VARIAN
medical systems

JUN 27 2014

K140823
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510(k) Summary

Submitter information:	Varian Medical Systems 2101 4th Ave., Suite 100 Seattle, WA 98121 Phone: 206-254-0600 Fax: 206-577-4597
Contact person:	Lisa Levine, PhD Director, Clinical and Pre-Market Regulatory Affairs
Date summary prepared:	March 28, 2014
Trade name:	Permanent Beacon transponder or Soft Tissue Beacon transponder, provided in the Soft Tissue Beacon Package
Common name:	Fiducial marker
Classification name:	Medical charged-particle radiation therapy system
Classification number:	CFR 892.5050
Class:	Class II
Product code:	IYE
Predicates:	Calypso System with Beacon transponders (K060906, K080726, K123137) Gold Soft Tissue Marker (K071614) ONC Gold Seed Marker (K071673)

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 14G 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 Soft Tissue Beacon Care Package. 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 peri-prostatic tissue (i.e., prostatic bed), and in soft tissue to align and monitor the treatment isocenter in real time during radiation therapy.

Substantial equivalence:
The subject device has the same intended use as the predicates. The technological characteristics of the subject device are supported by the technological characteristics of the predicates. The subject device is as safe and effective as the predicates. There are no different questions of safety or effectiveness. Thus, the subject device is substantially equivalent.

The substantial equivalence table is shown on the next page for reference.

Table 7-1. Substantial Equivalence Comparison Table

Item/Characteristic	Permanent Beacon Transponder with Expanded Indications	Permanent Beacon Transponder (predicate)	Gold Soft Tissue Marker (predicate)	ONC Gold Seed Marker (predicate)
K number	n/a	K060906, K080726, K123137	K071614	K071673
Product code	IYE	IYE	IYE	IYE
Intended use	Radiotherapy target localization	Radiotherapy target localization	Radiotherapy target localization	Radiotherapy target localization
Indications for use statement (bold emphasis added only as an aid to the reader)	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, including in the prostate and**	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 prostate and the peri-prostatic tissue**	The fiducial markers are intended to be **implanted into the body** to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization. Specifically, they can be used in intracranial diseases as gliomas, neuromas, meningiomoas, astrocytomas, arteriovenous malformations, and metastatic carcinomas. Additionally, they can be used in the body for treating hepatic, pancreatic, retroperitoneal, paraspinal, skeletal, prostatic and breast tumors.	The ONC Marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

Item/Characteristic	Permanent Beacon Transponder with Expanded Indications	Permanent Beacon Transponder (predicate)	Gold Soft Tissue Marker (predicate)	ONC Gold Seed Marker (predicate)
	the peri-prostatic tissue (i.e., prostatic bed), to align and monitor the treatment isocenter in real time during radiation therapy.	(i.e., prostatic bed) to align and monitor the treatment isocenter in real time during radiation therapy.		
Shape	Cylindrical	Cylindrical	Cylindrical	Cylindrical
Dimensions	1.8 mm dia. x 8.5 mm length	1.8 mm dia. x 8.5 mm length	1.6 mm dia. x 3 mm length	1.2 mm dia. x 10 mm length
Materials	Biocompatible-glass-encapsulated electrical circuit (primarily copper and ferrite)	Biocompatible-glass-encapsulated electrical circuit (primarily copper and ferrite)	Gold	Gold
Radiographic and ultrasound imaging	Radiopaque (kV x-rays, fluoroscopy, CT); Echogenic (ultrasound)	Radiopaque (kV x-rays, fluoroscopy, CT); Echogenic (ultrasound)	Radiopaque (kV x-rays, MV x-rays, CT); Echogenic (ultrasound)	No details provided but known to be radiopaque and echogenic
Means of radiotherapy target localization	Used as electromagnetic fiducial marker with Calypso system Used as radiographic fiducial marker with radiographic detector	Used as electromagnetic fiducial marker with Calypso system Used as radiographic fiducial marker with radiographic detector	Used as radiographic fiducial marker with radiographic detector	Used as radiographic fiducial marker with radiographic detector
MR status	MR conditional	MR conditional	MR conditional	MR conditional
Other characteristics	Rigid, no attachments	Rigid, no attachments	Rigid, no attachments, knurled	Rigid, no attachments
Introducer needle gauge	14G	14G	14G	17G
Introducer needles available	Provided with introducer needles	Provided with introducer needles	Provided with introducer needles	Provided with introducer needles
Single-use	For single-use	For single-use	For single-use	For single-use
Sterility	Provided sterile	Provided sterile	Provided sterile	Provided sterile
Permanent implantation	For permanent implantation	For permanent implantation	For permanent implantation	For permanent implantation

Item/Characteristic	Permanent Beacon Transponder with Expanded Indications	Permanent Beacon Transponder (predicate)	Gold Soft Tissue Marker (predicate)	ONC Gold Seed Marker (predicate)
Biocompatibility	Biocompatibility was evaluated per ISO 10993	Biocompatibility evaluated per ISO 10993	Biocompatibility evaluated per ISO 10993	No information
Sterilization	Sterilization: gamma irradiation	Sterilization: gamma irradiation	Sterilization method: EtO	Sterilization method: EtO

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

June 27, 2014

Varian Medical Systems, Inc.
% Lisa Levine, Ph.D.
Director, Clinical and Pre-Market Regulatory Affairs
2101 4th Avenue, Suite 100
SEATTLE WA 98121

Re: K140823
Trade/Device Name: Permanent and Soft Tissue Beacon Transponder
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 31, 2014
Received: April 1, 2014

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.

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,

Michael D. O'Hara for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K140823

Device Name: Permanent Beacon® Transponder

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.

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K140823