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

March 24, 2017

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

Re: K162615
Trade/Device Name: Mould Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: February 22, 2017
Received: February 23, 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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162615

Device Name
Mould Applicator Set

Indications for Use *(Describe)*
The Mould Applicator Set is indicated for IORT, interstitial and intraluminal treatments of cancer and treatments of cancer or other superficial disease 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)*

PREMARKET NOTIFICATION

510(k) Summary

Mould Applicator Set

As required by 21 CFR 807.92

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E110 Palo Alto CA94304 Contact Name: Peter J. Coronado Phone: 650/424.6320 Fax: 650/646.9200 Date: 9th Sep 2016
Proprietary Name:	Mould Applicator Set
Classification Name:	Remote controlled radionuclide applicator system 21CFR892.5700 Class II
Common/Usual Name:	Mould Applicator Set
Predicate Devices:	GammamedPlus HDR Afterloading System (K983436).
Device Description:	The Mould Applicator Set is an applicator for intraoperative, interstitial, intraluminal or surface 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 Mould Applicator Set can be steam sterilized with common parameters using Pre-vacuum sterilization. The mould probes Ø 2.8mm (GM11002280), which are part of the set, have a maximum implantation time of up to 24 hours. According to ISO 10993-1 they are categorised as medical devices, external communicating with tissue/bone communicating and a limited contact duration (A). They can be steam sterilized and used 25 times. The mould probes Ø 1.8mm (GM11002290) have a maximum implantation time of up to 7 days. According to ISO 10993-1 they

	are categorised as a medical device, external communicating with tissue/bone communicating and prolonged contact duration (B). When steam sterilised, they are a single use product and can be used for IORT, interstitial and intraluminal treatments. If only disinfected the probe can be used up to 10 times for treatment of superficial diseases. The Mould Applicator Set is CT compatible. The Mould Applicator Set is MR conditional for 1.5 and 3 Tesla when the mandrins have been removed from the mould probes after insertion in the patient.
Indications for Use:	The Mould Applicator Set is indicated for IORT, interstitial and intraluminal treatments of cancer and treatments of cancer or other superficial disease using HDR or PDR brachytherapy.

Technological Characteristics:

	1.5 and 2.8mm Catheters as part of GammaMedplus HDR Afterloading System K983436.	**Mould Applicator set**
Intended use	Covered by intended use of complete afterloader system in original submission: 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 Mould Applicator Set is intended for IORT, interstitial and intraluminal treatments of cancer and treatments of cancer or other superficial disease using HDR or PDR brachytherapy.
Indications for Use	Covered by indication for use of complete afterloader system in original submission: 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 Mould Applicator Set is indicated for IORT, interstitial and intraluminal treatments of cancer and treatments of cancer or other superficial disease using HDR or PDR brachytherapy.
Compatible Afterloader	GammaMedplus	GammaMedplus
Design	Catheters: • Diameter: 1.5 or 2.8mm • Length: 130cm	Mould Probe Diameter: 1.8 or 2.8mm Length: 320 mm 1.8mm Mould Probe supplied with mandrin
Materials	1.5mm Catheter: Polyamide 2.8mm Catheter: Fluorinated ethylene propylene (FEP) Probe connectors: Stainless steel	1.8mm Mould Probe: Polyamide (PA) 2.8mm Mould Probe: Fluorinated ethylene propylene (FEP) Probe connectors: Titanium Mandrin: Stainless steel
Packing	individual	Individual
Sterility	Provided non sterile	Provided non sterile

Sterilization method	Steam sterilization	1.8mm and 2.8mm Mould Probes: Manual Cleaning, Steam sterilization. 1.8mm Mould Probe is a single use product when steam sterilized.
Biocompatibility	Full biocompatibility	Full biocompatibility Max 24 hours contact for the 2.8mm Mould Probe. Max7 days contact for 1.8mm Mould Probe
Compatibility with the environment and other devices	No CT or MR claims	CT compatible, MR conditional 1.5 and 3 T
Where used	Brachytherapy treatment room	Brachytherapy treatment room

Non Clinical Tests Bench Testing has been performed to demonstrate that

- the devices function correctly with the specified afterloader;
- the devices can withstand the number of cycles of use they will experience in its lifetime;
- the devices enable the radioactive source to be located to the accuracy required,
- the devices are constructed of materials that are not significantly affected by the radiation to which they are exposed in the lifetime of the product;
- the devices may be sterilized effectively
- the devices can be used and sterilized for the specified number of times
- the positional accuracy of the source within the devices is adequate.
- the devices are biocompatible as per ISO10993 standards
- the devices can be used safely and effectively in CT environments
- testing of the Mould Applicator in MRI environments has demonstrated it is safe to use under the conditions specified in the labelling.

Usability has been 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