



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 29 1997

George Zacharopoulos
Certified Radiological Physicist
Aktina Medical Physics Corp.
360 North Route 9W
Congers, NY 10920

Re: K970384
Velos Constancy Check Device (CCD),
Model 55-145
Dated: June 2, 1997
Received: June 5, 1997
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. 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 (Pre-market 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

X970384

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

January 1, 1997

JUL 29 1997

1. General Provisions

Common/Usual Name: Constancy Check Device

Proprietary Name: Velos Constancy Check Device, model 55-145

Applicant Name and Address:

Aktina Medical Physics Corporation
360 North Route 9W
Congers, N.Y. 10920

2. Name of Predicate Devices:

(1) Keithly Instruments, Inc., Tracker Therapy Beam Evaluation system
(K874893)

3. Classification

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

4. Performance Standards

Performance standards for these devices have 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 as a means of verifying machine output on a daily basis in the delivery of external beam radiation therapy.

6. Biocompatibility

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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).

No issues of biocompatibility are raised with regard to this device.

7. Summary of Substantial Equivalence

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

CDRH DRAERD

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510(k) Number if known: K970384

Device Name: "Velos" Constancy Check Device

Indications for Use:

The AKTINA "Velos" Constancy Check Device, model 55-145, is intended for use in external beam radiation therapy in a similar way to that of the Tracker Therapy Beam Evaluation System (by Keithley Instruments, Inc.) previously cleared for marketing under K874893.

More specifically, its intended use is for daily, morning checks of machine output by staff technologists, under the supervision of a medical physicist. Not intended as a substitute for machine calibrations or validations of machine beam energy, these checks are quality assurance steps to safeguard accepted standards of good practice in Radiation Oncology.

"Velos" is designed to operate by either:

- a. being mounted on standard beamblock trays or,
- b. placed on a table, when measurements are needed from various SID's

and functions in an efficient and reliable way through reduction of setup time, remote control readings via CCTV, output constancy checks at all gantry angles (for compliance with TG-43) and fixed geometry for elimination of distance errors.

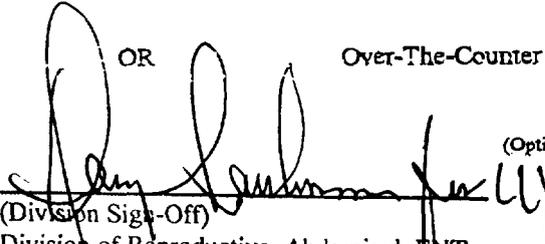
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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use


 (Division Sign-Off)
 Division of Reproductive, Abdominal, ENT,
 and Radiological Devices

(Optional Format 1-2-96)

510(k) Number K970384