K122236

PREMARKET NOTIFICATION

510(k) Summary

NOV 16 2012

VariSource iX and VariSource iX(t) Afterloaders

As required by 21 CFR 807.92

Submitter's Name:	Varian Medical Systems 911 Hansen Way, M/S C-255 Palo Alto CA94304
	Contact Name: Ms Vy Tran, Vice President, Regulatory Affairs and Quality Systems Phone: 650/424.5731 Fax:650/842.5040 vy.tran@varian.com Date: 30 April 2012
Proprietry Name:	VariSource iX VariSource iX(t)
Classification Name:	Remote controlled radionuclide applicator system 21CFR892.5700 Class II
Common/Usual Name:	VariSource iX afterloader, VariSource iX Series afterloaders, VariSource iX series afterloader systems, VariSource iX Series
Predicate Device:	VariSource iX HDR Afterloader (K071467)
Device Description:	The VariSource iX series afterloader systems are computer controlled remote electro/mechanical systems used for medical purposes, for placing a cable incorporating an irradiated iridium seed internally or close by a malignant tumor or tumor bed in a practice known as brachytherapy.
Indications for Use:	The VariSource iX Series is indicated for use in the treatment of both benign and malignant disease, for both curative and palliative intent, in the delivery of remote-controlled High Dose Rate (HDR) brachytherapy.

Substantial Equivalence Discussion

Intended Use

The VariSource iX Series is indicated for use in the treatment of both benign and malignant disease for both curative and palliative intent, in the delivery of remote controlled High Dose Rate (HDR) brachytherapy..

Differences

The differences with respect to the predicate are listed in the substantial equivalence chart.

With respect to the previous version of this device, which contained Console software Version 1.1, the changes are to Plan Importing, Partial treatment Options, Fraction Editing and Remote Service Access.

Technological Characteristics

Both the current device and the predicate are remote-controlled afterloading devices for brachytherapy. The systems both utilize a small, high activity Iridium-192 source that is fixed to a flexible metal cable and driven via one or more source guide tubes into an applicator(s) or needle(s) inserted for a specified clinical purpose into a patient.

Argument for Substantial Equivalence to the Predicate Device

There are few differences between the VariSource iX Series afterloaders and the predicate. Varian therefore believes that the VariSource iX Series afterloaders are substantially equivalent to the predicate.

Non Clinical Tests

Results of Verification and Validation Testing showed conformance to applicable requirements and specifications and assured hazard safeguards functioned properly.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

NOV 16 2012

Ms. Vy Tran
Vice President, Regulatory Affairs and Quality Systems
Varian Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304

Re: K122236
Trade/Device Name: VariSource iX and VariSource iX(t)
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: September 26, 2012
Received: October 4, 2012

Dear Ms. Tran:

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.

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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Michael D. O'Hara 2012.11.16 11:55:20 -05'00'

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122236

Device Name: VariSource iX and VariSource iX(t)

Indications for Use:

The VariSource iX and VariSource iX(t) are indicated for use in the treatment of both benign and malignant disease, for both curative and palliative intent, in the delivery of remote-controlled High Dose Rate (HDR) brachytherapy.

Prescription Use __Yes___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara 2012.11.16 11:56:44 -05'00'

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K122236