K964952

Exhibit "C"

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

JUL 21 1997

Date Summary was prepared:

November 21, 1996

Submitter's Name:

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
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Device Name:

Veridose V (five), Model number 37-705

Classification Name:

X-ray Radiation Therapy System

Predicate Device:

Patient Dose Monitor, Theta Model #526, 510(k) **#K912249/A**

Intended Use:

(Function): This device provides integrated dose and dose rate readout capabilities for radiation sensing diodes when used for patient dose verification or quality assurance in radiation therapy. The diodes produce a current directly proportional to the ionizing radiation to which they are exposed. The diodes are connected to this readout device. The purpose of the combination of the diodes and this product are to measure ionizing radiation independently at various points of interest. The VeriDose V is intended for use

by persons responsible for the proper interpretation of its readings and observing the appropiate safety procedures in the presence of radiation.

Product Description:

The product is a five channel diode dosimeter. The device will measure and display real time dose rate or integrated dose on up to 5 diodes simultaneously. The features include a keyboard, an ON / OFF switch, a power input connector (12VDC), 5 BNC connectors for diode inputs, a RS-232 connector, and a parallel printer port connector. Up to 21 sets of calibration data can be acquired, stored, and selected for use. Calibration and patient data is transmitted to a printer or the RS-232 port.

Specifications:

No. of input channels:	five (BNC)
Input polarity:	positive or negative
Rate range:	1.0 cGy/min to 1000 cGy/min
Dose range:	0.1 cGy to 1000 cGy.
Sensitivity adjustment:	0.1 to 10 nC / cGy
Particle types:	Electrons, Photons, Cobalt 60
Alarms:	one, user set / channel
Printer compatibility:	HP Inkjet, HP Laserjet, Seiko label printer
Reports:	TREATMENT REPORT CALIBRATION REPORT ENERGY CONSTANCY REPORT FLATNESS/SYMMETRY REPORT
Enclosure:	9" x 8.5" x 2.5" inches (width x depth x height) EMI coating
Weight:	3 lbs.
Power:	120VAC / 12VDC @ 1A power converter, UL, CSA 230VAC / 12VDC@ 1A power converter, CE

Comparison to predicate device: (Theta Systems PDM model 526)

Feature	**Veridose V**	**Model 526**
Channels:	5	2
Accuracy (%):	1	1
Reproduce(%):	0.5	0.5
Polarity:	Positive and Negative	Negative
Min Rate(cGy/min):	1	1
Max Rate(cGy/min):	1000	999
Min Dose (cGy):	0.1	0.1
Max Dose (cGy):	1000	999.9
Auto Zero:	yes	yes
Cal Adj (nC/cGy):	0.1 -10	0.01-9.99
Alarms:	yes	yes
Calibration Sets:	21	20
RS232 Port:	yes	no
Printer Port:	yes	yes
Weight(lb.):	3	5.5
<u>Environmental:</u> Operating temperature: Storage temperature: Relative humidity:	 10° C to 40° C 0° C to 70° 5 to 95% non-condensing	 10° C to 40° C 0° C to 70° 5 to 95% non-condensing

Similarities to predicate device (Theta Systems model 526):

The VeriDose V and the predicate device are technologically the same. Both are based on a multi-channel electrometer designed to measure the charge provided by a variety of diode detectors. Both devices convert this charge to a dose or dose rate value. The VeriDose V and the predicate device allow the results of a measurement to be transmitted to a printer. Both devices are similar in size. Each device allows the user to set an alarm value used to alert the user of a measurement exceeding this limit.

Differences predicate device:

The VeriDose V is a 5 channel device while the PDM (model 526) is a 2 channel device. The VeriDose V provides a RS232 interface allowing the results of a measurement to be transferred to a PC. These differences, while providing additional capability, do not degrade performance of the device.

