K974239

Summary of Safety and Effectiveness
Compliance with 513 (i) of the Federal Food, Drug and Cosmetic Act

November 8, 1997

FEB 10 1998

1. General Provisions

Trade Name: Photon Beam Blocking System
Common Name: Blocks, beam Shaping

Applicant Name and Address: Aktina Medical Physics Corporation
360 North Route 9 W
Congers, New York, 10920
Phone: 914-268-0101
FAX: 914-268-1700
Registration Number: 2436865

2. Name of Predicate Devices

Med-Tec, Inc., 360 degree, Half Beam Block, K941719[1]

3. Classification

This device is classified as a class II device according to 21 CFR 870.5710 .

4. Performance Standards

Performance standards for Beam Shaping Blocks not been established by the FDA under Section 514 of the Food, Drug and Cosmetic Act.

5. Intended Use and Device Description

This device is intended to be used in Radiation Therapy for creating irregularly shaping treatment fields.

6. Biocompatibility

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[1] Any statement made in conjunction with this submission regarding substantial equivalence to any other product only relates to whether the product can be lawfully marketed without pre-market approval or reclassification and is not to be interpreted as an admission or used as evidence in patent infringement litigation. As the Commissioner of the FDA has indicated, "...a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act relates to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Fed. Reg. 42,520 et seg. (1977).

No Biocompatability issues are raised with design or use of this device. Biocompatability testing was not performed.

7. Summary of Substantial Equivalence

This device is similar in design, construction, materials, intended use and performance characteristics to the predicate device. No new issues of safety or effectiveness are introduced by using this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 10 1998

Joan Zacharopoulos
Vice-President
Aktina Medical Physics Corporation
360 North Route 9W
Congers, NY 10920

Re: K974239
Photon Beam Blocking System
Dated: November 6, 1997
Received: November 12, 1997
Regulatory class: II
21 CFR 892.5710/Procode: 90 IXI

Dear Ms. Zacharopoulos:

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

Indications for Use

510(k) Number: K974293

Device Name: Photon Beam Blocking System

Indications for Use:

In Radiation Therapy, it is often necessary to create irregularly shaped fields to contour to the desired treatment shape. Irregular shaped fields can be achieved by supplementing the shaping ability of the treatment machines collimation system with tertiary beam blocks. These Beam Blocks are used to further collimate and contour the treatment field.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ or Over-The Counter Use: _ (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974239