K051497

JUL 18 2005

510(k) Summary
as required by section 807.92(c)

Date Prepared: June 2, 2005

Submitter: Varian Medical Systems, Inc.

Address: 3100 Hansen Way
Palo Alto, CA 94304

Phone: (650) 424-5731

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Contact: Vy Tran

Trade Name: Vitesse 2.0

Common Name: BrachyTherapy Planning System

Classification Name: system, planning, radiation therapy treatment CFR 892.5050

Predicate Device: Varian Medical Systems, Inc. - BrachyVision 6.0 K992762

Intended Use

Vitesse 2.0 is a software application used to facilitate intraoperative needle planning and anatomy contouring during the process of planning HDR brachytherapy procedures for patients with prostate cancer. Vitesse will export this data to be utilized for treatment planning.

Device Description

Vitesse 2.0 is a computer based software application which will allow for the facilitation of intraoperative needle planning and anatomy contouring during the process of planning High Dose Rate brachytherapy procedures. Vitesse provides image acquisition and needle planning functions. It does not provide any modeling of the HDR source nor dose it calculate radiation dose estimates. Vitesse only exports its images, contours and needle positions using the DICOM RT standard to the planning system where the source positions are modeled, and the dose is calculated, evaluated and the plan is finalized. Vitesse 2.0 does not provide a treatment plan, but instead exports a source location plan to treatment planning systems for completion.

Hardware Platform and Operating System

The application runs on standard Intel PCs under Microsoft Window® 32-bit operating systems.

Peripherals and Accessories

The application interfaces with video sources and network sources.

Software Features

1. *Image Acquisition/Import*: The ability to acquire patient data from which a plan or evaluation is constructed
2. *Structure Contouring*: The ability to define patient structures within the image space.
3. *Needle Placement*: The ability to plan needle placement and update positions based on actual insertion positions.
4. *Needle Identification*: The ability to identify needle positions based upon post implant imagery.
5. *2D visualization*: The ability to visualize the resulting needle placement and structures in 2D.
6. *Database functions*: The ability to manage the patient data in the application database including archiving, deleting and restoring data.
7. *Licensing*: The ability to license the system by application function and interface.
8. *Interface*: The ability to interface with other planning systems.

Application Development

The application was developed for 32-bit Microsoft Windows® operating system using Microsoft Visual C++.

Technological Characteristics

Vitesse 2.0 is substantially equivalent to the predicate device "BrachyVision". Refer to the "Substantial Equivalence Comparison Chart", Tab I.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 8 2005

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

Re: K051497
Trade/Device Name: Vitesse 2.0
Regulation Number: 21 CFR 892.5730
Regulation Name: Radionuclide brachytherapy source
Regulatory Class: II
Product Code: MUJ
Dated: June 2, 2005
Received: June 6, 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/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

Indications For Use

510(k) Number (if known): K051497

Device Name: Vitesse 2.0

Indications for use:

Vitesse is a software application used to facilitate brachytherapy high dose rate treatment planning for patients with prostate cancer.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lyons

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K051497