K040541

MAR 2 2 2004

510(k) Summary

The following information is provided following the format of 21 CFR 807.92 for the MammoSource High Dose Rate (HDR) Afterloader:

1. **Submitter:** Varian Medical Systems, Inc.,
3100 Hansen Way M/S E-110
Palo Alto, CA 94304
Contact Name: Vy Tran
Phone: (650) 424-5731
Fax: (650) 842-5040
Email: vy.tran@varian.com
Date: March 1, 2003

2. **Device Name:** MammoSource High Dose Rate (HDR) Remote Afterloader

Classification Name and No:	System, Applicator, Radionuclide, Remote-Controlled 21 CFR §892.5700 Class II Product Code: JAQ
Common/Usual Name:	MammoSource HDR Remote Afterloader
Proprietary Name:	MammoSource HDR Remote Afterloader

3. **Predicate Device:** GammaMed plus HDR Remote Afterloader, K983436

4. **Device Description:** The GammaMed Plus device has been modified to reduce the number of channels from 24 channels to one channel that will simplify the device and make the MammoSource ideal for treating breast tumors with the MammoSite RTS applicators, K011690 and K030558, as well as other cancers where a single channel HDR system would be useful.The system is designed to provide a predetermined dose of radiation to tissue and organs by means of manipulating a radioactive source from a shielded position within in the device into a catheter, applicator, or needle, which has been placed within or on a patient.

5. **Statement of Indications for Use:** MammoSource is indicated for high-dose-rate remotely controlled afterloading brachytherapy for the treatment of breast cancer and other cancers that can be treated with a single channel HDR system.

6. **Technological Characteristics:** See the "Substantial Equivalence Comparison Chart", Tab 6

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K040541
Trade/Device Name: MammoSource HDR Remote afterloader
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: 90 JAQ
Dated: March 1, 2004
Received: March 2, 2004

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): K040541
Device Name: MammoSource HDR Remote afterloader

Indications For Use:

MammoSource is indicated for high-dose-rate remotely controlled afterloading brachytherapy for the treatment of breast cancer and other cancers that can be treated with a single channel HDR system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use ✓

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040541