

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

Date Summary was prepared:

November 21, 1996

Submitter's Name:

JUN 13 1997

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

Contact Person:

Linda S. Morin
Director of Regulatory Affairs
and Quality Assurance
Phone: 216-248-9300
Fax: 216-248-9301

Device Name:

Veridose Diodes

Classification Name:

Medical Charged-Particle Radiation Therapy System

Predicate Device:

ISORAD Photon Detectors that are part of the Dual Dosimetry System, Model number 37-720, 510(k) number K940660/S1

Intended Use:

(Function): The VeriDose solid state detectors are used to make relative measurements of radiation in therapeutic oncology. Silicon diode detectors have been in use for many years for the measurement of both photons and electrons used in radiation. The VeriDose is intended for the detection of ionizing radiation, it should only be used by persons who have the proper interpretation of its readings and the appropriate safety procedures to be followed in the presence of radiation. The diodes are taped or otherwise attached to a

patient's skin during a therapeutic oncology session where the patient is being exposed to radiation. The diodes produce a current directly proportional to the ionizing radiation to which they are exposed. The diodes are more rugged and more sensitive than ionization chambers and are waterproof. They must be connected to an appropriate display device. The purpose of the diode is to measure ionizing radiation independently at various points of interest. The responsible operator should verify the characteristics of each specific detector if the exact parameter is critical to any given clinical application.

Product Description:

The product consists of a waterproof color coded molded plastic hemisphere containing the appropriate buildup material and a radiation sensitive diode attached to a coaxial cable. A BNC connector is supplied for connection to a readout device.

Model no. table

Model #	Description	Color Code
30-471	VeriDose Diode, 1-4 MV Photon, (positive polarity)	Blue
30-471-8000	VeriDose Diode, 1-4 MV Photon, (negative polarity)	Blue
30-472	VeriDose Diode, 6-12 MV Photon, (positive polarity)	Yellow
30-472-8000	VeriDose Diode, 6-12 MV Photon, (negative polarity)	Yellow
30-473	VeriDose Diode, 12-18 MV Photon, (positive polarity)	Red
30-473-8000	VeriDose Diode, 12-18 MV Photon, (negative polarity)	Red
30-474	VeriDose Diode, 18-25 MV Photon, (positive polarity)	Green
30-474-8000	VeriDose Diode, 18-25 MV Photon, (negative polarity)	Green
30-475	VeriDose Diode, 6-25 MeV Electron, (positive polarity)	Silver
30-475-8000	VeriDose Diode, 6-25 MeV Electron, (negative polarity)	Silver
30-476	VeriDose Diode, Energy Compensated Photon, (positive polarity)	Black
30-476-8000	VeriDose Diode, Energy Compensated, (negative polarity)	Black

GENERAL SPECIFICATIONS:

1. Range: 2.0 cGy / minute to 1000 cGy / minute.
2. Effective Detection Area: 2 mm²
3. Output, all models: 1.0 nC/R nominal
4. Cable length: 2 meters

Range	Particle	Optimal Build-up	mg/cm ²	Same as Isorad Build-up	Color Dot
1-4 MV	Photon	5 mm H ₂ O equiv.	826	Yes	Blue
6-12 MV	Photon	15 mm H ₂ O equiv.	1500	Yes	Yellow
12-18 MV	Photon	28 mm H ₂ O equiv.	2800	No	Red
18-25 MV	Photon	36 mm H ₂ O equiv.	3600	No	Green
6-25 MeV	Electron	1 mm Al equiv.	275	Yes	Silver
100-662 keV	Photons	Energy Compensated		No	Black

6. The sensitive area buildup material is hemispherical in shape.
7. The angular dependence is less than 5% over the 2 pi hemisphere from perpendicular incidence to 75 degrees and less than 10% from 75 to 90 degrees.
8. Linearity is better than 0.3% over the range of 2 cGy / min to 1000 cGy/min provided that dose-per-pulse remains constant.
9. There are both positive and negative polarity versions of each.
10. The temperature sensitivity is less than 0.3% per degree C.
11. The detectors are waterproof and are washable in cold disinfectant. They are molded in plastic that is non-hygroscopic.
12. The device has a BNC coaxial connector.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 13 1997

Linda S. Morin
Corporate Director of Regulatory
Affairs and Quality Assurance
Victoreen, inc.
6000 Cochran Road
Cleveland, Ohio 44139-3395

Re: K964785
VeriDose Diodes Medical Charged-Particle
Radiation Therapy System
Dated: April 18, 1997
Received: April 25, 1995
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Ms. Morin:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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

510(k) Number: K964785

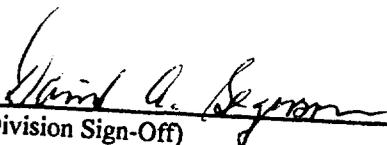
Device Name: Veridose Diodes

Indications for Use:

These diodes are used to provide dose verification and quality assurance for patients undergoing radiation therapy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K964785

Prescription Use or Over-The-Counter Use

FDA/DO