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

October 20, 2016

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

Re: K161540
Trade/Device Name: Advanced Breast Template System
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: September 12, 2016
Received: September 13, 2016

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)*
K161540

Device Name
Advanced Breast Template System

Indications for Use *(Describe)*
The Advanced Breast Template System is intended for use for cancer treatment of the breast or chest wall using high dose rate 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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510k Summary

510(k) Submission for Advanced Breast Template System

As required by 21 CFR 807.92, Reference: FDA's Guidance Document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" (June 2014).

I. SUBMITTER

Submitter's Name:	Varian Medical Systems 3100 Hansen Way, m/s E-110 Palo Alto CA 94304-1038
Contact Name:	Peter J. Coronado
Position:	Director, Regulatory Affairs
Phone:	1.650.424.6230
Fax:	1.650.646.9200
Email:	submissions.support@varian.com
Date Prepared:	June 1, 2016

II. DEVICE

Name of Device:	Advanced Breast Template System
Common/Usual Name:	System, Applicator, Radionuclide, Remote-Controlled
Regulation Name:	Remote controlled radionuclide applicator system (21 CFR 892.5700)

Regulatory Class: Class II
Product Code: JAQ

III. PREDICATE DEVICE

Name of Predicate: VariSource Breast Template System

510k Number: K023220

IV. DEVICE DESCRIPTION

The Advanced Breast Template System is an applicator for 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 device does not contain or consist of software/firmware. The device does not contain any biologics or drug components. The device has patient-contacting materials. The device is designed for repeated use. No parts of the system are provided sterile. The device can be steam sterilized with common parameters using pre-vacuum sterilization. This device is used on male and female patients.

The Advanced Breast Template System is compatible with the following afterloaders: VariSource iX™, VariSource 200™, GammaMedplus iX™ and GammaMedplus™.

The Advanced Breast Template System is CT compatible.

The device is 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.

V. INDICATIONS FOR USE

Indications for Use Statement: The Advanced Breast Template System is intended for use for cancer treatment of the breast or chest wall using high dose rate HDR Brachytherapy.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both the subject and predicate devices are intended for use in the treatment of cancer through interstitial brachytherapy.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Ratchet assembly and other device components are fully biocompatible
- Application in interstitial brachytherapy treatments
- Same anatomical treatment site/application
- Sterilized by user prior to use (and reuses)

The following main differences exist between the subject and predicate devices:

- Reworded indications for use
- Material change in the ratchet assembly
- Validation of machine cleaning and sterilization parameters
- Added CT compatibility
- Added GammaMed Afterloader compatibility

VI. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Non-Clinical Tests:

Biocompatibility Testing:

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. This included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Subacute Toxicity
- Implantation

According to ISO 10993-1 the components of the Advanced Breast Template System are categorized as a medical device, surface device in contact with breached or compromised surfaces and prolonged contact duration (>24h to 30d). (B).

Sterilization Testing:
Sterilization testing was performed for the subject device was conducted to assess the effectiveness of the provided cleaning, disinfection, and sterilization procedures for the device. Furthermore, the components of the subject set were subjected to sterilization cycles up to the stated use life and evaluated for performance and any damage that might affect safety or effectiveness.

- Validation/Efficacy Testing of Cleaning, Disinfection, Sterilization Cycles

Electrical Safety and Electromagnetic Compatibility (EMC):
This item is not applicable to the subject device. No electrical safety and electromagnetic compatibility tests have been included in this submission in support of the substantial equivalence determination.

Software Verification and Validation Testing:
This item is not applicable to the subject device; the device does not contain or consist of software/firmware. No software verification and validation testing has been included in this submission in support of the substantial equivalence determination.

Mechanical and Acoustic Testing:

- CT Compatibility Tests and Analysis

Declaration of Conformity:
The following list are standards to which the subject device declares conformity:

- ISO 10993-1
- ISO 10993-5
- ISO 10993-10

- AAMI ANSI ST-79
- AAMI ANSI ST-81
- AAMI TIR-12
- AAMI TIR-30
- IEC 62366
- EN ISO 17664

Animal Study / Clinical Tests:

No animal studies or clinical tests have been included in this submission in support of the substantial equivalence determination.

VII. CONCLUSIONS

The results of the non-clinical tests support the safety and effectiveness of the device under the specified use conditions. Varian believes that the validation and verification testing demonstrates that the subject device performs comparably to the predicate device, meeting the intended use.