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K992762

Premarket Notification [510K] Summary as required by 21 CFR 807.92

Date Summary was prepared:
August 12, 1999

Submitter's Name:
Varian Medical Systems
3100 Hansen Way
Palo Alto, CA 94304

Contact Person:
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Regulatory Affairs and Quality Assurance Manager
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Device Name:
Brachyvision 6.0

Classification Name:
Source, Brachytherapy, Radionuclide

Predicate Device:
Nucletron Plato Brachytherapy

Varian Associates, Inc. 3045 Hanover Street Palo Alto, California 94304-1129 U.S.A.
650.493.4000 FAX: 650.424.4830

Product Description:

BrachyVision is a computer based product used for calculating and displaying prospective or verification treatment plans for particular patients undergoing a course of Brachytherapy. The system consists of a computer with graphics display, film scanner input, and plotter output. Patient data may be entered from network connection, via the film scanner, via the optional back lit digitizer, or via the keyboard. Source placement information may be added to the patient data and isodose distributions, which would result from those source placements, may be displayed, analyzed and plotted. For use with remote afterloader devices, source dwell times may be optimized to user selected criteria.

Intended Use:

Brachyvision 6.0 is designed to allow the dose distribution of an implant or applicator to be individually shaped for each patient. BrachyVision is a general purpose brachytherapy planning system used for prospective and confirmation dose calculations for patients undergoing a course of brachytherapy, using either temporary or permanent implants of various radioisotopes.

Technological Characteristics:

See Specifications/Features Comparison Chart

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Linda Nash
Regulatory Affairs & Quality Assurance Manager
Varian Associates, Inc.
3045 Hanover Street
Palo Alto, California 94304-1129

Re: K992762
BrachyVision 6.0
Dated: December 13, 1999
Received: December 14, 1999
Regulatory Class: II
21 CFR 892.5730/Procode: 90 MUJ

Dear Ms. Nash:

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 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). 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) 594-4591. 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 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

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Indications For Use

510(k) Number (if known): K992762

Device Name: Brachyvision 6.0

Indications for Use:

BrachyVison 6.0 may be used for any brachytherapy planning activity, but has been specifically optimized for use with remote afterloaders (especially the VariSource unit from Varian), and for use with 3D images such as may be obtained from CT or MRI, or Ultrasound images.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use___
(per 21 CFR 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992762

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