



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Varian Medical Systems, Inc.
% Mr. Peter Coronado
Director, Varian Oncology Systems Regulatory Affairs
911 Hansen Way
PALO ALTO CA 94304

February 28, 2017

Re: K162018

Trade/Device Name: Surface Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: February 9, 2017
Received: February 10, 2017

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 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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a faint, large "FDA" watermark.

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

Indications for Use

510(k) Number (if known)

K162018

Device Name

Surface Applicator Set

Indications for Use (Describe)

The Surface Applicator Set is intended for treatment of small skin tumours or other superficial disease (such as keloid formations) with HDR Brachytherapy.

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.

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Premarket Notification [510(k)] Summary

Surface Applicator Set

The following information is provided following the format of 21 CFR 807.92(c).

Submitter's Name:	Varian Medical Systems, Inc. 3100 Hansen Way E-110 Palo Alto, CA 94304 Contact Name: Peter J. Coronado Phone: 650.424.6320 Fax: 650.646.9200 Date: February 9, 2017
Proprietary Name:	Surface Applicator Set
Classification Name:	Remote controlled radionuclide applicator system 21 CFR 892.5700, Class II Product Code: JAQ
Common/Usual Name:	Remote controlled radionuclide applicator system
Predicate Devices:	Surface Applicator Set with Leipzig-style Cone (K123815)
Device Description:	The Surface Applicator Set is an applicator for Brachytherapy. Brachytherapy is a form of radiotherapy using Gamma rays from a radioactive source placed at locations close to or within a tumor or other treatment area 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.
Intended Use Statement	The Surface Applicator Set is intended for treatment of small skin tumours or other superficial disease (such as keloid formations) with HDR Brachytherapy.
Indications for Use Statement	The Surface Applicator Set is intended for treatment of small skin tumours or other superficial disease (such as keloid formations) with HDR Brachytherapy.

Technological Characteristics:

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	SURFACE APPLICATOR SET WITH LEIPZIG-STYLE CONE (K123815)	MODIFIED DEVICE – SURFACE APPLICATOR SET
Compatible Afterloader	GammaMedplus Series	GammaMedplus Series
Intended 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.	The Surface Applicator Set is intended for treatment of small skin tumours or other superficial disease (such as keloid formations) with HDR Brachytherapy.
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.	The Surface Applicator Set is intended for treatment of small skin tumours or other superficial disease (such as keloid formations) with HDR Brachytherapy.
Design/Component list	Shielding for tubus with a vertical source entrance: <ul style="list-style-type: none"> • \varnothing 10-25 mm and \varnothing 30-45 mm with fixation Surface cone inset set: <ul style="list-style-type: none"> • \varnothing30, 35, 40 mm round Sterilization Plug GM11009960 and Leak Stop Button GM11003810	Shielding for the cone with a vertical source entrance: <ul style="list-style-type: none"> • \varnothing 10-25 mm and \varnothing 30-45 mm with fixation Surface cone inset set: <ul style="list-style-type: none"> • \varnothing15, 20, 25, 30, 35, 40 mm round • \varnothing 30 x 20 mm and \varnothing 45 x 25 mm oval Cleaning Caps (K152018)
Materials	<ul style="list-style-type: none"> • Surface cone inset: Tungsten/hard PVC • Leipzig Style Cone: Tungsten/ Stainless Steel 	<ul style="list-style-type: none"> • Surface cone inset: Tungsten/hard PVC • Shielding for cones with fixation: Tungsten/Stainless steel
Packing	Individual	Individual
Sterility	Delivered in non-sterile condition.	Delivered in non-sterile condition.
Sterilization method	Device is not sterilized.	Device is not sterilized.
Repeated Use	500 times	500 times

Cleaning cycles	100	100
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
Compatible with CT or MR	No	No
Where used	Brachytherapy treatment room	Brachytherapy treatment room

Performance Data:

Bench testing was performed to evaluate the suitability of the applicator sets repeated use for up to 500 times and 100 cleaning cycles. Non-clinical testing showed the test articles met the pre-defined acceptance criteria, thereby demonstrating that the device performs as intended.

Clinical Tests No clinical tests have been included in this pre-market submission

Conclusions

The non-clinical data support the safety of the device and the bench testing demonstrates that the Surface Applicator Set performs as intended. Varian therefore considers Surface Applicator Set to be safe and effective and to perform at least as well as the predicate device.