

NOV 19 1998

Victoreen, LLC

K982937



EXHIBIT A

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

**Date Summary was prepared:**

August 18, 1998

**Submitter's Name:**

Victoreen, LLC  
6000 Cochran Road  
Cleveland, OH 44139-3395

**Contact Person:**

Mary Jo Nero  
Quality Assurance Associate  
Phone: (440) 248-9300 ext. 215  
Fax: (440) 248-9301

**Device Name:**

Model 580-006 Radiation Therapy Ionization Chamber

**Classification Name:**

Medical Charged-Particle Radiation Therapy System

**Predicate Device Name:**

Model 500-6 Radiation Therapy Ionization Chamber  
510(k) Number: K932342

6000 Cochran Road  
Cleveland, Ohio 44139-3395  
(440) 248-9300  
FAX (440) 248-9301  
(800) 850-4608

**EXHIBIT A**

	<b>Model 580-006 <u>New Device</u></b>	<b>Model 500-6 <u>Predicate Device</u></b>
<b>Performance Standards Under Section 514:</b>	No Performance Standard established for this device	No Performance Standard established for this device
<b>Labeling:</b>		
<b>Label:</b>	580-006	500-6
<b>Advertising Brochure: (Product Data Sheet)</b>	Reference Exhibit C	Reference Exhibit B

**Intended Use:**

This instrument is intended for the purpose of calibrating and measuring the ionizing radiation outputs from medical therapy machines.

**Product Description**

The Model 580-006 Radiation Therapy Ionization Chamber is modeled after the traditional 0.6cm<sup>3</sup> Farmer-type chamber used for absolute dosimetry measurements of medical linear accelerators and <sup>60</sup>Co machines. Each chamber includes an energy response chart, a PMMA <sup>60</sup>Co buildup cap, a convenient low noise one meter cable with triaxial BNC connector and a custom carrying case.

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**Specification Comparison Table**

<b>Feature</b>	<b>New Device Model 580-006</b>	<b>Predicate Device Model 500-6</b>
Volume	0.61 cm <sup>3</sup>	0.6 cm <sup>3</sup>
Sensitivity	2.0 x 10 <sup>-8</sup> cGy <sup>-1</sup>	2 x 10 <sup>-10</sup> A/R/s
Leakage	<4 x 10 <sup>-15</sup> A	< 10 <sup>-15</sup> A
Wall Material	PMMA acrylic with graphite layer	Tissue equivalent plastic
Wall area material density	78.5 mg/cm <sup>2</sup>	58 mg/cm <sup>2</sup>
Collector	Pure aluminum, 1mm diameter x 20.0mm long	Tissue equivalent plastic
Cable length	1 meter	15 meters
Range of Temperature	+10°C to +40°C	+10°C to +40°C
Relative air humidity	75%, non-condensing	20% to 75%, non- condensing
Build-up cap material	PMMA for <sup>60</sup> Co	Acrylic 1.2 g/cm <sup>3</sup>
Chamber length	23.6 mm	24.4 mm
Chamber diameter	5.95 mm	7.1
Build-up cap diameter	16.3 mm	13.3 mm
Probe length	157 mm	124 mm
Energy Range without build-up cap	21keV to 662 keV	70keV to 662 keV
Energy Range with build-up cap	662 keV to 1.5 MeV	1.2 MeV to 1.5 MeV
Maximum exposure range for 99.5% efficiency @ 300 V	3.0Gy s <sup>-1</sup>	4000 R/min

## **EXHIBIT A**

### **Similarities to predicate device (500-6)**

The 580-006 and the predicate device are similar. Both units are an air filled ionization chamber that produce a current when exposed to ionizing radiation produced by a medical therapy machine. The 580-006 and the 500-6 are connected to an approved electrometer by a triaxial BNC connector.

### **Differences to predicate device**

The 580-006 uses a pure aluminum electrode while the 500-6 uses a tissue equivalent plastic electrode. Also the 580-006 uses a PMMA acrylic chamber material coated with a graphite material while the 500-6 uses a tissue equivalent plastic for its chamber material. The 580-006 has a wider energy response range ( 21 keV to 662 keV) than the 500-6. (70 keV to 662 keV)

### **Possible Customer Use and Misuse**

The customer may use this device as a quality assurance or a absolute dosimetry measurement of a medical therapy machine, with the appropriate electrometer, when calibrated by the necessary approved calibration lab. A misuse may occur if the user forgets or does not use the appropriate build-up material for the energy of the radiation that they are measuring.

### **Fail Safe / Safety**

The 580-006 will not produce the appropriate current if it is not connect properly to an electrometer. The 300-500VDC bias voltage is present only on the inside of the chamber and can not be touched by the operator.

### **Risk / Hazard Analysis**

A Risk / Hazard Analysis has been conducted on this product per Victoreen product development procedures.

This product is used to measure the absolute dose outputs from medical therapy machines. The device is not used to monitor the dose delivered to the patient during treatment. Since the device is used only by a qualified medical physicist and must be calibrated on a periodic cycle, by a qualified calibration lab, it does not affect the administration of radiation to the patient or the performance of the therapy machine.

## **EXHIBIT A**

### **Failure Mode**

The 580-006 triaxial connector may fail electrically. This failure will be evident to the user by either physically touching the connector or the electrometer failure to measure the correct current.

### **Labeling, Warnings, Standard Identification**

Product marking will include:

Victoreen, Model Number and serial number.

All advertising, brochures, sales literature, etc. will conform to FDA and Victoreen Standards.

Warning:

This device is intended to be used for the detection and measurement of ionizing radiation. It should be used only by persons who have been trained in the proper interpretation of its readings and the appropriate safety procedures to be followed in the presence of radiation.

Although the equipment was designed and manufactured in compliance with all applicable safety standards, certain hazards are inherent in the use of electronic and radiometric equipment.

### **Calibration**

Factory calibration of the product will, at a minimum, consist of a calibration factor for the following NIST techniques M50, M250, Cesium 137 and Cobalt 60. This calibration will not be used as a substitute for an approved calibration facility for the measurement of absolute dose.

### **Storage Needs / Shelf Life / Disposability**

Shelf life is indefinite. Storage shall be in a cool, dry environment free of corrosive materials, fluctuation in temperature and humidity, or vibration and shock. There are no disposability restrictions.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Edward W. Siurek III  
Director of Regulatory Affairs  
& Quality Assurance  
Victoreen, LLC  
6000 Cochran Road  
Cleveland, Ohio 44139Re: K982937  
Model 580-006 Radiation Therapy Ionization Chamber  
Dated: August 19, 1998  
Received: August 21, 1998  
Regulatory class: II  
21 CFR 892.5050/Procode: 90 LHN

Dear Mr. Siurek:

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 requirements, 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/dsma/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

# INDICATION FOR USE STATEMENT

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510(k) Number (if known): Unknown

Device Name: Model 580-006 Radiation Therapy Ionization Chamber

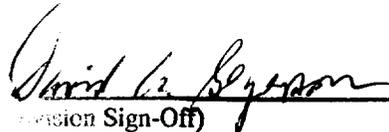
## Indications for Use:

This instrument is intended for the purpose of calibrating and measuring the ionizing radiation outputs for medical therapy machines.

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

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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 K982937

Prescription Use  \_\_\_\_\_  
(Per 21CFR801.109)

or Over-the-Counter Use \_\_\_\_\_