



September 25, 2018

Health Beacons, Inc.
% Felicia Hosey
Principal Specialist
Regulatory and Quality Solutions, LLC.
2790 Mossy Boulevard, Suite 800
Monroeville, Pennsylvania 15146

Re: K181692

Trade/Device Name: 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)

Regulation Number: 21 CFR 878.4300

Regulation Name: Implantable clip

Regulatory Class: Class II

Product Code: NEU

Dated: June 21, 2018

Received: June 27, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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,

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

Indications for Use

510(k) Number (if known)

K181692

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.

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510(k) SUMMARY

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92 on June 21, 2018.

I. Submitter

Submitter's Name: Health Beacons, Inc.

Contact Person: Ms. Nancy Confrey
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II. Application Correspondent

Contact's Name: Regulatory and Quality Solutions, LLC.

Contact Person: Mrs. Felicia Hosey, RAC
Principal Specialist

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Monroeville, PA 15146

Telephone: (877) 652-0830 ext. 161

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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

- Cianna Medical SAVI Scout Reflector and SAVI Scout System
 - K171767 (Cianna Medical, Inc.), FDA cleared on 10/31/2017

V. Reference Devices

- Health Beacons RFID Localization System - Localizer Reader, RFID Localization System - Localizer Surgical Probe, RFID Localization System - Localizer Surgical Probe (5 Pack), RFID Localization System - Tag Applicator, RFID Localization System - Tag Applicator (10 Pack)
 - K163667 (Health Beacons Inc.), FDA cleared on 04/28/2017
- JAMM Technologies Verichip Health Information Microtransponder And Pocket Reader
 - DEN040007/K033440 (Digital Angel Corporation), FDA cleared on 10/12/2004

VI. Device Description

The Tag, Tag Applicator, 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.

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 the same indications for use, principles of operation and similar fundamental scientific technology and materials as the predicate device Cianna Medical SAVI Scout Reflector and SAVI Scout System.

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 Cianna Medical SAVI Scout Reflector and SAVI Scout System (K171767)
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.	The SAVI Scout Reflector is intended to be placed percutaneously in breast tissue to mark (>30 days) a biopsy site or a lumpectomy site intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or aided by non-imaging guidance (SAVI Scout System) the SAVI Scout Reflector is located and surgically removed with the target tissue. The SAVI Scout System is intended only for the non-imaging detection and localization of the SAVI Scout Reflector that has been implanted in a breast biopsy site or a lumpectomy site intended for surgical removal.
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)	X-ray, Ultrasound and MRI
Primary Device Components	RFID Tag pre-loaded in Tag Applicator, Reader, and Surgical Probe	Electromagnetic wave reflective device (Reflector) pre-loaded in Delivery System, Handpiece, and Console
Principle of Operation	Radiofrequency wave technology to detect tissue marker	Electromagnetic wave technology to detect the tissue marker
Indicators	Visual and Audible	-same-
Implant Delivery Device Size/Working Length	<ul style="list-style-type: none"> • 12 Gauge/5cm • 12 Gauge/7cm • 12 Gauge/10cm 	<ul style="list-style-type: none"> • 16 Gauge/13cm

Table 7-1: General Technological Characteristics Comparison

Product Features	Proposed Device Health Beacons, Inc. RFID Localization System (RFLS)	Predicate Device Cianna Medical SAVI Scout Reflector and SAVI Scout System (K171767)
Implant Delivery Device Needle Marking	1 cm marker increments	-same-
Implant Dimensions	Approximately 0.09” (2.3 mm) diameter x 0.37” (10.6 mm) long	Approximately 0.05” (1.27 mm) x 0.49” (12.4 mm) long
Patient Contacting Materials	<ul style="list-style-type: none"> • <i>Tag</i>: Soda lime bioglass, polypropylene homopolymer • <i>Tag Applicator</i>: 304 Stainless Steel • <i>Surgical Probe</i>: Acrylonitrile butadiene styrene, 304 Stainless Steel, TPU, Silicone Elastomer • <i>Reader</i>: Polycarbonate, Polyester Film (label) 	<ul style="list-style-type: none"> • <i>Reflector</i>: 3922 Loctite, Nitinol SE508, light oxide • <i>Delivery System</i>: 304 Stainless Steel • <i>Handpiece</i>: Acrylonitrile butadiene styrene, Polyester film, Loctite 4011, NPO (COG) K20 (Dielectric material) • <i>Console</i>: N/A (no patient contact)
Sterilization Method (sterile, single-use components)	<ul style="list-style-type: none"> • <i>Tag Applicator and RFID Tag</i>: Ethylene Oxide • <i>Surgical Probe</i>: Gamma 	<ul style="list-style-type: none"> • <i>Delivery System and Reflector</i>: Ethylene Oxide • <i>Handpiece</i>: Ethylene Oxide

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.

- RFLS System Verification
- Reader/Probe Design Verification
- Localizer System and Component Accuracy, Repeatability Evaluation
- Test Media Evaluation
- Reader and Surgical Probe Operating Environment Evaluation
- Tissue Marker Migration Evaluation
- Usability Verification and Validation
- Electrosurgical tool compatibility
- Packaging Validation
- Sterilization Validation

Biocompatibility

A biocompatibility evaluation was completed for the proposed RFID Localization System (RFLS), which has identical patient contacting materials as the Reference Device, Health Beacons RFID Localization System (K163667). 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 04/28/2017 (K163667).

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 (K163667).

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 (K163667). 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*”.

X. Conclusion

The proposed RFID Localization System (RFLS) has the same indications for use, principles of operation and similar fundamental scientific technology and materials as the predicate device, Cianna Medical SAVI Scout Reflector and SAVI Scout System. The differences in fundamental scientific technology, principles of operation and materials do not raise new safety and effectiveness questions as compared to a legally marketed predicate device. Therefore, the information provided in this submission supports safety and effectiveness of the proposed device for its intended use and demonstrates that the device is substantially equivalent to its predicate.