



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, Regulatory Affairs
911 Hansen Way
PALO ALTO CA 94304

July 17, 2015

Re: K150839

Trade/Device Name: 3D Interstitial Ring Applicator Sets (60° and 90°) and the Ring
Applicator Sets (45°, 60° and 90°)
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: June 18, 2015
Received: June 19, 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. Behind the signature, there is a faint, large watermark of the letters "FDA" in a stylized font.

For

Robert Ochs, Ph.D.
Acting 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)
K150839

Device Name

3D Interstitial Ring Applicator Sets (60° and 90°) and the Ring Applicator Sets (45°, 60° and 90°)

Indications for Use (Describe)

The 3D Interstitial Ring Applicator Sets (60° and 90°) and the Ring Applicator Sets (45°, 60° and 90°) are intended for use for cancer treatment of the vagina, cervix, and uterus using HDR or PDR 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

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PREMARKET NOTIFICATION

510(k) Summary

Remote Controlled Radionuclide applicator System

As required by 21 CFR 807.92

Submitter's Name: Varian Medical Systems
3100 Hansen Way, m/s E-110
Palo Alto CA94304

Contact Name: Peter J. Coronado
Phone: 650/424.6230
Fax: 650/646.9200

Date: March 27th 2015

Proprietary Name: 3D Interstitial Ring Applicator Set 60°
3D Interstitial Ring Applicator Set 90°
Ring Applicator Set 45°
Ring Applicator Set 60°
Ring Applicator Set 90°

Classification Name: Remote controlled radionuclide applicator system
21CFR892.5700
Class II

Common/Usual Name: Remote controlled radionuclide applicator system

Predicate Devices: The Mick Radio Nuclear Instruments, Inc. CT HDR Tandem/Ring Applicator With Rectal Ring Retractor (K030110)

Device Description: The **3D Interstitial Ring Applicator Sets (60° and 90°)**, are applicators for intracavitary or intracavitary/interstitial 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.

The **Ring Applicator Sets (45°, 60° and 90°)**, are applicators for intracavitary 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.

Indications for Use:

The 3D Interstitial Ring Applicator Sets (60° and 90°) and the Ring Applicator Sets (45°, 60° and 90°) are intended for use for cancer treatment of the vagina, cervix, and uterus using HDR or PDR brachytherapy.

Technological Characteristics:

FEATURE AND/OR SPECIFICATION OF NEW/MODIFIED DEVICE	510(k) ID K030110 CT HDR TANDEM/RING APPLICATOR WITH RECTAL RETRACTOR	3D INTERSTITIAL RING APPLICATOR SETS (60° AND 90°) AND RING APPLICATOR SETS (45°, 60° AND 90°)
Compatible Afterloader	GammaMed plus GammaMed 12i(t) VariSource	GammaMedplus iX GammaMedplus
Intended use	High dose rate Brachytherapy treatment of the uterus and cervix	The 3D Interstitial Ring Applicator Sets 60° and 90°) and the Ring Applicator Sets (45°, 60° and 90°) are intended for use for cancer treatment of the vagina, cervix, and uterus using HDR or PDR brachytherapy.
Indications for Use	The Mick Radio-Nuclear Instruments, Inc. CT HDR Tandem/Ring Applicator with Rectal Retractor is indicated for High Dose Rate irradiation of the uterus and cervix	The 3D Interstitial Ring Applicator Sets (60° and 90°) and the Ring Applicator Sets (45°, 60° and 90°) are intended for use for cancer treatment of the vagina, cervix, and uterus using HDR or PDR brachytherapy.

Design	<p>Ring applicators 30°, 45°, and 60°; 32mm diameter</p> <p>Intrauterine tandems 30°, 45°, and 60°; 20mm, 40mm, 60mm, and 80mm lengths</p>	<p>3D interstitial ring applicators Sets (60° and 90°)</p> <p>30mm diameter Intrauterine tandems 60°and, 90°; 30mm, 40mm, 50mm, 60mm, 70mm, and 80mm lengths</p> <p>3D interstitial ring applicators and intrauterine tandems in sets possess holes to allow for needle application.</p> <p>Ring applicators Sets (45°,60°and 90°)</p> <p>(same as predicate, angle measured from different position); 26mm, and 30mm diameter</p> <p>Intrauterine tandems 45°,60°, and 90°; 30mm, 40mm, 50mm, 60mm, 70mm, and 80mm lengths</p>
Materials	Stainless Steel, PPSU, PEEK, Titanium	PEEK, Titanium
Packing	Individual	Individual
Sterility	Provided non sterile	Provided non sterile
Sterilization method	<p>Steam sterilization</p> <p>15 minutes @ 121°C</p> <p>5 minutes @ 134°C</p> <p>18 minutes @ 134°C</p>	<p>Steam sterilization</p> <p>4 minutes @ 132°C</p> <p>3 minutes @ 134°C</p> <p>5 minutes @ 134°C</p>
Biocompatibility	Full biocompatibility	Full biocompatibility
Anatomical sites	Uterus, cervix	Uterus, cervix, vagina
Compatibility with the environment and other devices	CT compatible	<p>CT compatible</p> <p>MR conditional for 1.5 and 3 Tesla</p>
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;
- the device can withstand the number of cycles of use that it will experience in its lifetime;
- the device enables the radioactive source to be located to the accuracy required,
- 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;
- the device may be sterilized effectively

- the device can be used and sterilized for the specified number of times
- 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. Body of testing provides evidence that the devices are safe and effective to perform as well or better than the predicate.