K123815

PREMARKET NOTIFICATION

510(k) Summary

Surface Applicator Set with Leipzig-style Cone

As required by 21 CFR 807.92

MAR 1 1 2013

Submitter's Name:

Varian Medical Systems
911 Hansen Way, M/S C-260
Palo Alto CA94304

Contact Name: Peter J. Coronado
Phone: 650/424.6320
Fax:650/842.5051
Date: 30 November 2012

Proprietary Name:

GM11010080 Surface Applicator Set with Leipzig-style Cone

Classification Name:

Remote controlled radionuclide applicator system
21CFR892.5700
Class II

Common/Usual Name:

Surface Applicator Set(s), Surface Applicator

Predicate Devices:

Surface Applicator as part of GammaMedplus HDR remote afterloader system. K983436.

Device Description:

The Surface Applicator Set with Leipzig-style Cone is a Brachytherapy applicator set. Brachytherapy is a form of radiotherapy using Gamma rays from a radioactive source placed at locations close to or within a tumour to a predefined treatment plan. The treatment plan defines the positions and times for the source to ensure the correct dose for the treatment area. The applicator acts to guide the radioactive source to the correct location or locations for treatment..
The devices are intended to be used by trained and qualified personnel such as Radiation Oncologists, Physicians, Radiologists, Dosimetrists, Medical Physicists, and Nurses/MTRAs/Radiology Technicians/Radiographers in a hospital environment.

Indications for Use:

The Surface Applicator Set with Leipzig-style cone-GM11010080 is indicated for treatment of small skin tumours or other superficial disease (such as keloid formations) with HDR brachytherapy.

Technological Characteristics of the device compared with the predicate device:

	Surface Applicator	***GM11010080 Surface Applicator Set with Leipzig-style Cone***
Predicate Device Clearance Number:	GammaMedplus Afterloader system with applicators and accessories K983436	N/A
Compatible Afterloader	GammaMedplus GammaMed 12i(t)	GammaMedplus series VariSource Series
Intended use	The intended use of the GammaMed Plus transportable high-dose-rate remotely controlled afterloading brachytherapy device is for the treatment of cancer by intracavitary, interstitial, intraluminal and intraoperative irradiation.	The Surface Applicator Set with Leipzig-style Cone is intended for the treatment of small skin tumours or other superficial disease (such as keloid formations) with HDR brachytherapy.
Indications for Use	The intended use of the GammaMed Plus transportable high-dose-rate remotely controlled afterloading brachytherapy device is for the treatment of cancer by intracavitary, interstitial, intraluminal and intraoperative irradiation.	The Surface Applicator Set with Leipzig-style Cone is intended for the treatment of small skin tumours or other superficial disease (such as keloid formations) with HDR brachytherapy.
Target population	No specific population	No specific population
Design	Shielding for tubus with a vertical source entrance: Ø 10-25 mm and Ø 30-45 mm with fixation Surface tubus inset set: Ø10-25 mm, round Ø30-45 mm, round Ø30-45 mm, oval	Leipzig-style Cone with a horizontal source entrance: Ø 30-45 mm, with holder and guide Surface cone inset: Ø 30 mm, 35 mm, 40 mm, 45 mm, round
Materials	Shielding: Tungsten / Stainless Steel Surface tubus insets: Tungsten / PVC	Leipzig-style Cone: Tungsten / Stainless Steel Surface cone insets: Tungsten / PVC
Packing	individual	individual
Sterility	Non sterile	Non sterile
Sterilization method	Devices are not sterilized.	Devices are not sterilized.
Biocompatibility	N/A. The use of a sterile plastic envelope or surgical foil is required to prevent any parts of the applicator from having body contact.	N/A. The use of a sterile plastic envelope or surgical foil is required to prevent any parts of the applicator from having body contact.
Anatomical sites	skin	skin
Where used	Brachytherapy Treatment Room	Brachytherapy Treatment Room

Non Clinical Tests	Bench Testing has been performed to demonstrate • that the device functions correctly with the specified afterloaders; • that the device can withstand the number of cycles of use that it will experience in its lifetime; • that the device enables the radioactive source to be located to the accuracy required, • that the device is constructed of materials that are not significantly affected by the radiation to which they are exposed in the lifetime of the product; • that the positional accuracy of the source within the applicator is adequate. Usability was assessed to the requirements of IEC 62366:2007. Results of Bench Testing showed conformance to applicable requirements and specifications
Clinical Tests	No clinical tests have been included in this pre-market submission.
Conclusions	All the tests that were performed met the applied pass criteria. Varian considers the devices to be safe and effective and to perform as well or better than the predicate

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

Peter J Coronado
Director, Regulatory Affairs
Varian Medical Systems, Inc
911 Hansen Way
PALO ALTO CA 94304

March 11, 2013

Re: K123815
Trade/Device Name: Surface Applicator Set with Leipzing-style Cone
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: November 30, 2012
Received: December 12, 2012

Dear Mr. Coronado:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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): K123815

Device Name: **Surface Applicator Set with Leipzig-style Cone.**

Indications for Use:

GM110010080 Surface Applicator Set with Leipzig-style Cone.

The Surface Applicator Set with Leipzig-style cone-GM11010080 is indicated for treatment of small skin tumours or other superficial disease (such as keloid formations) with HDR brachytherapy.

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 Diagnostic Devices (OIVD)

Michael D. O'Hara

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K123815