K071381

JUL 18 2007

510(k) Summary

The following information is provided following the format of 21 CFR 807.92 for the GammaMed*plus* iX Series HDR Brachytherapy Afterloader.

1. **Submitter:** Varian Medical Systems
   3100 Hansen Way M/S E-110
   Palo Alto, CA 94304-1129
   Contact Name: Vy Tran
   Phone: (650) 424-5731
   Fax: (650) 842-5040
   Email: vy.tran@varian.com
   Date summary was prepared: May 9, 2007

2. **Name of the Device:** **GammaMed*plus* iX Series HDR Afterloader;**
   Trade/Proprietary Name: GammaMed*plus* iX Series HDR Afterloader
   Common or Usual Name:
   Classification Name: Radiological Image Processing System
   21 CFR §892.5700
   Class II
   Product Code: JAQ

3. **Predicate Devices** to claim substantial equivalence:
   a. GammaMed*plus* (K983436)
   b. GammaMed*plus* 3/24 (K031524)

4. **Description of the Device:** The GammaMed*plus* iX Series High Dose Rate Afterloader system is a computer controlled remote electro/mechanical system 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. The device has up to 24 channels.

   Hardware Platform and Operating System
   The console control application runs on validated PCs under a Microsoft®[1] windows operating system. The firmware controlling the High Dose Rate Afterloader runs on an embedded Intel 8085 processor. In addition, embedded processors, both based on the Intel 8051, control the afterloaders control desk and its junction interface box.

   Peripherals and Accessories
   The iX Series control console provides real time information of wire position and system status and interfaces with a printer in order to provide a hard copy of a treatment prescriptions and delivery records. In addition the iX Series control

[1] Registered Trade Mark of Microsoft Corporation

console can receive treatment plans from a treatment planning application (not part of this submission), this information is transferred either manually using a USB[2] drive, or via a network interface.

5. Intended Use Statement: The GammaMed*plus* iX Series is computer controlled remote HDR Afterloader used to place a high activity radioactive source within a needle(s) or applicator(s) which have previously been placed for a specified clinical purpose in a patient.

The radioactive source (enclosed within the wire/cable) is driven via coupling catheters (Transfer Guide Tubes) from the Afterloader into needles or applicators within or on the patient.

The length of time and position that the High Dose Rate source spends within the needle or applicator is controlled in accordance with an Irradiation Treatment Prescription.

6. Summary of the Technological Characteristics: The Substantial Equivalence Comparison Charts provide a comparison of the technological characteristics to those of the predicate devices. These charts are located in Tab 9 of the submission.

[2] USB- Universal Serial Bus

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 18 2007

Ms. Vy Tran
Corporate Director, Regulatory Affairs
Varian Medical Systems, Inc.
3100 Hansen Way, M/S E-110
PALO ALTO CA 94304-1038

Re: K071381
Trade/Device Name: GammaMed iX Series HDR Brachytherapy Afterloader
Regulation Number: 21 CFR §892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: May 16, 2007
Received: May 17, 2007

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 (Premarket Approval), 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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): K071381
Device Name: GammaMed iX Series HDR Brachytherapy Afterloader

Indications For Use:

Both the GammaMed*plus* iX and GammaMed*plus* 3/24 iX are indicated, in the treatment of both benign and malignant disease, for both curative and palliative intent, in the delivery of remote controlled high dose rate brachytherapy for conditions anywhere in the body when brachytherapy treatment is indicated.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K071381