DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

March 10, 2017

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

Re: K160815
Trade/Device Name: Interstitial Needles
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: February 27, 2017
Received: March 1, 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)* K160815

Device Name
Interstitial Needles

Indications for Use *(Describe)*
The Interstitial Needles and their corresponding obturators are indicated for use for interstitial irradiation treatments of soft tissues such as breast, head and neck, tongue.

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.

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PREMARKET NOTIFICATION

510(k) Summary

Interstitial Needles

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: 2nd March 2017
Proprietary Name:	Interstitial Needles
Classification Name:	Remote controlled radionuclide applicator system 21CFR892.5700 Class II
Common/Usual Name:	Interstitial Needles
Predicate Devices:	K093291. Varian Interstitial Titanium Needles.
Device Description:	The Interstitial Needles and their corresponding Obturators/Mandrins are intended for interstitial irradiation treatments of soft tissues including breast, head and neck, and tongue using HDR or PDR brachytherapy and are compatible with the following afterloaders: VariSource iX™, VariSource 200™, GammaMedplus iX™ and GammaMedplus™ and can be used in combination with the appropriate accessories. 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. There are two versions of the needle included in this submission: titanium and stainless steel.
Indications for Use:	The Interstitial Needles and their corresponding obturators are indicated for use for interstitial irradiation treatments of soft tissues such as breast, head and neck, tongue.

Technological Characteristics:

	Cleared Device Feature/Specification	New / Modified Device	New / Modified Device
Feature and/or Specification of new/modified device	**K093291=predicate** **17G Interstitial Titanium needles: GM11009700, GM11009710, GM11009720, GM11009730**	**17G Interstitial Titanium needles: GM11009700, GM11009710, GM11009720, GM11009730** **16G Titanium Interstitial Needles: GM11010210, GM1010220, GM11010230, GM11010240, GM11010410, GM11010420, GM11010430, GM11010440** **Mandrin for 16G Needle: GM11003340, GM11003270, GM1101080, GM11003100**	**17G Stainless Steel Needle: GM11009500, GM11009510, GM11009520, GM11009530** **18G Stainless Steel Needle: GM11009550, GM11009560, GM11009570, GM11009580** **Obturator for 17G and 18G Needle: GM11009800, GM11009810, GM11009820, GM11009830**
Intended use	The Interstitial Needles are used with Varian High Dose Rate Afterloaders	The Interstitial Needles and their corresponding obturators are intended for use in interstitial irradiation treatments of soft tissues such as breast, head and neck, tongue, using HDR or PDR brachytherapy.	The Interstitial Needles and their corresponding obturators are intended for use in interstitial irradiation treatments of soft tissues such as breast, head and neck, tongue, using HDR or PDR brachytherapy.
Indication for use	The Interstitial Needles are used with Varian High Dose Rate Afterloaders	The Interstitial Needles and their corresponding obturators are indicated for use for interstitial irradiation treatments of soft tissues such as breast, head and neck, tongue, using HDR or PDR brachytherapy.	The Interstitial Needles and their corresponding obturators are intended for use in interstitial irradiation treatments of soft tissues such as breast, head and neck, tongue, using HDR or PDR brachytherapy.
Compatible Afterloader	GammaMedplus afterloader series VariSource 200 and iX afterloader	GammaMedplus afterloader series VariSource 200 and iX afterloader	GammaMedplus afterloader series VariSource 200 and iX afterloader 18G Stainless Steel Needle and Obturator only compatible with VariSource 200 and iX afterloader.

Design	**17G Titanium Needle** The needles have a sharp trocar point and will be available in the following dimensions: • Length: 113mm, 220mm, 250mm and 320 mm • Diameter: 17 Gauge (ø 1.47 mm)	**17G Titanium Needle** The needles have a sharp trocar point and will be available in the following dimensions: • Length: 113mm, 220mm, 250mm and 320 mm • Diameter: 17 Gauge (ø 1.47 mm) **16G Titanium Needle** The needles have a sharp and blunt trocar point and will be available in following dimensions: • Length: 113 mm, 200 mm, 250 mm, 320 mm • Diameter: 16 Gauge (ø 1.65 mm)	The needles have a sharp trocar point and will be available in the following dimensions: • Length: 113mm, 220mm, 250mm and 320 mm • Diameter: 17 Gauge and 18 Gauge(ø 1.47 mm and ø1.27 mm) The obturators will be suitable for following dimensions: • Length: 113mm, 200mm, 250mm and 320mm Diameter: 17 Gauge and 18 Gauge (ø 1.47mm and ø 1.27mm)
Materials	**Needle**: Titanium **Obturator**: Stainless steel	**Needle**: Titanium **Obturator, Mandrin**: Stainless steel	**Needle**: Stainless steel **Obturator**: Stainless steel
Packing	Individual	Individual	Individual
Sterility	Delivered in non-sterile condition. To be sterilized at customer site Needle 25 cycles Obturator: 100 cycles	Delivered in non-sterile condition. To be sterilized at customer site Needle 25 cycles Obturator, Mandrin: 100 cycles	Delivered in non-sterile condition. To be sterilized at customer site. Number of sterilization cycle: Needle 25 cycles Obturator: 100 cycles
Sterilization method	Manual Cleaning Steam sterilization	Manual and Machine Cleaning Steam sterilization	Manual and Machine Cleaning Steam sterilization
Biocompatibility	Biocompatible titanium and stainless steel (mandrins and obturators only) used. (ISO 10993)	Biocompatible titanium and stainless steel (mandrins and obturators only) used. (ISO 10993)	Biocompatible Stainless Steel used. (ISO 10993)
Anatomical sites	Breast, prostate, head and neck, tongue or soft tissue structure	Breast, prostate, head and neck, tongue or soft tissue structure	Breast, prostate, head and neck, tongue or soft tissue structure
Compatibility with the environment and other devices	Compatible with CT imaging modalities	Compatible with CT imaging modalities	Compatible with CT imaging modalities
Where used	Brachytherapy treatment room	Brachytherapy treatment room	Brachytherapy treatment room

Non Clinical Tests Bench Testing has been performed to demonstrate that

- the devices function correctly with the specified afterloaders;
- 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 ISO10933 standards
- the devices can be used safely and effectively in CT environments

Usability was assessed to the requirements of IEC 62366:2007.
Results of Bench Testing showed conformance to applicable requirements and specifications

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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