September 13, 2019

Health Beacons, Inc.
% Ms. Carol Vierling
Sr. Principal Advisor
R&Q Solutions
2790 Mosside Blvd, Suite 800
Monroeville, Pennsylvania 15146

Re: K190932
Trade/Device Name: RFID Localization System
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: May 3, 2019
Received: August 13, 2019

Dear Carol Vierling:

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 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)*
K190932

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 April 8, 2019.

I. Submitter

Submitter's Name:	Health Beacons, Inc.
Contact Person:	Ms. Nancy Confrey Chief Executive Officer
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Telephone:	(978) 287-4635
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Email:	nconfrey@healthbeacons.com

II. Application Correspondent

Contact's Name:	Regulatory and Quality Solutions, LLC.
Contact Person:	Ms. Carol Vierling, RAC (Consultant) Senior Principal Advisor
Address:	2790 Mosside Blvd #800 Monroeville, PA 15146
Telephone:	877-652-0830
Email:	cvierling@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 - 5cm Tag Applicator, 7cm Tag Applicator, 10 Cm Tag Applicator, 5 Cm Tag Applicator (10 Pack), 7cm Tag Applicator (10 Pack), 10cm Tag Applicator (10 Pack), LOCalizer Surgical Probe, LOCalizer Surgical Probe (5 Pack)
    - K181692 (Health Beacons Inc.), FDA cleared on September 25th, 2018

V. Device Description

The Tag, Tag Applicator, Tag Applicator S, LOCalizer Reader, and LOCalizer Surgical Probe are components of the Health Beacons RFID Localization System (RFLS). The proposed device 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 Tag, when used in conjunction with the Reader and Surgical Probe, can be used as a guide for the surgeon during the excision of tissue. The RFLS is a prescription device meant only for use by trained professionals, specifically breast surgeons and diagnostic radiologists.

VI. 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.

There have been no changes to the indication for use.

VII. Comparison of Technological Characteristics with the Predicate Device

Product Features	**Modified Device** **Health Beacons, Inc. RFID Localization System**	**Predicate Device** **Health Beacons RFID Localization System (K181692)**
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 RFID tag emits no radiation, the Reader provides an accurate distance measurement to the tag, and the RFID Tag can be placed at a convenient time before surgery without migration prior to removal.	Same except that there is only one Tag Applicator

Product Features	Modified Device Health Beacons, Inc. RFID Localization System	Predicate Device Health Beacons RFID Localization System (K181692)
Intended Use	The Tag of the RFLS is intended for percutaneous placement in the breast to mark a lesion intended for surgical removal.	-same-
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-
Breast 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-
Tag Applicator Tip Geometry	22° bevel	28° bevel
Tag Implant Dimensions	Approximately 0.08” (2.29mm) diameter x 0.43” (10.8mm) long	Approximately 0.09” (2.26 mm) diameter x 0.37” (9.52 mm) long

Product Features	Modified Device Health Beacons, Inc. RFID Localization System	Predicate Device Health Beacons RFID Localization System (K181692)
Patient Contacting Materials	• *Tag*: Soda lime Bioglass, Kimble R6, Biobond™, (a.k.a. Pro-fax PF-531) Polypropylene Homopolymer • *Tag Applicator:* 304 Stainless Steel with silicone coating • *Tag Applicator S:* 304 Stainless Steel with 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	• *Tag*: -same- • *Tag Applicator:* 304 Stainless Steel • *Surgical Probe:* -same- • *Reader:* -same-
Sterilization Method (sterile, single-use components)	• *Tag Applicator and RFID Tag:* Ethylene Oxide • *Surgical Probe:* Gamma	-same-
Tissue Marker Locator	Reusable, non-sterile Console	-same-

VIII. Design Control Activities

A risk analysis was performed to identify new risks based on the device modification. Risks are mitigated as far as possible. All verification and validation activities identified as necessary were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. The manufacturing facility fulfills design procedure requirements.

The following performance testing was provided to support the substantial equivalence determination.

- Magnetic field emission testing per IEC 60601-1-2:2014
- Delivery testing
- Deployment Force testing
- Needle Penetration Force testing
- Usability testing

IX. Conclusion

The proposed RFID Localization System (RFLS) has the same indications for use, principles of operation and fundamental scientific technology as the predicate device, Health Beacons RFID Localization System. The proposed changes do not raise any new questions regarding safety and effectiveness of the RFLS. Therefore, the information provided in this submission supports the RFLS being as safe and effective as the predicate device for its intended use and demonstrates that the device is substantially equivalent to its predicate.