



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

April 13, 2016

Re: K160021

Trade/Device Name: Varian Sterilization Boxes
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: March 9, 2016
Received: March 11, 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,

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)

K160021

Device Name

Varian Sterilization Boxes

Indications for Use (Describe)

The Varian Sterilization boxes are intended to securely store the applicator parts during steam sterilization process and subsequent storage.

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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Varian Medical Systems, Inc.
 3100 Hansen Way
 Palo Alto, CA 94304-1038
 USA
 Tel +1 650 493 4000
 www.varian.com

Premarket Notification [510(k)] Summary

Varian Sterilization Boxes

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

Submitter's Name:	<p>Varian Medical Systems, Inc. 3100 Hansen Way E-110 Palo Alto, CA 94304</p> <p>Contact Name: Peter J. Coronado Phone: 650.424.6320 Fax: 650.646.9200</p> <p>Date: February 22, 2016</p>
Proprietary Name:	Varian Sterilization Boxes
Classification Name:	Remote controlled radionuclide applicator system 21 CFR 892.5700, JAQ, Class II
Common/Usual Name:	Remote controlled radionuclide applicator system
Predicate Devices:	[K980576] VariSource Endometrial Applicator for VariSource Remote High Dose Rate Afterloader (predicate is the Sterilization Tray which is a component of the applicator set).
Device Description:	The Varian Sterilization boxes consist of an aluminium box with hinged lid and fasteners. There are arrays of holes in the top and bottom surfaces to allow evacuation during pre-vacuum processes. In the Universal Sterilization Box there is a perforated plastic inlay to allow placement of the components or devices to be sterilized. In the device-specific boxes there are supports to hold the components.
Intended Use Statement	The Varian Sterilization boxes are intended to securely store the applicator parts during steam sterilization process and subsequent storage.
Indications for Use Statement	The Varian Sterilization boxes are indicated to securely store the applicator parts during steam sterilization process and subsequent storage.

Technological Characteristics:

	<p><i>VARIAN ENDOMETRIAL APPLICATOR FOR VARISOURCE REMOTE HIGH DOSE RATE AFTERLOADER K980576</i></p> <p><i>Predicate: Sterilization Tray GM11009940 (Component of VariSource Endometrial Applicator Set K980576)</i></p>	<p><i>Varian Sterilization Boxes GM11010300, GM11010310 GM11010320, GM11010340</i></p>
<p>Intended use</p>	<p>The Varian VariSource Remote High Dose Rate Afterloader [system, including applicators and accessories] is a device intended to be used by properly trained and licensed medical personnel to provide radiation brachytherapy. The VariSource Endometrial Applicator which is the subject of this 510(k) is a component of the VariSource system.</p> <p>The sterilization tray is intended to securely store the applicator parts during steam sterilization process and subsequent storage.</p> <p>[The intended use for the sterilization tray isn't specifically cleared however it is a component of the cleared applicator set K980576 and this is the intended use for the component at that time.]</p>	<p>The Varian Sterilization boxes are intended to securely store the applicator parts during steam sterilization process and subsequent storage.</p>

