K041403

JUL 2 6 2004

VARIAN
medical systems

Varian Medical Systems, Inc.
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510(k) Summary

The following information is provided following the format of 21 CFR 807.92 for the Eclipse with AAA.

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 summary was prepared: May 20, 2004

2. **Name of the Device:** **Eclipse with AAA**
   Trade/Proprietary Name: Eclipse with AAA
   Common or Usual Name: Treatment Planning System
   Classification Name: Medical charge-particle radiation therapy system
   21 CFR §892.5050
   Class II
   Product Code: 90 MUJ

3. Predicate Devices to claim substantial equivalence:
   a. Varian Eclipse, K030981

4. Description of the Device: The Varian Eclipse™ Treatment Planning System has been modified to include a new a new photon dose calculation algorithm, Analytical Anisotropic Algorithm (AAA). The AAA dose calculation model is a 3D convolution/superposition algorithm that models primary photons, photons scattered in the medium, contamination electrons and transport electrons near tissue heterogeneities. The AAA dose calculation model is comprised of two main components, one being the configuration algorithm and the other one the actual dose calculation algorithm.

5. Intended Use Statement: The Varian Eclipse device is a treatment planning system used for diagnostic image analysis, contouring and segmentation, geometrical planning, photon and electron dose calculation and plan review.

6. Summary of the Technological Characteristics: The Substantial Equivalence Comparison Chart provides a comparison of the technological characteristics to those of the predicate devices. This chart is located in Tab 8 of the submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 6 2004

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

Re: K041403
Trade/Device Name: Eclipse with AAA
Regulatory Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: July 9, 2004
Received: July 12, 2004

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 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 the 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" (21CFR Part 807.97) you may obtain. 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

510(k) Number (if known): K041403
Device Name: Eclipse with AAA

Indications For Use:

The Varian Eclipse device is used to plan photon and electron radiation therapy treatments employing linear accelerators and other similar teletherapy devices with x-ray energies from 1-50 MV, as well as Cobalt-60, and electron energies from 1-50 MeV. Eclipse will plan the 3D radiotherapy treatment approaches to combined modality plans, coplanar and non-coplanar fields, static and ARC fields, beam modifiers, and beam intensity modulators.

Eclipse also includes tools for treatment preparation (diagnostic image and analysis, contouring and segmentation) and plan review.

(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)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, Radiological Devices
510(k) Number K041403

Prescription Use ✓