DEC 11 1998

K981678

ROSSES MEDICAL

10620 Guilford Road, Suite 201
Jessup, Maryland 20794
(301) 490-2304 · (301) 490-2982 (fax)

510(k) Summary

The 510(k) summary information required by 21 CFR 807.92 is as follows:

Classification Name: Source, Brachytherapy, Radionuclide or Accelerator, Linear, Medical or Other

Common/Usual Name: Brachtherapy Treatment Planning System

Proprietary Name: STRATA

Substantial equivalence: Prowess 2000 (SSGI, Inc.) and Therpac PLUS B3D TUI (Multimedia Medical Systems, Inc.)

Device description: The proposed Strata device is a computer system developed for the use of assisting in the placement of anatomical localization and low dose rate isotope implants. This treatment planning procedure is used for lesions, benign or malignant, seated in human tissue. Strata uses multiple two dimensional images including Ultrasound and DICOM (imaging file format) images which are outlined by a qualified medical staff member, then reconstructed to create three dimensional structures and matrices. The information gathered is used for localization, visualization of regional interest, calculating dose of implanted radioisotopes, and finally out putting data in hardcopy form (printer/plotter).

Intended Use: The proposed Strata device is to used only by a qualified clinician, Medical Physicist or Dosimetrist, the results should then be approved by a licensed Radiation Oncologist. Strata is intended to assist the clinician in determining optimal placement of Low Dose Rate radioisotopes. Strata is not intended to prescribe dose, invade the patient or control hardware which can directly harm the patient.

Technological characteristics: The proposed Strata device is similar to predicate devices, and existent methodologies in its intended use.

The proposed device is different than the predicate devices in that it gives the user more flexibility with image acquisition and structure definition.

Submitted,
Rosses Medical Systesm

Rene Spector
Regulatory/SQA Manager
Phone/Fax

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 1998

Rene Spector
Regulatory/SQA Manager
Rosses Medical
Columbia Gateway Drive
Suite 160
Columbia, Maryland 21046

Re: K981678
STRATA (Brachytherapy RTP System)
Dated: September 28, 1998
Received: September 28, 1998
Regulatory class: II
21 CFR 892.5730/Procode: 90 MUJ

Dear Mr. Spector:

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,

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):

Device Name:

Indications For Use:

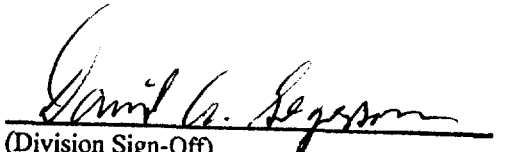
The proposed Strata system must be used by a qualified clinical staff member (generally a Medical Physicist or Dosimetrist), the results should then be approved by a licensed Radiation Oncologist.

The proposed Strata device is intended to assist the clinician in determining optimal placement of Low Dose Rate radioisotopes about a lesion or tumor (benign or malignant) seated in human tissue. The information gathered in this planning system is used for localization, visualization of regional interest, calculating dose of implanted radioisotopes, and finally out putting data in hardcopy form (printer/plotter).

Strata is not intended to prescribe dose, invade the patient or control hardware which can directly harm the patient.

(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 K981678

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

(Optional Format 1-2-96)