JUL 30 1999

K991546

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

April 26, 1999

1. General Provisions

Trade Name: Tilt Board
Common Name: Breast Board

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

Huestis Medical Flexi-board (K904005) and Med-Tec Corporation MT-200 Breast Boards (K935412). 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).

3. Classification

This device is classified as a class II device according to 21 CFR 892.5050.

4. Performance Standards

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

5. Intended Use and Device Description

The AKTINA Medical Physics Corporation Tilt Board is intended for use in Radiation Therapy as an aid in patient positioning for breast treatments.

6. Biocompatibility

The Tilt Board is not in contact with the patient at any time when in use as a sheet is to be placed between the patient's skin surface and the treatment support when in use. Additionally there are no new materials introduced in the manufacture of this device, therefore, no biocompatibility studies were undertaken for the device.

7. Summary of Substantial Equivalence

This device is similar in design and construction, and identical in materials, intended use and performance characteristics to the predicate devices. 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

JUL 30 1999

Joan Zacharopoulos
Vice-President
AKTINA Medical Physics Corporation
360 North Route 9W
Congers, New York 10920

Re: K991546
Tilt Board
Dated: April 26, 1999
Received: May 3, 1999
Regulatory Class: II
21 CFR 892.5050/Procode: 90 IYE

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 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

510(k) Number:

Device Name: Tilt Board

Indications for Use:

Tilt Boards are also commonly known as Breast Boards and are intended for use in Radiation Therapy to facilitate patient positioning in irradiation of the breast.

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 K991546