3/5/99

K982952

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Information:

Dated: August 21, 1998

Siemens Medical Systems
Oncology Care Systems Group
4040 Nelson Avenue
Concord, CA 94520

Contact Person: Kathryn B. Dodd
Vice President Regulatory Affairs and Quality Assurance

Common or Usual Name: Radiation therapy beam shaping block
Proprietary Name: **IMFAST**
Classification Name: Radiation therapy beam shaping block
21 CFR § 892.5710
Class II, Product Code: RA 90 IXI

Predicate Device: BeamShaper, 510(k) No. K961902

Description of Device: IMFAST is a MLC optimization algorithm that sets the MLC jaws for modulated intensity profiles, thereby eliminating the need for BeamShaper like products or compensator blocks.

Statement of intended use: The intended use of the IMFAST is to take from the radiotherapy Treatment planning (RTP) system an intensity map or a matrix of compensator thicknesses and calculate a sequence of multi-leaf collimator (MLC) segments.

Statement of technological characteristics: IMFAST takes from the radiotherapy treatment planning (RTP) system an intensity map or a matrix of compensator thickness and calculates a sequence of multi-leaf collimator (MLC) segments. The plan can be reviewed for accuracy and treatment time. These resulting segments are then written to a file, allowing the V&R system or the RTP system to pick it up for further processing. In the case of SIEMENS' LANTIS and PRIMEVIEW, the file can be imported and the segments can be grouped into intensity modulation groups. The treatment can then be delivered in sequence using SIMTEC and an MLC, thus providing the patient with automated, computer-controlled intensity modulation radiotherapy (IMRT).

Differences: The configuration and specification differences between the Siemens BeamShaper and the IMFAST MLC algorithm does not alter the intended use of either products for setting the MLC jaws which eliminates the need for blocks; nor do they introduce new safety issues.

Performance Standards: No applicable performance standards have been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Siemens considers the BeamShaper and IMFAST to be equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 5 1999

Kathryn B. Dodd
Vice President, Regulatory Affairs
and Quality Assurance
Siemens Medical Systems, Inc.
Oncology Care Systems
404 Nelson Avenue
Concord, California 94520

RE: K982952
Siemens IMFAST
Dated: December 8, 1998
Received: December 10, 1998
Regulatory Class: II
21 CFR 892.5050/Procode: 90 LHN

Dear Ms. Dodd:

This letter corrects our substantially equivalent letter of March 5, 1999, which neglected to have the correct classification and procode for the Siemens IMFAST device. Please note the correct classification for this above.

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.

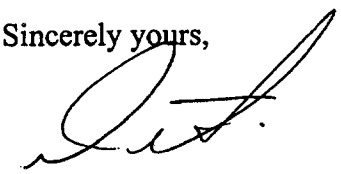
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action.

In addition, the Food and Drug Administration (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 continue 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 that 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 their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



CAPT Daniel Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE:

The IMFAST product is intended to calculate a sequence of multi-leaf collimator (MLC) segments. These resulting segments are then written to a file, allowing the V&R system or the RTP system to pick it up for further processing. In the case of SIEMENS' LANTIS and PRIMEVIEW, the file can be imported and the segments can be grouped into intensity modulation groups. The treatment can then be delivered in sequence using SIMTEC and an MLC, thus providing the patient with automated, computer-controlled intensity modulation radiotherapy (IMRT).

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982952

Prescription Use ✓
(Per 21 CFR 801.109)