K062781

Symtium Corporation

Sean Comer, President and CEO
SYMTIUM CORPORATION
11503 Jones Maltsberger Suite 710
San Antonio TX 78216

NOV 2 1 2006

Summary

Trade Name: Mod1 Compensators for Radiation Beam Therapy

Common Name: Compensator

Classification Name: block, beam shaping, radiation therapy

Predicate Device: The predicate device is Southeastern Radiation Products, Inc. K040804, ".Decimal Tissue Compensator/Intensity Modulator".

Device Description:

The Symtium Corporation Mod1 Compensators for Radiation Beam Therapy are used for modulation of beam intensity during radiation therapy (IMRT). Initially, a plan for the compensator design is generated by the staff of the Cancer Center using treatment planning software such as Pinnacle, Eclipse, or CMS (and others). This compensator design file is then transferred to Symtium Corporation via secure online data transfer, and imported into their custom designed manufacturing software. Typically, a brass round is used as a basis for the compensator. It is placed into the milling machine and worked into precise X, Y and Z dimensions to match the treatment planning output. It is then removed from the milling machine and subjected to an extensive QA process to verify the accuracy of the process and the match between the physical dimensions of the compensator and the treatment planning output. The device is then mounted onto a carrier specific to the linear accelerator (LINAC) used for patient treatment. The finished device is then packaged and mailed to the Cancer Center via commercial package transport companies.

Once received by the Cancer Center, the compensator is unpackaged and once again undergoes a QA process to confirm the accuracy of the manufacturing process in producing a radiation fluency map as well as radiation dose. At this point, the device is moved into the LINAC vault for patient treatment. The compensator is then locked into place on the LINAC in the accessory collar.

During patient treatment, a photon beam is generated by the LINAC and directed toward the patient. The compensator attenuates the photon beam based upon the thickness and shape of the brass. In general, the device shields sensitive portions of the body during the treatment, and maximizes the effect of the radiation on the tumor. Brass is a heavy, dense material with the ability to "attenuate" or block the amount of radiation that passes through it. When the milled brass compensator is mounted in the accessory collar of the LINAC, the photon beam aimed at the patient is "attenuated" in the area according to the thickness of the brass. Thicker areas "attenuate" or block more photon beam than the thinner areas. Generally, the thinner areas of the compensator would correspond to the tumor, while the

thicker areas would overly surrounding "normal" tissue. In this way the tumor receives a maximum, effective dose of radiation while surrounding areas receive little or no radiation, sparing them from damage and the patient from side effects of the treatment.

Intended Use of the Device:

The Symtium Corporation Mod1 Compensator for Radiation Beam Therapy is designed specifically for application in external beam radiation therapy in cancer treatment. The device could be used in this application for all types of cancer treatable by external beam radiation therapy, with a universal application to this patient population.

Technological Characteristics of the Device:

The predicate device for comparison purposes is the Southeastern Radiation Products, Inc. K040804, ".Decimal Tissue Compensator/Intensity Modulator". The design and material composition of the Symtium Corporation Radiation Beam Therapy Compensator is identical to those of the predicate device.

Determination of Substantial Equivalence:

The determination of substantial equivalence was based on assessment of clinical data sets. The compensator production was verified through a QA process. Using a treatment plan adopted from a prostate case, brass compensators were milled to specification and shipped to the participating Cancer Center site for testing. Each compensator was tested using equivalent dose rates with two separate industry standard QA devices specifically for IMRT measurements. These test results are shown in Step 20 – Clinical Test Results. Measured composite dose was within 2% of the expected value. Isodose lines and distance to agreement were within industry standard Van Dyke criteria.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

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NOV 2 1 2006

Mr. Sean Comer
President and CEO
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SAN ANTONIO TX 78216

Re: K062781
Trade/Device Name: Mod 1 Compensators for Radiation Beam Therapy
Regulation Number: 21 CFR 892.5710
Regulation Name: Radiation therapy beam-shaping block
Regulatory Class: II
Product Code: IXI
Dated: September 12, 2006
Received: September 18, 2006

Dear Mr. Comer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SymtiumCorporation

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San Antonio TX 78216

A. Indications for Use

510(k) Number (if known): _____

Device Name: Mod1 Compensators for Radiation Beam Therapy

Indications for Use:

The Symtium Corporation precision milled brass compensators are used for modulation of beam intensity during radiation therapy.

David A. Seyman
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062781

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)