EXHIBIT A

Victoreen, Inc.

K973960

Premarket Notification [510k] Summary as required by section 807.92(c)

JAN 14 1998

Date Summary was prepared:

September 30, 1997

Submitter's Name

Victoreen, Inc.
6000 Cochran Road
Cleveland, Ohio 44139-3395

Contact Person:

Linda S. Nash
Director of Regulatory Affairs
and Quality Assurance
Phone: 440-248-9300
Fax: 440-248-9301

Device Name:

Model 37-185

Classification Name:

Medical charged - particle radiation therapy system

Predicate Device:

Beam Scan, Model 37-201, 510(k) #K853671A

Product Description:

The product consists of two main parts; the readout module, and the scanner (data acquisition) module. The readout module is located outside the treatment room while the scanner is positioned on the treatment couch in such a manner as to allow the detectors to transverse the radiation beam as determined by the operator. The readout and the scanner are connected via a single 25 meter (75 foot) shielded cable.

The readout contains a LCD (Liquid Crystal Display) and 8 softkeys providing the operator interface. The readout also includes the microprocessor system, memory, printer interface and computer interface. Connections are provided for the power supply, parallel printer, computer RS-232 interface and the scanner cable.

The scanner module contains a stepper motor and a transport mechanism that moves a light detecting diode and a radiation detecting diode 50 cm, in a straight line to obtain a beam or light field profile during a measurement cycle. There is a fixed radiation detecting diode located in the center of the scanner which acts as a reference to null out any fluctuations in the amplitude of the radiation beam (as a function of time). The stepper motor controller and detector pre-amplifiers are also housed in the scanner assembly. The product includes a separate leveling mechanism to level the scanner module and rotate it 90 degrees.

Intended Use:

(Function): The Model 37-185 provides a means of scanning the light field and radiation field generated by radiation therapy machines and presents this data for quality control purposes only. Sequential scans of the light field and the radiation field provides information as to whether the cross hairs in the light field are in the center of the radiation field (per TG-40), the coincidence of the light field to the radiation field, and beam flatness and symmetry. These data aid in the determination of the therapy machine's performance characteristics. The Model 37-185 is intended for use by persons responsible for the proper interpretation of its readings and observing the appropriate safety procedures in the presence of radiation.

As a quality control tool the use of this product does not involve patient contact nor is it used to evaluate patient treatment planning. The patient is not in the room while this product is in use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 1999

Linda S.Nash
Director of Regulatory Affairs
& Quality Assurance
Victoreen, Inc.
6000 Cochran Road
Cleveland, OH 44139-3395

Re: K973960
Beam Scan Model 37-185
Dated: October 14, 1997
Received: October 16, 1997
Regulatory class: II
21 CFR 892.5050/Procode: 90 LHN

Dear Ms. Nash:

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,

William Yin

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

510(k) Number: K973960

Device Name: Model 37-185

Indications for Use:

Model 37-185 is used to provide a means of scanning the light field and radiation field generated by radiation therapy machines and presents this data for quality control purposes only. Sequential scans of the light field and the radiation field provides information as to whether the cross hairs in the light field are in the center of the radiation field (per TG-40), the coincidence of the light field to the radiation field, and beam flatness and symmetry. These data aid in the determination of the therapy machine's performance characteristics.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973960

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