K013689
Page 1 of 2

JUL - 2 2002

SUN NUCLEAR CORPORATION
425-A Pineda Court
Melbourne, FL 32940-7508 U.S.A.
Fax: 321 259 7979 **321 259 6862**

Date: October 26, 2001

Subject: 510(k) Safety and Effectiveness Summary (SMDA Summary) for the Model 1008 Re-entrant Chamber / Model 44D Re-entrant Chamber

Trade Name: Model 1008 Re-entrant Chamber or
Model 44D Re-entrant Chamber

Common Name: Ion Chamber

Product Code: 90JAQ

Classification Name: System, Applicator, Radionuclide, Remote-Controlled

Substantial Equivalence: Standard Imaging HDR- 1000 Ion Chamber, K922554
Standard Imaging IVB 1000 Ion Chamber, K001825

Contact: Jim Mixon, Quality Assurance Manager

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 1992 also referred to as SMDA.

Description and Use:

The Model 1008 / Model 44D is a well-type re-entrant ionization chamber designed for application with brachytherapy and intravascular brachyterapy source measurement. The chamber is hermetically sealed, therefore, there is no air density correction requirement. The fill gas is pure argon at an absolute pressure of 23.5 psi, which provides several distinct benefits. These include enhancing the response at low photon energies from both gamma and Bremsstahlung from beta radiation, higher ion collection efficiency and long term constancy measurements.

The Model 1008/44D is fully guarded into the chamber and is equipped with a 1.5 meter low-noise triaxial signal cable terminated with a triaxial collection electrode inside the chamber. When properly connected to a dosimetry electrometer, the chamber housing will be common to the electrometer housing; the collection electrode will be floating with the guard at the chamber bias potential. Therefore, no shock hazard should exist. However, prudent handling of the connectors and equipment is always recommended whenever there is chamber bias being applied.

Sun Nuclear has deemed the device safe and effective for its intended uses as long as it is operated in accordance with all of the accompanying labeling and instructions. Sun Nuclear believes that responsible design and quality assurance practices were followed during the development and manufacture of the Model 1008 / Model 44D Re-entrant Chamber.

E-Mail: Mail@sunnuclear.com
http://www.sunnuclear.com

SAFETY FEATURE LIST FOR MODEL 1008 / 44D

	FEATURE	PURPOSE
1.	Hermetically sealed chamber	No air density correction necessary
2.	Positive Pressure	Long term constancy measurements
3.	Floating collection electrode	Eliminate shock hazard

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Mr. William E. Simon
President
Sun Nuclear Corporation
425-A Pineda Court
MELBOURNE FL 32940

Re: K013689
Trade/Device Name: Model 1008 Re-entrant Chamber
Model 44D Re-entrant Chamber
Regulation Number: 21 CFR 892.1360
Regulation Name: Radio-nuclide dose calibrator
Regulatory Class: II
Product Code: 90 KPT
Dated: April 1, 2002
Received: April 3, 2002

Dear Mr. Simon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

Edited 07-02-02

510(k) Number (if known)	K 013689
Device Name	*Sun Nuclear Corporation* *Model 1008 Re-Entrant Chamber /Model 44D Re-entrant Chamber*
Indications for Use	The Model 1008 (44D as marketed under CNMC) is a well-type, re-entrant ionization chamber intended for measurement of source strength of both clinical HDR and LDR brachytherapy sources and intravascular brachytherapy (IVB) sources. Both types of IVB sources can be measured; those designed to deliver a gamma dose and those designed to deliver a beta dose. The chamber must be calibrated before any measurement of a clinical source takes place. Source strength calculation must be done with the accompanying calibration certificate from the calibration laboratory. The calibration must be performed by an accredited dosimetry calibration laboratory, with the same source type and isotope that is used clinically. The chamber constancy must be monitored after calibration with a proper Measurement Quality Assurance program in order to validate the chamber calibration over a period of time.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David E. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013689

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter Use _____