MAY 12 1999

K984241

510(k) SUMMARY

Submitter:	Radiation Oncology Computer Systems, Inc. 6190 Corte Del Cedro Carlsbad, CA 92009 (760) 929-1811
Contact:	Charlene Neblett, Manager, Quality Assurance
Date Prepared:	November 25, 1998
Device Name:	ROCS Ultraseed™
Common Name:	Prostate Ultrasound-guided Brachytherapy Planning System
Classification Name: Number:	Accelerator, Linear, Medical, Accessory 90 IYE (892.5050)
Predicate Device:	Radiation Oncology Computer Systems Treatment Planning System 510(k) notification K862643

Device Description:

ROCS Ultraseed is software that executes well known and documented algorithms to produce radiation dose estimations for prostate ultrasound-guided brachytherapy. All data is user controlled and is in a table look-up format. Information is presented graphically on CRT screens and in hardcopy reports. The software is designed to run on a PC platform utilizing the Microsoft® Windows® operating systems. All dates are four digit numbers so the system is able to handle the year 2000.

Intended Use:

ROCS ULTRASEED™ (Prostate Ultrasound-guided Brachytherapy Planning System) is intended to be used for the computation, display, evaluation and output documentation of radiation dose estimations for prostate ultrasound-guided brachytherapy to be submitted for independent clinical review and judgment. The goal of this system is to provide a tool that will provide consistent results using well documented algorithms. This system does not provide direct or indirect control over any treatment delivery device or system in any form. The device only provides output data in the form of displays, hardcopy prints and/or plots to guide a physician in selecting the optimum patient treatment plan and for documenting the actual implant. It is intended to provide a report to be used by a competent health professional such as a radiation oncologist, medical physicist, radiation therapist or dosimetrist.

ROCS ULTRASEED™ 510(k) Summary

Technological Characteristics:

ROCS Ultraseed™ is designed to run on the Microsoft® Windows 95®, Windows 98®or Microsoft® Windows NT® operating system. The user interface has been based upon the standard Microsoft® Windows® graphical user interface providing ease of use for anyone familiar with windows products. This differs from the predicate device in that the operating system is now Microsoft® Windows®; whereas, the predicate device utilized the DOS operating system. Additionally, ROCS Ultraseed™ is designed for ultrasound image input.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Charlene Neblett
Manager, Quality Assurance
Radiation Oncology Computer System
6190 Corte Del Cedro
Carlsbad, CA 92009

Re: K984241
ROCS UltraSeed
Dated: March 5, 1999
Received: March 8, 1999
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Neblett:

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 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). 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,

CAPT Daniel G. 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

Enclosure

INDICATIONS FOR USE

ROCS ULTRASEED™

ROCS ULTRASEED™ (Prostate Ultrasound-guided Brachytherapy Planning System) is intended to be used for the computation, display, evaluation and output documentation of radiation dose estimations for prostate ultrasound-guided brachytherapy to be submitted for independent clinical review and judgment. The device provides output data in the form of displays, hardcopy prints and/or plots to guide a physician in selecting the optimum patient treatment plan and for documenting the actual implant. It is intended to provide a report to be used by a competent health professional such as a radiation oncologist, medical physicist, radiation therapist or dosimetrist.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984241

Prescription Use ✓
(Per 21 CFR 801.109)