FEB 16 2005

# Premarket Notification [510K] Summary

K042360

**Submitter's Name:** Varian Medical Systems
3100 Hansen Way M/S E-110
Palo Alto, CA 94304
Contact Name: Vy Tran
Phone: (650) 424-5731
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Email: vy.tran@varian.com
Date: August 25, 2004

**Proprietary Name:** Nasopharynx Applicator

Classification Name: Accessory to remote afterloader, 21 CFR 892.5700, Class II
Common/Usual Name: Nasopharynx Applicator

**Predicate Device:** Nucletron's Rotterdam Nasopharynx Mould Set, K983337

**Product Description:** The Nasopharynx Applicator Set has been designed for the treatment in the upper throat space. The design of the ENT mould probe permits an application in the nasopharyngeal to oropharyngeal area (ENT = Ear Nose Throat). The set contains two different ENT mould probes, one with and one without balloon.

**Statement of Intended Use:** Varian's Nasopharynx Applicator set is designed for use with Varian high dose rate afterloaders: VariSource, GM Plus, GM 3/24, and MammoSource for intracavitary nasopharynx brachytherapy. The applicator provides a means of delivering a prescribed radiation dose to the intended treatment area.

**Technological Characteristics:** The Nasopharynx Applicator is substantially equivalent to Nucletron's Rotterdam Nasopharynx Mould Set. Refer to the "Substantial Equivalence Comparison Chart", Tab F.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2005

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

Re: K042360
Trade/Device Name: Nasopharynx Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: 90 JAQ
Dated: January 28, 2005
Received: February 2, 2005

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/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): K04 2360

Device Name: Nasopharynx Applicator

Indications For Use:

Varian's Nasopharynx Applicator is a device used to facilitate the delivery of a therapeutic dose of radiation therapy to treat cancer in the upper throat, nasal cavity and nasopharengeal regions.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K042360