EXHIBIT A
K974112

JAN 29 1998

**Victoreen, Inc.**

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

**Date Summary was prepared:**

October 20, 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
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**Device Name:**

VacuDAP, Model 2000, 2001

**Classification Name:**

Stationary X-ray System (accessory)

**Predicate Device:**

DAP(Dose-Area-Product) Meter, Model 07-205, 510(k) #K941931

**Product Description:**

The basic unit VacuDAP 2000 consists of the square ionization chamber and the chamber electronics including the high voltage generation, amplifier, microcontroller and a 8-digit display. These components are designed as a compact unit. The VacuDAP 2001 is completed with the remote control (terminal) which makes it possible to operate from everywhere. Optional a printer is available.

The X-ray generates an electric charge in the ionization chamber which is measured by the electronic evaluator as chamber current. The microcontroller calculate the dose area product and dose area product rate including the factor of the chamber. The results are transmitted to the serial interface on request of the terminal microcontroller. The measuring operation is working irrespective of the data displayed and is cumulating until the electronic evaluator is reset. The

power is supplied via a low voltage socket (1, 3mm). To start a treatment, the measuring system has to be reset by pushing the button RESET. All X-rays will be measured and displayed automatically.

**Intended Use:**

(Function): The Model 2000, 2001 is intended to measure the radiation output of diagnostic X-ray generating machines during imaging of patients in both radiography and fluoroscopy. The instrument measures and displays Dose Area Product, a parameter that can be related to patient dose by a Medical Physicist. The Dose Area Product measurement includes the influence of dose rate, screening time and used field quantity variables. The instrument accumulates Dose Area Product values until manually reset by the user.

## Specification Comparison Table

| Feature | New Device<br>VacuDAP<br>Model 2000, 2001 | Predicate Device<br>Dose Area Product Meter<br>Model 07-205 |
|---|---|---|
| **System accuracy** | max. ± 20% | better than ± 20% |
| **Interface** | RS485 | RS232 |
| **Relative Humidity** | < 75% | 95%RH non-condensing |
| **Temperature Range** | +10° to +40°C | +10° to +40°C |
| **Dap range** | .001 to 100,000 $Gy/cm^2$ | .001 to 9999 $Gy/cm^2$ |
| Dap rate | .001 to 300 $Gy/cm^2/s$ | .001 to 100 $Gy/cm^2/s$ |
| **Resolution** | 0.1 $mGycm^2$ | ± 0.01% of full scale |
| | | |
| **Light Transmission** | >75% | 70% |
| **Sensitivity** | $8 \times 10^{-8}$ As /$Gycm^2$ | $3X10^{-3}$ $3X10^{2}$ $Gycm^2$ $S^{-1}$ |
| **Al equivalent / filter effects** | 0.4mm | 0.5mm |
| **Energy Range** | 50 to 200kV | 50 to 150kV |
| **Chamber Power** | 12VDC / 250mA | 90VAC to 132VAC<br>180 VAC to 264VAC @10VA |
| | | |
| **Terminal Power** | 12/150mA | Info unavailable |
| | | |

**Similarities to predicate device** (Dose Area Product Meter, Model 07-205):

The VacuDAP and the predicate device are similar. Both are using an air filled ionization chamber and a connected electrometer designed to measure the charge generated by the X-ray radiation. The microcontroller calculates the dose area product, the dose area product rate and the exposure time. The VacuDAP and the predicate device allow the results of a measurement to be transmitted to a printer.

**Differences to predicate device:**

The ionization chamber designed for the VacuDAP devices has a higher light transmission, a lower filter effect and a higher sensitivity. These differences improve the performance of the device.

The VacuDAP 2000 has an attached electronic unit including all functions and display. The VacuDAP 2001 is provided with a serial interface RS485 for connecting the terminal controller. This interface is also used for connecting more ionization chambers to build up a multi-chamber system. The interface allows to connect additional standard devices and to transmit the measuring results to a PC.

**Possible Customer Use and Misuse**

The customer can use this product either as a quality assurance device or for precise monitoring of the dose which is given to the patient. A misuse could occur if the customer takes the product as a calibration device to measure the absolute dose or internal dose. This product is not recommended to be used for any absolute dose or internal dose measurements.

Moreover the user could forget to push the RESET before an examination or push the RESET before the end of an examination. Then the measuring result will be incorrect. The measured value needs also a proper interpretation when an additional filter is used behind the ionization chamber in the beam line.

**Fail Safe / Safety:**

The failure mode(s) are anticipated to be: cable(s) not connected or power supply not plugged in. In these cases the device can not be operated and would be observable in the display. The device is supplied with low voltage (12 V DC). The high voltage of 300 V DC is only present inside the product and can not be touched by the operator. The high voltage generates an electrical power of 0.5 mW and breaks down in case of a malfunction. 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:**

The VacuDAP devices cause no hazards.

**Risk Assessment:**

This product is not a primary delivered dose measurement device. Therefore it poses no user or patient risk. Since this product is an independent quality assurance device used for monitoring delivered dose, it does not affect the administration of radiation to the patient or the performance of the X-ray diagnostics system.

**Failure Modes:**

The ionization chamber and 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 will be evident to the user by 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, Al Equivalent, Energy Range and Warning.

All advertising, brochures, sales literature, etc. will conform to FDA, and Victoreen / NAD standards.

The manual will conform to Victoreen / NAD standards.

**Calibration:**

Factory calibration of the product is limited to calibration of the ionization chamber with a radiation source. The measuring results have been compared against a reference instrument calibrated by the Physikalisch-Technische Bundesanstalt, Braunschweig (Germany).

The determined calibration factor is stored in the device's memory and used for the calculation of the dose area product.

The user can check the chamber and the electronics by using the test routine. If the test result is out of the range the device has to be checked by authorized personnel.

**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

JAN 29 1998

Linda S. Nash
Corporate Director of Regulatory
Affairs & Quality Assurance
Victoreen, Inc.
6000 Cochran Rd.
Solon, OH 44139

Re: K974112
VacuDAP, Model 2000, 2001
Dated: October 20, 1997
Received: October 31, 1997
Regulatory class: II
21 CFR 892.1680/Procode: 90 KPR

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:

Device Name: VacuDAP - Model number 2000, 2001

Indications for Use:

The Nuclear Associates VacuDAP - Model 2000, 2001 is intended to measure the radiation output of diagnostic X-ray generating machines during imaging of patients in both radiography and fluoroscopy. The instrument measures and displays Dose Area Product, a parameter that can be related to patient dose by a Medical Physicist. The Dose Area Product measurement includes the influence of dose rate, screening time and used field quantity variables. The instrument accumulates Dose Area Product values until manually reset by the user.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K974112

Prescription Use ✓ or Over-The Counter Use

(Per 21 CFR 801.109)