OCT 2 9 1998

GAMMAMED USA
2464 E. Stadium Blvd., Ann Arbor, Michigan 48104
Tel: 734-975-4500; Fax: 734-975-4300

25 September 1998

K983436

510(k) Summary

Section 807.92(a)

(1) **Submitter:**

GammaMed USA
2464 E. Stadium Blvd.
Ann Arbor, MI 48104

Tel: 743-975-4500
Fax: 734-975-4300

Establishment Registration Number: 9023144

Contact Person: John J. Munro III, CEO

(2) Device Name:

Classification Name: Remote Controlled Radionuclide Applicator System (892.5700)

Common or Usual Name: High Dose Rate Remote Afterloading System

Proprietary Name: GammaMed Plus High Dose Rate Remote Afterloading System

(3) Legally Marketed Predicate Device: GammaMed 12it (K912555/A dated 17 July 1991) Substantial equivalence determined through premarket notification process

(4) Description of GammaMed Plus:

The GammaMed Plus is a transportable high-dose-rate remotely controlled afterloading brachytherapy device. The unit is designed to provide a predetermined dose of radiation to tissues and organs by means of manipulating a radioactive source from a shielded position within the device into an applicator, which has been previously placed within or on a patient. The GammaMed plus system is based on a further development of the existing GammaMed 12it system.

The GammaMed plus system consists of the following components:

- Treatment device including computer and control software
- Applicators and accessories
- Treatment planning system

(5) Intended use of the GammaMed Plus

The intended use of the GammaMed Plus transportable high-dose-rate remotely controlled afterloading brachytherapy device is for the treatment of cancer by intracavitary, interstitial, intralumenal and intraoperative irradiation.

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(6) Technological Characteristics

The GammaMed Plus is a modification of the GammaMed 12it High Dose Rate Remote Afterloading System, which was cleared under 510(k) Number K912555/A, dated 17 July 1991. The changes made to the GammaMed plus represent routine engineering changes. These modifications do not affect the intended use of the device or alter the fundamental scientific technology of the device. There are no differences between the GammaMed Plus and the GammaMed 12it that adversely affects the safety or effectiveness of the device.

The changes are:

Industrial Design: The style and appearance of the GammaMed Plus has been changed from the GammaMed 12it to be more compatible with the modern hospital equipment. Change in the housing results in a smaller device.

Electronics: Several electronic circuit boards have been combined to one single board. Consequently, the electronics can be housed in a smaller volume, which makes it possible to decrease the size of the housing.

Source: The materials and construction of the new source will be the same as that used in the GammaMed 12it. The diameter of the source has been reduced from 1.1 mm to 0.9 mm.

Operator Console: The operator console has been reduced in size to reduce the space required for operation of the device.

Operating Software: The control software, GammaWin, is a modification and refinement of the GammaMed control software, which has been used with the GammaMed 12it and GammaMed 12i afterloading devices. The GammaWin control software operates under the Windows operating system. The previous GammaMed control software operates under DOS. The GammaWin control software is also compatible with the GammaMed 12it and GammaMed 12i.

Treatment Planning Software: The treatment planning software, ABACUS, is a modification and refinement of the GammaDot treatment planning software, which has been used with the GammaMed 12it and GammaMed 12i afterloading devices. The ABACUS treatment planning software operates under the Windows operating system. The previous GammaDot treatment planning software operates under DOS. The ABACUS treatment planning software is also compatible with the GammaMed 12it and GammaMed 12i.

John J. Munro III
Chief Executive Officer

25 September 1998

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 29 1998

John J. Munro, III
Chief, Executive Officer
Gammå Med USA
2464 E. Stadium Blvd.
Ann Arbor, Michigan 48104

Re: K983436
GammaMed Plus HDR Afterloading System
Dated: September 25, 1998
Received: September 29, 1998
Regulatory class: II
21 CFR 892.5730/Procode: 90 MUJ

Dear Mr. Munro:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

GAMMAMED USA
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Tel: 734-975-4500; Fax: 734-975-4300

510(k) Number 983436

Device Name: GammaMed Plus High Dose Rate Remote Afterloading System

Indications for Use:

The intended use of the GammaMed Plus transportable high-dose-rate remotely controlled afterloading brachytherapy device is for the treatment of cancer by intracavitary, interstitial, intralumenal and intraoperative irradiation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___
(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983436