SEP - 8 1997 K972275

SUMMARY OF SAFETY AND EFFECTIVENESS

1. **Submitter's Information:** Dated: June 9. 1997

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:** Record and Verify Radiation Treatment System
Proprietary Name: **LANTIS TREATSTATION**
Classification Names: Record and Verify Radiation Treatment System
21 CFR § 892.5710
Class II, Product Code: RA 90 IYE

3. **Predicate Device:** Impac Medical Systems' Sequencer (K913612)

4. **Description of Device:** LANTIS TREATSTATION is a direct replacement for the sequencing/VMI module of the Impac Sequencer Record and Verify Radiation Treatment System. The TREATSTATION coexists with the LANTIS Commander application on the target platform to allow the user access to the information system's other functions and provide the complete spectrum of required functionality.

5. **Statement of intended use:** The intended use of the LANTIS TREATSTATION is to allow the radiation therapist to deliver treatment to the patient using the MEVATRON and all available accessories. This entails selecting a patient, selecting today's treatment for that patient, setting up and delivering the treatment fields, and recording the delivered treatment. TREATSTATION supports auto sequencing, a process of automatically downloading a group of fields or segments from the verification and record system to the control of the linear accelerator sequentially, without user intervention. In addition, LANTIS TREATSTATION supports intensity modulation (IM), a process of shaping, modifying and moving the beam around a target to maximize the dose at the target and minimize the dose to normal structures.
The intended use is the same as the predicate device.

6. **Statement of technological characteristics:** The LANTIS TREATSTATION software 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 minor configuration and specification differences between the LANTIS TREATSTATION and Impac's Sequencer does not alter the intended use or affect the safety and effectiveness of the LANTIS TREATSTATION when used as labeled.

8. **Performance Evaluation:** Performance tests were conducted and the results indicated that the device consistently performed within the design parameters and equivalently to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 1997

Kathryn B. Dodd
Vice President Regulatory
and Affairs and Quality Assurance
Siemens Medical Systems, Inc.
4040 Nelson Avenue
Concord, CA 94520

Re: K972275
Lantis Treatstation
Dated: June 9, 1997
Receivced: June 18, 1997
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 requirement, 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/dsmamain.html".

Sincerely yours,

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

510(k) Number (if known): K972275

Device Name: LANTIS TREATSTATION

Indications For Use:

The intended use of the LANTIS TREATSTATION is to allow the radiation therapist to deliver treatment to the patient using the MEVATRON and all available accessories. This entails selecting a patient, selecting today's treatment for that patient, setting up and delivering the treatment fields, and recording the delivered treatment. TREATSTATION supports auto sequencing, a process of automatically downloading a group of fields or segments from the verification and record system to the control of the linear accelerator sequentially, without user intervention. In addition, LANTIS TREATSTATION supports intensity modulation (IM), a process of shaping, modifying, and moving the beam around a target to maximize the dose at the target and minimize the dose to all normal structures.

The intended use is the same as the predicate device.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K972275

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)