Possible Customer Use and Misuse:

The customer may use this product as a quality assurance device only. Misuse is when the customer uses this as a calibration device to measure absolute dose or internal dose. This product is not recommended to be used for any absolute or internal dose measurements. The user could select the incorrect detector group, and cause the incorrect calibration factors to be applied. The VeriDose 5 is intended as a readout for detector diodes (user supplied) used for the detection of ionizing radiation, it should only be used by responsible persons who have the proper interpretation of its readings and the appropiate safety procedures to be followed in the presence of radiation.

Fail Safe / Safety:

The failure mode(s) are anticipated to be: cable(s) not connected or power supply not plugged in. This would be immediately observable in the output. There is only low voltage DC present inside the product (12 VDC). The product will perform a self diagnostic on power-up to test internal electronics integrity and notify the user if there are any problems.

Hazard Analysis:

Possible hazards are:

1. The user could plug the wrong diodes into the inputs and thereby use the wrong correction constants yielding incorrect information. The result would be an incorrect reading.

2. The user could select the incorrect diode group and thereby use the wrong correction constants. The result would be an incorrect reading.

To help prevent mis-use the diodes are color coded and clearly marked. The VeriDose V gives indication of each diode type per channel and provides a print out of the set up for record keeping. It is the user's responsibility to clearly mark the diode and its' connector to prevent connection to the wrong input channel. If the incorrect diode group set was selected it would be noticeable on the printout thus providing a check. The VeriDose V is intended as a readout device for detector diodes (user supplied) used for the detection of inonizing radiation, it should only be used by responsible persons who have proper interpretation of its readings and the appropriate safety procedures to be followed in the presence of radiation.

Risk Assessment:

This product is not a primary delivered dose measurement device, therefore, poses no user or patient risk. Since this product is an independent quality assurance device used for monitoring delivered dose, it plays no role whatsoever in the administration of radiation to the patient and in no way affects the performance of the radiation therapy system.

Failure Modes:

The diodes or the electrometer inputs may fail electrically. The memory, electronics or microprocessor may fail. Any connectors or the power supply may not be plugged in. These failures would be evident to the user by the either a message on the display indicating the source of the failure, or lack of display, as in the case of a power supply failure.

Labeling, Warnings, Standard Identification:

Product markings will include:

Nuclear Associates, Product Name, Model Number, Serial Number, Indication of Channel number.

Calibration:

Factory calibration of the product is limited to calibration of each of the five channels with a current source to a nominal 2 nC = 1 cGy.

User calibration includes placing the user supplied diodes in a (star) phantom. In the calibration mode, the serial numbers, associated channels, detector group number, machine ID, and Energy ID are entered, by the user, via the keyboard or via the RS-232 interface. The diodes are exposed to a known quantity of radiation and the charge acquired. The actual radiation exposure will be entered by the user. The device will calculate the calibration factor in units of cGy / nC. This data is stored in the devices' memory. The calibration requires user entry of a predetermined password preventing

unauthorized users from altering calibration factors. The calibration data can be printed or transmitted through the RS-232 port. A calibration (star) phantom is included with this product.

Storage Needs / Shelf Life / Disposability:

Shelf life is indefinite. The storage temperature is 0 degrees C to 70 degrees C. The relative humidity is 5 to 95% non-condensing. There are no disposability restrictions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Linda S. Nash
Director, Regulatory Affairs & Q.A.
Victoreen, Inc.
6000 Cochran Road
Cleveland, Ohio 44139-3395

Re: K964952
Varidose V (Patient Dose Monitor)
Dated: April 18, 1997
Received: April 21, 1997
Regulatory Class: II
21 CFR 892.5900/Procode: 90 JAD
21 CFR 892.5050/Procode: 90 LHN

JUL 21 1997

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: K964952

Device Name: Veridose V (Five) - Model Number 37-705

Indications for Use:

The Veridose V (Five) - Model Number 37-705 is used to provide integrated dose and dose rate readout capabilities for radiation sensing diodes when used for patient dose verification or quality assurance in 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 K964952

Prescription Use X or Over-The-Counter Use _____