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

April 28, 2017

Health Beacons, Inc.
Ms. Nancy Confrey
Chief Executive Officer
34 Walden Street, #753
Concord, Massachusetts 01742

Re: K163667
Trade/Device Name: RFID Localization System- Localizer Reader, RFID Localization System- Localizer Surgical Probe, RFID Localization System- Localizer Surgical Probe (5 Pack), RFID Localization System- Tag Applicator, RFIDd Localization System -tag Applicator (10 Pack)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: PBY
Dated: April 21, 2017
Received: April 24, 2017

Dear Ms. Confrey:

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" (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.

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163667

Device Name
RFID Localization System

Indications for Use *(Describe)*

The Tag of the RFLS is intended for percutaneous placement in the breast to temporarily (<30 days) mark 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 summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. SUBMITTER

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Date Prepared
December 23, 2016

II. DEVICE

Trade Name:	RFID Localization System (RFLS)
Common Name:	Temporary Tissue Marker
Classification Name:	Implantable clip
Classification:	21 CFR§ 878.4300
Product Code:	PBY
Device Class:	Class II

III. PREDICATE

Cianna Medical, Inc. SAVI Scout Reflector and SAVI Scout System (K161507)

IV. DEVICE DESCRIPTION

The RFID Localization System (RFLS) 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, Reader, and Surgical Probe. 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.

V. INDICATIONS FOR USE

The Tag of the RFLS is intended for percutaneous placement in the breast to temporarily (<30 days) mark 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The RFLS has similar features as compared to the predicate device as shown in the following table:

Manufacturer	**Cianna Medical, Inc.**	**Health Beacons, Inc.**
Device Name	**SAVI Scout Reflector and SAVI Scout System**	**RFID Localization System (RFLS)**
510(k) Number	**K161507**	**TBD**
Anatomical Locations	Breast Tissue	Same
Primary Device Components	Electromagnetic wave reflective device (Reflector) pre-loaded in Delivery System, Handpiece, and Console	RFID Tag pre-loaded in Tag Applicator, Reader, and Surgical Probe
Breast Tissue Penetration / Delivery Device	Needle Implanter	Same
Visibility	X-ray, Ultrasound	Same
Principles of Operation	electromagnetic wave technology to detect the tissue marker	radiofrequency wave technology to detect tissue marker
Localization Accuracy	Unknown	±7 mm

Manufacturer	**Cianna Medical, Inc.**	**Health Beacons, Inc.**
Device Name	**SAVI Scout Reflector and SAVI Scout System**	**RFID Localization System (RFLS)**
510(k) Number	**K161507**	**TBD**
Indicators	Visual and Audible	Same
Implant Delivery Device Size/Working Length	16 Ga/130mm	12 Ga/100mm
Implant Delivery Device Needle Marking	1 cm marker increments	Same
Implant Dimensions	Approximately 0.05" (1.27 mm) x 0.49" (12.4 mm) long	Approximately 0.09" (2.3 mm) diameter x 0.37" (10.6 mm) long
Patient Contact Materials	• Reflector: 3922 Loctite, Nitinol SE508, light oxide • Delivery System: 304 Stainless Steel • Handpiece: Acrylonitrile butadiene styrene, Polyester film, Loctite 4011, NPO (COG) K20 (Dielectric material) • Console: N/A (no patient contact)	• Tag: Soda lime bioglass, polypropylene homopolymer • Tag Applicator: 304 Stainless Steel • Surgical Probe: Acrylonitrile butadiene styrene, 304 Stainless Steel, TPU, Silicone Elastomer • Reader: Polycarbonate, Polyester film (label)
Sterilization Method	Single-use, sterilized components: • Implanter and reflector (Ethylene Oxide) • Handpiece (Ethylene Oxide)	Single-use, sterilized components: • Tag Applicator and RFID Tag (Ethylene Oxide) • Surgical Probe (Gamma)
Tissue Marker Locator	Reusable, non-sterile Console	Reusable, non-sterile Reader
Conformance to Standards	ISO 10993 IEC 60601-1 IEC 60601-1-2 ASTM F2119-07	ISO 10993 IEC 60601-1 (3rd edition) IEC 60601-1-2 (4th edition) FCC 47 CFR Part 15 subpart C ASTM F2119-07 (2013)

The technological characteristics and principals of operation of the RFLS is substantially equivalent to the named predicate device. The primary difference between the two systems is the Savi Scout device uses electromagnetic wave technology to detect the tissue marker, while the subject device tissue marker is located using RFID technology (radiofrequency wave). However, this minor difference in technology does not raise new or different questions of safety and effectiveness. The performance testing included in the 510k demonstrates the safety of the system for its intended use and confirms the performance of the system for use in intra-operative surgical guidance. Specifically, the performance testing demonstrates the safe use of the system to facilitate intra-operative guided surgical procedures by detecting the presence of the Tag by providing an audible tone which

increases pitch and volume with decreased distance, a visible bar indicator, and a measurement readout.

VII. PERFORMANCE DATA

Performance testing was conducted to evaluate and characterize the performance of the RFLS. The following performance testing was conducted on the RFLS to support a determination of substantial equivalence to the predicate device.

- 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
- EMC/Safety Testing
- Biocompatibility
- Magnetic Resonance Testing
- Packaging Validation
- Sterilization Validation

VIII. CONCLUSIONS

The RFLS has been carefully compared to the legally marketed predicate device with respect to intended use/indications for use, technological characteristics, anatomical sites, performance, safety characteristics, and labeling. In addition, non-clinical testing was conducted to verify and validate the performance of the device and ensure the RFLS functions as intended and meets design specifications. The comparison and non-clinical performance testing results demonstrate that the device is substantially equivalent to the predicate device for its intended use.