Varian Medical Systems, Inc.
% Lisa Levine, Ph.D.
Director, Clinical and Pre-Market Regulatory Affairs
3100 Hansen Way
PALO ALTO CA 94304

April 6, 2018

Re: K170570
Trade/Device Name: Anchored Beacon® Transponder
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 21, 2018
Received: March 23, 2018

Dear Dr. Levine:

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.

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.

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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*
K170570

Device Name
Anchored Beacon® transponder, Anchored transponder, Beacon Care Package - Lung

Indications for Use *(Describe)*
The Calypso System is intended for use as an adjunct in treatment planning and radiation therapy, to align and/or monitor the patient's position relative to the isocenter of a radiation therapy system. The Calypso System provides accurate, precise, and continuous localization of a treatment isocenter by using two or more Beacon transponders.

Anchored Beacon transponders are indicated for permanent implantation in small airways in the lung to align and/or monitor the internal position of targets that move with respiratory and other patient motion in real time during radiation therapy.

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

Submitter's name:	Varian Medical Systems Inc 3100 Hansen Way Palo Alto, CA 94304 USA
Contact person:	Lisa Levine, PhD Director, Clinical and Pre-Market Regulatory Affairs Phone: 206-254-0600 Fax: 206-254-0606
Date summary prepared:	March 21, 2018
Trade name(s):	Anchored Beacon® transponder Anchored transponder Beacon® Care Package - Lung
Common name:	Fiducial marker
Classification name:	Medical charged-particle radiation therapy system
Classification number:	CFR 892.5050
Class:	Class II
Product code:	IYE
Predicate:	Permanent Beacon transponder (K140823)

Device description:
The Anchored Beacon® transponder is a small passive implant, intended for permanent implantation in small airways in the lung. It is provided pre-loaded in a single-use delivery catheter for bronchoscopic implantation in a lung airway.

The Anchored Transponder is comprised of a Permanent Beacon Transponder (glass-encapsulated electrical circuit) coupled to a stability feature (self-expanding 5-legged structure in a shell assembly). When implanted in a small diameter airway, the anchor legs of the stability feature expand independently to contact the airway wall.

When used with the Calypso® System, the Anchored Transponder signals enable real-time, objective measurement of the location of the treatment target in four dimensions. The system operator uses this information to align the patient's treatment target to the isocenter of the linear accelerator prior to radiation therapy and/or to monitor the position of the treatment target during treatment.

Intended use/Indications for use:

The Calypso System is intended for use as an adjunct in treatment planning and radiation therapy, to align and/or monitor the patient's position relative to the isocenter of a radiation therapy system. The Calypso System provides accurate, precise, and continuous localization of a treatment isocenter by using two or more Beacon transponders.

Anchored Beacon transponders are indicated for permanent implantation in small airways in the lung to align and/or monitor the internal position of targets that move with respiratory and other patient motion in real time during radiation therapy.

Predicate discussion:
This 510(k) notification is for a new Beacon transponder called the Anchored Beacon transponder, designed to be permanently implanted in the lung. The selected predicates are the following fiducial markers: the Soft Tissue Transponder 14G (K140823) and the superlock cobra marker (K120796). A comparison of the similarities and differences of the intended use/indications for use, technology, and other characteristics between the new device and the predicates is shown in the table below and discussed in the text following the table.

