DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 23 1997

Larry A. Kroger, Ph.D.
Acting Manager
Quality, Safety and Regulatory Programs
GE Medical Systems
P.O. Box 414, W-709
Milwaukee, WI 53201

Re: K965010
Target 2 Version 1.1 Radiation
Treatment Planning (RTP) System
Dated: May 9, 1997
Received: May 12, 1997
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Dr. Kroger:

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,

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

K965010

GE Medical Systems

General Electric Company
P.O. Box 414, Milwaukee, WI 53201

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.87 (h).

JUL 23 1997

Identification Of Submitter

Submitter: Larry A. Kroger, Ph.D
GE Medical Systems
3000 N. Grandview Blvd., W-709
Waukesha, WI 53188
Telephone: (414) 544-3894
Fax: (414) 544-3863
Date Of Preparation: December 12, 1996

Identification Of The Product

Device Proprietary Name: Target 2 Version 1.1
Common Name: Radiation Oncology Treatment Planning System
Classification Name: Radiation Therapy Simulation System, 21 CFR 892.5840

Establishment Reg. Number: 2126677
Import Agent For: GE Medical Systems - Europe
283 Rue de la Miniere
78530 Buc, France

Marketed Devices

Predicate Device:

System	Manufacturer	510(k) #
Target 2 Version 1.0	GE Medical Systems	K896353

Device Description

The Target 2 V1.1 is an independent radiation oncology treatment planning system which uses CT and non-CT data to produce External Beam and Irregular Field plans, and non-CT data to provide Interstitial/Intracavitary Dosimetry plans.

The system is interactive, using an optical mouse and defined display screen areas on the monitor, in conjunction with operating menus, to produce accurate planning routines.

The treatment plan is contructed and displayed on the patient image. Plans can be stored on the system disk, output as hard copy and archived.

Indications For Use

The Target 2 V1.1 is a radiation oncology treatment planning system which uses CT and non-CT data to produce External Beam and Irregular Field plans, and non-CT data to provide Interstitial/Intracavitary Dosimetry plans.

Comparison With Predicate Device

The Target 2 V1.1 is a modification to the Target 2 Version 1.0 predicate device. They are independent oncology treatment planning systems that use CT and non-CT images to produce external beam dose distributions. A comparison of the features indicates that the Target 2 V1.1 has the same intended use as Target 2 Version 1.0. No new safety or effectiveness concerns are raised by the design of Target 2 V1.1. It shares common hardware with the predicate device.

Summary Of Studies

Test results indicate that Target 2 V1.1 performs its intended use and meets specifications in a safe and effective manner.

Conclusions

In the opinion of GE Medical Systems, the Target 2 V1.1 is substantially equivalent to the Target 2 Version 1.0 (510(k) # K896353). The Target 2 V1.1 is a modification of the predicate device and has the same intended use. No new safety or effectiveness concerns are raised by the design of the Target 2 V1.1.

510(k) Number (if known): K965010

Device Name: Target 2 Version 1.1 Radiotherapy Treatment Planning System

Indications For Use:

The Target 2 V1.1 is a radiation oncology treatment planning system which uses CT and non-CT data to produce External Beam and Irregular Field plans, and non-CT data to provide Interstitial/Intracavitary Dosimetry plans.

(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 K965010

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