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

Varian Medical Systems, Inc.
% Ms. Marcia Page
Director Quality Assurance and Regulatory Affairs
2101 4th Avenue, Suite 100
SEATTLE WA 98121

November 25, 2015

Re: K152761
Trade/Device Name: Permanent Beacon Transponder
Soft Tissue Beacon Transponder
Beacon Care Package - Soft Tissue (17G)
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: November 16, 2015
Received: November 17, 2015

Dear Ms. Page:

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 yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152761

Device Name
Permanent Beacon Transponder
Soft Tissue Beacon Transponder
Beacon Care Package - Soft Tissue (17G)

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.

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-prostate tissue (i.e. prostatic bed), and in soft tissue to align and monitor the treatment isocenter 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

This 510(k) Summary is provided in accordance with 21 CFR 807.92(c).

Date of preparation:	22 September 2015
Submitter information:	Varian Medical Systems 2101 Fourth Avenue, Suite 100 Seattle, WA 98121 USA Phone: 206-254-0600 Fax: 206-254-0606
Contact:	Marcia A Page Director Quality Assurance and Regulatory Affairs
Device trade name:	Permanent Beacon® Transponder, or Soft Tissue Beacon transponder, provided in the Beacon® Care Package – Soft Tissue (17G)
Common name:	Fiducial marker
Classification:	CFR 892.5050 Class II Product code – IYE
Classification name:	Medical charged-particle radiation therapy system
Predicate device:	Beacon Care Package – Soft Tissue (14G) (K140823)

Device Description:

The Soft Tissue Beacon Transponder is a small, radiopaque, echogenic, electromagnetic fiducial marker designed for permanent implantation and intended for radiotherapy target localization to ensure accurate positioning for radiation therapy. It consists of a sealed biocompatible glass capsule containing a small, passive electrical circuit. The Soft Tissue Beacon Transponder may be used with the Calypso System (3.0 or later) as an electromagnetic fiducial marker, or with radiographic-based systems (e.g., kV x-ray, fluoroscopy, and CT) as a radiographic fiducial marker.

Each transponder is implanted with a separate 17G introducer needle Introducer) in or near the tumor or Intended radiation target. Three Soft Tissue Beacon Transponders and three single use introducers are provided in each Beacon Care Package – Soft Tissue (17G). The device is single use and provided sterile.

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.

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 the peri-prostatic tissue (i.e., prostatic bed) and in soft tissue to align and monitor the treatment isocenter in real time during radiation therapy.

Technological Characteristics – See device comparison table below

Feature/Specification	**BCP-Soft Tissue (14G) K140823**	**BCP-Soft Tissue (17G) This Submission**
Product Code	IYE	No Change
Transponder Frequencies	300kHz 400kHz 500kHz	No Change
Transponder dimensions	1.8mm (dia) x 8.5mm (length)	1.3 mm (dia) x 8.7 mm (length)
Patient Contacting Material	Glass	No Change
Introducer Needle	304 Stainless Steel 14G Cannula	304 Stainless Steel 17G Cannula
Labeling	General for soft tissue and specific for prostate/prostatic bed	No Change
Sterile Barrier	Mylar/Tyvek Pouch Double Barrier	No Change
Sterilization Method	Gamma Radiation	No Change
MR Safety	MR Conditional	No Change
Shelflife	2 Years	No Change
Calypso System	For use with v3.0 or higher	No Change