Item	New Device: Anchored Beacon transponder	Predicate #1: Soft Tissue transponder (K140823)	Predicate #2: superlock cobra marker (K120796)
Intended use/indications for use	The Calypso System is intended for use as an adjunct in treatment planning and radiation therapy, to align and/or monitor the patient's position relative to the isocenter of a radiation therapy system. The Calypso System provides accurate, precise, and continuous localization of a treatment isocenter by using two or more Beacon transponders. Anchored Beacon transponders are indicated for permanent implantation in small airways in the lung to align and/or monitor the internal position of targets that move with respiratory and other patient motion in real time during radiation therapy.	The Calypso System is intended for use as an adjunct in treatment planning and radiation therapy, to align and/or monitor the patient's position relative to the isocenter of a radiation therapy system. The Calypso System provides accurate, precise, and continuous localization of a treatment isocenter by using two or more Beacon transponders. Implanted Beacon transponders are indicated for use to radiographically and electromagnetically mark soft tissue for future therapeutic procedures. Permanent Beacon transponders are indicated for implantation in the body, specifically in the prostate and peri-prostatic tissue (i.e., prostatic bed), and in soft tissue to align and monitor the treatment isocenter in real time during radiation therapy.	The superDimension superLock Cobra is intended to be used to radiographically mark soft tissue for future surgical or therapeutic purposes.

Item	New Device: Anchored Beacon transponder	Predicate #1: Soft Tissue transponder (K140823)	Predicate #2: superlock cobra marker (K120796)
Technology (design and materials)	The anchored transponder is constructed by adding a self-expanding nitinol stabilization feature to Predicate #1. The unconstrained diameter of the nitinol stabilization feature is approximately 5 mm.	Cylinder consisting of small electrical circuit encased in biocompatible glass. No stabilization feature.	Gold cylinder with self-expanding nitinol stabilization feature. The unconstrained diameter of the nitinol stabilization feature is 4.1 mm.
Permanent implant	Yes	Yes	Yes
Sterility	Provided sterile (radiation sterilized).	Provided sterile (radiation sterilized).	Provided sterile (radiation sterilized).
Single use	Yes	Yes	Yes

The new device and the two predicates are intended to be used as fiducial markers. The Anchored transponder is intended for implantation in small airways in the lung, while the predicates are intended for implantation in soft tissue, and additionally in the prostate/prostatic bed for Predicate #2.

The Anchored transponder is constructed by adding a self-expanding nitinol stabilization feature to Predicate #1, so both the new transponder and Predicate #1 have this predicate in common. The Anchored transponder and Predicate #2 both have a cylindrical body with an attached self-expanding nitinol stabilization feature. The stabilization features prevent migration based on the same principle: the stabilization features expand against the surrounding tissue and hold the fiducial marker in place. The unconstrained diameters of the two stabilization features are similar.

The new device and the two predicates are permanent implants, provided radiation sterilized for single use.

Bench testing was performed and demonstrated: (1) the Anchored transponder satisfied the established performance requirements, including related to use in the lung; (2) biocompatibility testing in conformance with ISO 10993 supports safety of the Anchored transponder materials and the delivery catheter materials; and (3) the packaging provides protection and a sterile barrier.

Clinical study data obtained in lung cancer patients undergoing radiation therapy (69-patient cohort) showed the Anchored transponders can be localized to monitor patient

position, that the Anchored transponder is positionally stable in the airway, and that the Anchored transponder is safe as a permanent implant in the lung.

A long-term follow-up analysis comparing the stability of the anchored transponders in a subset of study patients to a matched cohort of patients with commercially-available fiducial markers implanted in lung (including the predicate, the superlock Cobra) showed equivalence of stability over time.

An analysis was performed of the long term radiographic changes in a separate cohort of patients treated with implanted anchored transponders who had undergone thoracic radiotherapy. The analysis shows that the presence of the transponders is unassociated with radiographic pulmonary abnormalities attributable to the transponder. Analysis of the clinical safety of the device in this expanded cohort confirms the safety profile is consistent with the original study patient data.

The clinical data show that the Anchored transponders can be localized to monitor patient position, that the Anchored transponder is positionally stable in the airway, and that the Anchored transponder is safe as a permanent implant in the lung.

Overall, the bench, biocompatibility, and clinical testing have demonstrated the Anchored transponder to be safe and effective for use in the lung.

After comparing the devices and considering the bench, biocompatibility, and clinical data, no new questions of safety and effectiveness are raised.

Thus, the new device is shown to be substantially equivalent to the predicates.