MRI (artifact only)	-same-
Primary Device Components	RFID Tag pre-loaded in Tag Applicator, Reader, and Surgical Probe	-same-
Principle of Operation	Radiofrequency wave technology to detect tissue marker	-same-
Indicators	Visual and Audible	-same-
Implant Delivery Device Size/Working Length	• 12 Gauge/5cm • 12 Gauge/7cm • 12 Gauge/10cm	-same-
Implant Delivery Device Needle Marking	1 cm marker increments	-same-
Implant Dimensions	Approximately 0.08” (2.29 mm) diameter x 0.43 (10.8 mm) long	-same-

Table 7-1: General Technological Characteristics Comparison

Product Features	Proposed Device Health Beacons, Inc. RFID Localization System (RFLS)	Predicate Device Health Beacons RFID Localization System (K190932)
Patient Contacting Materials	• *Tag*: Soda lime Bioglass, Kimble R6, Pro-fax PF-531 Polypropylene Homopolymer • *Tag Applicator:* 304 Stainless Steel with Dow Corning MDX4-4159 Medical Grade Dispersion Silicone coating • *Tag Applicator S:* 304 Stainless Steel with Dow Corning MDX4-4159 Medical Grade Dispersion Silicone coating • *Surgical Probe:* Acrylonitrile Butadiene Styrene (ABS), Sabic Cycolac HMG94-8H7D195, 304 Stainless Steel, Thermoplastic polyurethane (TPU) IROGRANR A75 E 5040, white, Silicone Elastomer • *Reader:* Polycarbonate, LTL Color Compounds Colorfast PC200, Polyester, Flexcon Compucal Excel 10442 Label Stock	-same-
Sterilization Method (sterile, single-use components)	• *Tag Applicator and RFID Tag:* Ethylene Oxide • *Surgical Probe:* Gamma	-same-

IX. Performance Data

The following performance data was considered in support of the substantial equivalence determination.

Performance Testing

The following tests were performed to demonstrate that the proposed RFID Localization System (RFLS) met the applicable design and performance requirements and support a determination of substantial equivalence. Where applicable, testing was done per applicable ISO and other international standards.

Table 7-2: Performance Testing

Type	Description
RFLS System Design Verification	RFID Localization System verification testing was conducted to demonstrate that the RFID Localization System (RFLS) meets product specifications as defined in the design requirement documentation. Performance has previously been established through testing for the RFID Localization System (K181692 and K190932).
	Testing was conducted to measure the effect of multiple tags on tag-to-probe distance readings.
Tissue Marker Migration Evaluation	A migration evaluation was performed to assess migration of the RFID Tag due to MRI-induced forces as well as simple migration resultant from body movement. Migration has previously been established through evaluation for the RFID Localization System (K163667 and K181692).
Usability Verification and Validation	Usability testing was conducted to demonstrate that the RFID Localization System (RFLS) design meets Usability requirements. Usability has previously been established through evaluation for the RFID Localization System (K181692 and K190932).
Electrosurgery and MRI Compatibility	Testing was conducted to assess electromagnetic interference and RFID Tag functionality after direct exposure to electrical current from an electrosurgery instrument. Electrosurgical compatibility has previously been established through testing for the RFID Localization System (K163667).
	Testing was conducted to evaluate the interaction (safety and compatibility) of the RFID Tag in the magnetic resonance (MR) environment. MRI compatibility has previously been established through testing for the RFID Localization System (K163667 and K190932).
Packaging Validation	Package Qualification Testing for sterile components was completed in accordance with the following standards: • ISO 11607-1 • ASTM D4169-09 • ASTM F1886/F1886M-16 • ASTM F2096-11 • ASTM F88/F88M-15 • ASTM F1929-98 (2004) Packaging qualification has previously been established through testing for the RFID Localization System (K163667).
	Ship testing was completed in accordance with ASTM D4149 and ISTA 2A

Table 7-2: Performance Testing

Type	Description
	Shipping evaluations has previously been established through testing for the RFID Localization System (K190932).
Sterilization Validation	Sterilization Validation for the sterile components was completed in accordance with the following standards, as appropriate: • AAMI ANSI ISO 11137-1 • AAMI ANSI ISO 11137-2 • AAMI ANSI ISO 10993-7 Sterilization parameters have previously been validated through testing for the RFID Localization System (K163667, K181692 and K190932)
Stability Testing	Shelf-life evaluations were conducted in accordance the Food & Drug Administrations; "Shelf Life of Medical Devices" and the ASTM Standard "F1980, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices". Device shelf-life has previously been established through testing for the RFID Localization System (K163667, K181692 and K190932)

Biocompatibility

The proposed RFID Localization System (RFLS) has identical patient contacting materials, expected contact category, type and duration as the Predicate Device, Health Beacons RFID Localization System (K190932) and Reference Device, JAMM Technologies Verichip Health Information Microtransponder And Pocket Reader, (DEN040007/K033440). There have been no changes to the Health Beacons RFID Localization System patient contacting materials or manufacturing process since the device was originally cleared on 09/13/2019 (K190932).

Testing completed met the requirements of the respective test methods per the International Standard ISO 10993-1 "*Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process*" as appropriate for the expected contact category, type and duration. Therefore, biocompatibility has previously been established through biocompatibility testing for the RFID Localization System patient contacting materials (K190932 and DEN040007/K033440).

Electrical Safety and Electromagnetic Compatibility (EMC)

An electromagnetic compatibility evaluation was completed for the proposed RFID Localization System (RFLS), which has the same technological characteristics as the Reference Device, Health Beacons RFID Localization System (K190932). Electrical safety and EMC safety testing was performed to, and passed, the following standards:

- IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: electromagnetic compatibility – Requirements and tests

Software Verification and Validation Testing

Software verification and validation testing for the proposed RFID Localization System (RFLS) was conducted and documentation provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*" and "*Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices*". Reference K181692 and K190932

X. Conclusion

The proposed RFID Localization System (RFLS) has identical indications for use, principles of operation, fundamental scientific technology, and materials as the predicate device Health Beacons RFID Localization System. Information provided in this submission supports the continued safety and effectiveness of the proposed device for its intended use and demonstrates that the device is substantially equivalent to its predicate.