<p>Indications for Use</p>	<p>The Varian VariSource Remote High Dose Rate Afterloader [system, including applicators and accessories] is a device intended to be used by properly trained and licensed medical personnel to provide radiation brachytherapy. The VariSource Endometrial Applicator which is the subject of this 510(k) is a component of the VariSource system.</p> <p>The sterilization tray is intended to securely store the applicator parts during steam sterilization process and subsequent storage.</p> <p>[The indications for use for the sterilization tray aren't specifically cleared however it is a component of the cleared applicator set K980576 and this is the indications for use for the component at that time.]</p>	<p>The Varian Sterilization boxes are intended to securely store the applicator parts during steam sterilization process and subsequent storage.</p>
<p>Design</p>	<p>The box has rectangular base with a latch able lid. The box has perforations on the lid and bottom to allow sterilant penetration.</p>	<p>The box has rectangular base with a latch able lid. The box has perforations on the lid and bottom to allow sterilant penetration.</p>
<p>Materials</p>	<p>Aluminum alloy, silicone, stainless steel</p>	<p>Aluminum alloy, silicone, stainless steel</p>
<p>Physical Properties</p>	<p>Dimensionally stable</p> <p>No water absorption</p>	<p>Dimensionally stable</p> <p>No water absorption</p>
<p>Chemical Properties</p>	<p>N/A, no polymeric composites used as packing materials.</p>	<p>N/A, no polymeric composites used as packing materials.</p>
<p>Configuration/ Dimension</p>	<p>L400mm x W260mm x H70mm</p> <p>Volume = 7280cm³</p>	<p>GM11010300: L399mm x W259mm x H75mm Volume = 7751 cm³</p> <p>GM11010310: L408mm x W262mm x H75mm Volume = 8017 cm³</p> <p>GM11010320: L399mm x W259mm x H75mm Volume = 7751 cm³</p> <p>GM11010340: L407mm x W262mm x H75mm. Volume = 7997 cm³</p>
<p>Air permeance</p>	<p>N/A, the box does not provide a sterile barrier. Sterilization wrap has to be used.</p>	<p>N/A, the boxes does not provide a sterile barrier. Sterilization wrap has to be used.</p>

Percent of surface perforations	11%	GM11010300: 18% GM11010310: 17% GM11010320: 18% GM11010340: 19%
Method of holding applicators in place	Brackets	Silicone mat upon which items can be placed
Sterility	Provided non-sterile	Provided non-sterile
Sterilization method	<p>Steam sterilization up to 500 times Pre-vacuum autoclave cycles have been validated for use in the health care facilities as follows:</p> <p>132°C (270°F) exposure temperature set-point, 4 minute exposure time, 25 minute drying time</p> <p>134°C (273°F) exposure temperature set-point, 3 minute exposure time, 25 minute drying time</p> <p>134°C (273°F) exposure temperature set-point, 5 minute exposure time, 25 minute drying time</p>	<p>Steam sterilization up to 500 times Pre-vacuum autoclave cycles have been validated for use in the health care facilities as follows:</p> <p>132°C (270°F) exposure temperature set-point, 4 minute exposure time, 25 minute drying time</p> <p>134°C (273°F) exposure temperature set-point, 3 minute exposure time, 25 minute drying time</p> <p>134°C (273°F) exposure temperature set-point, 5 minute exposure time, 25 minute drying time</p>
Microbial Barrier Properties (Packaging Integrity)	The device does not provide a sterile barrier. Sterilization wrap has to be used. Hospital is responsible for wrapping materials, as well as method and shelf life validation.	The device does not provide a sterile barrier. Sterilization wrap has to be used. Hospital is responsible for wrapping materials, as well as method and shelf life validation.
Material Compatibility	Compatible to steam and can be used 500 times.	Compatible to steam and can be used 500 times.
Toxicological Properties (Biocompatibility, including Sterilant Residue Limits)	N/A, According to ISO 10993-1/FDA G-95-1 the Sterilization Box is a non-invasive product and is not intended to have any patient contact.	N/A, According to ISO 10993-1 / FDA G-95-1 the Sterilization Box is a non-invasive product and are not intended to have any patient contact.
Shelf Life	No sterile wrap is supplied with the sterilization box.	No sterile wrap is supplied with the sterilization box.
Drying time	25 minutes	25 minutes
Aeration time	N/A	N/A
Where used	Reprocessing units	Reprocessing units

Non Clinical Tests Bench Testing has been performed to demonstrate that:

- the device can withstand the number of steam autoclave cycles specified in the instructions for use.
- the device enables the components of the applicators to be stored to give easy access and does not damage them.
- Sterilization validation has been performed on equivalent devices to demonstrate that the specified applicator components and accessories can be sterilized in the sterilization box.

- Usability was reviewed in comparison to other similar devices 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 device to be safe and effective and to perform as well or better than the predicate.