DEC 2 4 2003

VARIAN
medical systems

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K033371

510(k) Summary

The following information is provided following the format of 21 CFR 807.92 for the Intracavitary Brachytherapy Applicators

1) Submitter:

Varian Medical Systems, Inc.
3100 Hansen Way/ MS E-110
Palo Alto, California 94304
Contact Person: Vy Tran, Director, Corporate Regulatory Affairs
Telephone: (650) 424 5731
Facsimile: (650) 842 5040
Email: vy.tran@varian.com
Date Prepared: October 16, 2003

2) Device Name: Intracavitary BrachyTherapy Applicators
11-00404 Cervix Applicator Set;
11-00414 Vaginal Applicator Set;
11-00415 Segmented Cylinder Set;
11-00416 Stump Applicator Set;
11-00438 Shielded Applicator Set;
11-00454 Segmented Cervix Applicator Set

Common Name: Intracavitary Brachytherapy Applicators

3) Predicate Device Name: GammaMed Plus High Dose Rate Afterloader System applicators, K 983436

4) Description: The applicator sets in this submission are designed to be used with the VariSource High Dose Rate Afterloaders to deliver brachytherapy treatment for gynecological and rectal applications. The applicators will be used in medical intracavitary for treatment of cancerous tumors. The Intracavitary applicators are designed to be inserted into a body cavity.

5) Intended Use: Six intracavitary applicator sets are included in this submission. The intended use of each applicator is described below.

11-00404 Cervix Applicator Set
Cervix Applicator set is designed for use in medical intracavitary brachytherapy for treatment of cancerous gynological tumors. It is suitable (combined) irradiation of the vagina and the endometrium. It is also to irradiate the uterus, vaginal stump or rectum. The maximum implantation time for this applicator is 2 days.

11-00414 Vaginal Applicator Set
Vaginal Applicator Set is developed for intracavitary brachytherapy to treat cancer of the vagina or rectum. The maximum implantation time for this applicator is 30 days.

11-00415 Segmented Cylinder Set
Segmented Cylinder Set is developed to treat cancer of the vagina and the vaginal stump. It is also suitable to treat rectal cancer. The applicator set is MR and CT compatible. The maximum implantation time for this applicator is 2 days.

11-00416 Stump Applicator Set
Stump Applicator Set is developed for post-operative irradiation of the vaginal stump. The flexible applicator probe has a connector made of titanium, so that position checks can be made using CT or MRI. The maximum implantation time for this applicator is 30 days.

11-00438 Shielded Applicator Set
Shielded Applicator Set is developed to treat cancer of the vagina or rectum where partial shielding is required. The maximum implantation time for this applicator is 2 days.

11-00454 Segmented Cervix Applicator Set
Segmented Cervix Applicator Set is developed to irradiate the cervix, the vagina and the vaginal stump. The applicator set is MR and CT compatible. The cylinder segments can be used with cervical sleeves (Smit), flexible intra-uterine probes or without intra-uterine probes. The segmented construction of the applicator allows an individual adaptation to the patient's anatomy. The maximum implantation time for the Segmented Cervix Applicator is 7 days.

6) **Technological Considerations:** The applicators are identical or equivalent to the predicate devices in materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 4 2003

Ms. Vy Tran
Director, Corporate Regulatory Affairs
VARIAN Medical Systems, Inc.
3100 Hansen Way
PALO ALTO CA 94304-1038

Re: K033371
Trade/Device Name: Intracavitary Brachy Therapy Applicators
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: 90 JAQ
Dated: October 16, 2003
Received: October 21, 2003

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033371

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Indications for use:

The applicators will be used with the VariSource High Dose Rate Afterloaders to deliver brachytherapy treatment for gynecological and rectal applications. The applicators will be used in medical intracavitary for treatment of cancerous tumors.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

David A. Lazzara

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033371