VARIAN
medical systems

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510(k) Summary

K030745

The following information is provided following the format of 21 CFR 807.92 for the Gammamed 212 and 232 Source Assembly

MAR 1 2 2003

1. Submitter: Varian Medical Systems
3100 Hansen Way M/S H055
Palo Alto, CA 94304-1129
Contact Name: Vy Tran
Phone: (650) 424-5731
Fax: (650) 842-5040
Email: vy.tran@varian.com
Date: March 7, 2003

2. Device Name: Gammamed 212 and 232 Source Assembly

Classification Name:	Radionuclide brachytherapy source
Common/Usual Name:	Gammamed 212 and 232 Source Assembly
Proprietary Name:	Gammamed 212 and 232 Source Assembly

3. Equivalent Device: Gammamed 12i, K891131

4. Device Description: The Gammamed 212 and 232 Source Assemblies are brachytherapy sources that are used in conjunction with Gammamed remote afterloaders. The Gammamed 212 Source Assembly is used in conjunction with the Gammamed 12i or 12it remote afterloader. The Gammamed 232 Source Assembly is used with either the Gammamed Plus or Gammamed 3/24 afterloader.

5. Statement of Intended Use: The Gammamed Model 212 and 232 source assemblies are designed for use in medical brachytherapy applications.

6. Comparison to substantially equivalent devices:

Features / Products		GAMMAMED 12i	GAMMAMED 212	GAMMAMED 232
Device	FDA approval	K891131	Pending	Pending
	Isotope	Ir-192	Ir-192	Ir-192
	Nominal Activity	370 GBq (10 Ci)	370 GBq (10 Ci)	370 GBq (10 Ci)
	Active dimensions ∅ x length	0.6 x 4.0 mm	0.6 x 3.5 mm	0.6 x 3.5 mm
	cable length	2100 mm	2100 mm	2100 mm
	cable diameter	1.1 mm	1.1 mm	0.9 mm
	manufacturing process	electron beam	laser welding	laser welding

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 12 2003

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

Re: K030745
Trade/Device Name: Gammamed 212 and 232 Source Assembly
Regulation Number: 21 CFR §892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: 90 KXK
Dated: March 7, 2003
Received: March 10, 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 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 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 this 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" (21 CFR Part 807.97). 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

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Statement of Indications for Use

510(k) Number (if known): K030745

Device Name: **The Gammamed Model 212 and 232 source assembly**

Indications For Use: **The Gammamed Model 212 and 232 source assembly is designed to be used in conditions typically associated with hospitals and medical facilities for the 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 _X_ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Lyerman
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030745