



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
PALA ALTO CA 94304

September 11, 2015

Re: K152018

Trade/Device Name: Varian Cleaning Caps, Leak Stop Buttons, Leak Stop Channel
Marker Sets

Regulation Number: 21 CFR 892.5700

Regulation Name: Remote controlled radionuclide applicator system

Regulatory Class: II

Product Code: JAQ

Dated: July 14, 2015

Received: July 21, 2015

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 watermark of the FDA logo.

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)

K152018

Device Name

Cleaning Cap, Leak Stop Buttons & Leak Stop Channel Marker Sets

Indications for Use (Describe)

The Cleaning Cap is intended to close the lumens of applicator parts during the cleaning and disinfection process. New sterilized Cleaning Caps can be placed onto applicators during patient insertion if this is desired.

The Leak Stop Buttons are intended to prevent liquid entering the applicator or source guide tube connector during implantation and treatment. They are also used for fixation of the individual channel marker clips.

The Leak Stop Channel Marker Sets are intended for the individual numbering of the multiple channels in combination of avoiding liquid entering the applicator or source guide tube connectors.

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

Cleaning Caps, Leak Stop Channel Markers & Leak Stop Buttons

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

- I. Submitter's Name:** Varian Medical Systems, Inc.
3120 Hansen Way C-260
Palo Alto, CA 94304
- Contact Name: Peter J. Coronado
Phone: 650.424.5731
Fax: 650.842.5040
Date: July 2015
- II. Trade Name:** Varian Cleaning Caps, Leak Stop Channel Marker Sets & Leak Stop Buttons
- Common Name:** Cleaning Caps, Leak Stop Channel Marker Sets & Leak Stop Buttons
- Classification Name:** Medical charged-particle radiation therapy system
21 CFR 892.5700, Class II
Product Code: JAQ
- III. Predicate Device:** Plastic interstitial needles: K141624
- IV. Device Description:** The Cleaning Caps, the Leak Stop Buttons and Leak Stop Channel Marker Sets are brachytherapy applicator accessories. The Cleaning Cap is used to close the lumens of applicator parts during the cleaning and disinfection process. During treatment the Leak Stop Buttons and Leak Stop Channel Marker Sets prevent blood or liquid from entering the source guide tube connector.
- V. Intended Use Statement:** The Cleaning Cap, the Leak Stop Channel Marker Sets and the Leak Stop Buttons are designed for brachytherapy treatment in areas such as the head and neck, gynecological, breast and prostate.
- Indications for Use Statement** The Cleaning Cap is intended to close the lumens of applicator parts during the cleaning and disinfection process. New sterilized Cleaning Caps can be placed onto applicators during patient insertion if this is desired.
- The Leak Stop Buttons are intended to prevent liquid entering the applicator or source guide tube connector during implantation and treatment. They are also used for fixation of the individual channel marker clips.
- The Leak Stop Channel Marker Sets are intended for the individual numbering of the multiple channels in combination of avoiding liquid entering the applicator or source guide tube connectors.

Premarket Notification [510(k)] Summary

Cleaning Caps, Leak Stop Channel Markers & Leak Stop Buttons

VI. Technological Characteristics:

FEATURE/ SPECIFICATION	PLASTIC INTERSTITIAL NEEDLES 510(k) ID # K141624	CLEANING CAPS, LEAK STOP CHANNEL MARKER SETS & LEAK STOP BUTTONS
Materials:	Needles: PEEK/Titanium Obturator/Mandrin: Stainless Steel Cleaning Caps: Silicone Leak Stop Channel Marker: Silicone Leak Stop Buttons: Silicone	Cleaning Caps: Silicone Leak Stop Channel Marker: Silicone Leak Stop Buttons: Silicone
Compatibility with the environment and other devices	CT compatible, MR conditional for 1.5 and 3.0T	CT compatible; MR safe Designed to be used with all Varian applicator probes, tandems or needles with the ClickFit™ connector.
Dimensions	Plastic needle: <ul style="list-style-type: none"> • Diameter: 2 mm • Length: 113, 200, 320mm • Tip styles: Sharp tip Blunt tip (320mm length only) Cleaning Caps: <ul style="list-style-type: none"> • Diameter: 5.1mm • Length: 13.5mm Leak Stop Channel Marker: <ul style="list-style-type: none"> • Diameter: 10.0mm • Length: 2.0mm Leak Stop Buttons: <ul style="list-style-type: none"> • Diameter: 10.0mm • Length: 2.0mm 	Cleaning Caps: <ul style="list-style-type: none"> • Diameter: 5.1mm • Length: 13.5mm Leak Stop Channel Marker: <ul style="list-style-type: none"> • Diameter: 10.0mm • Length: 2.0mm Leak Stop Buttons: <ul style="list-style-type: none"> • Diameter: 10.0mm • Length: 2.0mm
Packing	Individual packaging for needles Cleaning Caps: Pack of 25 Leak Stop Channel Marker: <ul style="list-style-type: none"> • Sets contain packs of 25 (for each channel); • Sets are Channels 1-12, Channels 13-24, and Channels 25-30 Leak Stop Buttons: Pack of 50	Cleaning Caps: Pack of 25 Leak Stop Channel Marker: <ul style="list-style-type: none"> • Sets contain packs of 25 (for each channel); • Sets are Channels 1-12, Channels 13-24, and Channels 25-30 Leak Stop Buttons: Pack of 50

Premarket Notification [510(k)] Summary

Cleaning Caps, Leak Stop Channel Markers & Leak Stop Buttons

VII. Summary of performance testing:

Results of verification and validation testing showed conformance to applicable requirements specifications and assured hazard safeguards functioned properly.

Biocompatibility testing requirements for irritation, sensitization, and acute systemic injection have been met.

Cleaning validation test requirements have been met.

Standards conformance:

The Varian Cleaning Caps, Leak Stop Channel Marker Sets & Leak Stop Buttons conform in whole or in part with the following standards:

ISO 14971:2012	IEC 62366:2007
ISO 10993-1:2009	ANSI/AAMI/ISO 10993-5:2009
ISO 10993-10:2010	ANSI/AAMI/ISO 10993-6:2007
ISO 10993-12:2012	ANSI/AAMI/ISO 10993-11:2010

Conclusion:

Based on the verification, validation and non-clinical 10993 standard testing, the The Varian Cleaning Caps, Leak Stop Channel Marker Sets & Leak Stop Buttons are as safe, effective and performs as well as or better than the legally marketed device identified in section III above.