

JAN 14 1998

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

October 10, 1997

**1. General Provisions**

Trade Name: Electron Beam Field Shaping 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**

Clark Research and Development, Clark Precision Block Cutter K842615<sup>1</sup>

**3. Classification**

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

**4. Performance Standards**

The FDA under Section 514 of the Food, Drug and Cosmetic Act has not established performance standards for Beam Shaping Blocks.

**5. Intended Use and Device Description**

This device is intended to be used in Radiation Therapy for creating irregularly shaped treatment fields in electron beam therapy.

**6. Biocompatibility**

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<sup>1</sup> 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 seq. (1977).

The electron beam block is mounted in the end of an electron cone and is not in contact with the patient at any time when in use. Therefore, no biocompatibility studies were undertaken for the device. Only the optional accessory, the Polycarbonate Inserts, used to transfer an outline of the area that requires beam blocking from the patients skin to the Styrofoam that must be cut with the hot wire cutter to produce a cerrobend mask, come in contact with the patient. The extent of patient contact is very short in duration (less than 2 minutes per use). As clearly stated in section 11 of the Material Data Safety Sheet supplied by the manufacturer of the Polycarbonate material, there are no adverse eye, skin or inhalation effects observed in toxicological testing .

#### **7. Summary of Substantial Equivalence**

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

Re: K973953  
Akinta Medical Physics Corporation Electron  
Beam Shaping System  
Dated: October 10, 1997  
Received: October 16, 1997  
Regulatory class: II  
21 CFR 892.5710/Procode: 90 IXI

JAN 14 1998

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:

Device Name: Electron Beam Field Shaping System

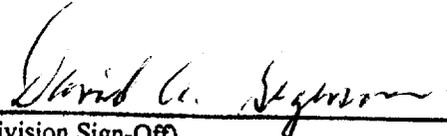
Indications for Use:

In Radiation Therapy, it is often necessary to create irregularly shaped fields to contour to the desired treatment shape. Irregular shaped fields for electron beam cases can be achieved by supplementing the shaping ability of the treatment machine's electron collimation system with tertiary beam blocks. These Beam Blocks are inserted into the ends of the electron cones. The electron beam blocks are created from low melting point lead alloy that is poured in a molten state into a pre-cut Styrofoam form. When the molten lead alloy cools it creates a hard, lead shield custom shaped for the desired form.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K973953