K982502

JUL 31 1998

## SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitter's Information:** **Dated: July 17, 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

2. **Common or Usual Name:** Linear Accelerator
**Proprietary Name:** **GENESIS™ IMRT Medical Linear Accelerator**
**Classification Name:** Medical Charged Particle Radiation Therapy System
21 CFR § 892.5710
Class II, Product Code: RA 90 IYE

3. **Predicate Device:** MEVATRON M Class, 510(k) No. K882729

4. **Description of Device:** The GENESIS™ Linear Accelerator is a single energy, high dose medical linear accelerator. The GENESIS™ includes a Multileaf Collimator (MLC), Dual Asymmetric Capability, Virtual Wedge™, and PRIMEVIEW.

5. **Statement of intended use:** The intended use of the GENESIS™ is to deliver x-ray radiation for therapeutic treatment of cancer. The intended use of the GENESIS™ is the same as the 6 MV MEVATRON M Class and has not changed as a result of this modification

6. **Statement of technological characteristics:** The GENESIS™ linear accelerator does not have significant changes in materials, energy source or performance characteristics compared to the predicate devices. The intended use and the performance characteristics are the same as the predicate device and therefore we believe it is substantially equivalent to it.

7. **Differences:** The main difference between the 6 MV MEVATRON M Class system and the GENESIS™ Linear Accelerator is the path of the electrons prior to striking the target. In the MEVATRON M machine, the axis of the accelerator is parallel in the isocentric plane; thus electrons must exit the structure through a 270° bend. In contrast, the axis of the GENESIS™ is perpendicular to the isocentric plane and is aligned with the radiation axis. Electrons in both types of accelerators produce photons by striking a target made from high-Z (i.e., high atomic number) material. From this point on, the design and functionality for the GENESIS™ and 6 MV MEVATRON M Class are essentially the same.

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

**Siemens considers the MEVATRON M Class system and the GENESIS™ to be equivalent.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 31 1998

Kathryn Berry Dodd
Vice-President, RA & QA
Siemens Medical Systems, Inc.
Oncology Care Systems
4040 Nelson Avenue
Concord, CA 94520

Re: K982502
Genesis IMRT Linear Accelerator
Dated: July 17, 1998
Received: July 20, 1998
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Dodd:

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 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) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note 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 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,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**SIEMENS**

510(k) Number: K982502
Product: GENESIS, IMRT LINEAR ACCELERATOR

## INDICATIONS FOR USE

The GENESIS IMRT Linear Accelerator is intended to deliver megavoltage x-ray treatment for therapeutic application in the treatment of cancer. The GENESIS delivers these treatments conformally, shaping the field of radiation to the tumor volume. The depth of penetration emulating from the GENESIS ideally suits itself for treating deep-seated tumors while providing a skin sparing effect.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K982502

Prescription Use ✓
(Per 21 CFR 801.109)

**Siemens Medical Systems, Inc.**

Oncology Care Systems
4040 Nelson Avenue
Concord, CA 94520
Tel: (510) 246-8200
FAX (510) 246-8284