OCT 2 3 2000

K002446

SAFETY AND EFFECTIVENESS SUMMARY FOR MODEL 1008 Re-Entrant Chamber/ Model 44D Re-Entrant Chamber

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 it's 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.

SAFETY FEATURE LIST FOR 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

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510(k) Premarket Notification Summary

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Contact: Noel Downey

Date: March 30, 1998

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

Common Name: Ion Chamber

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

Product Code: 90JAQ

Substantial Equivalence: Standard Imaging HDR- 1000 Ion Chamber #K922554

Description and Use:

The Model 1008/Model 44D is a well type re-entrant ionization chamber designed for application with brachytherapy source strength 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 emitted from isotopes, higher ion collection efficiency and long term constancy measurements.

Similarities/Differences with predicate devices:

Similarities between the Sun Nuclear Model Re-entrant Chamber and the Standard Imaging HDR- 1000 Ion Chamber include the following:

- A well for source insertion
- Source fixtures for reproducible positioning
- Location on axis where response is stable
- Low leakage current
- High impedance, fully guarded collector
- Triax cable and connector to mate with electrometer

Other similarities include good ion collection efficiency at (HDR) high dose rate Ir-192 activities and elimination of beta contamination during isotope measurement.

The major difference between the 1010/44D re-entrant chamber and the HDR-1000 ion chamber is the internal gas contributing the ionization. The 1008/44D is a sealed chamber with an Argon fill gas, there is no need for air density correction. The HDR-1000 is a vented ion chamber with air serving as the measuring gas and requiring air density correction.

Another difference is in the electrode construction. In the 1008/44D, the bottom of the well and the collection electrode form a gap which is a continuation of the sensitive volume of the ionization chamber. As the source moves down along the axis past the most sensitive point in the chamber, the sensitivity loss due to axial drop off is compensated by the sensitivity gain as the source moves closer to the bottom gap. This causes a pick up in the sensitivity which flattens the axial response curve and provides a region where the change is less than 0.1% over a 2 cm region. The HDR-1000 does not have a bottom gap and the axial response is more of a parabolic shape, with the center calibration region actually a peak on the axial response curve.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2000

Thomas L. Powers
President
Sun Nuclear Corporation
425-A Pineda Court
Melbourne, FL 32940

Re: K002446
Model 1008/44D Reentrant Chamber
Dated: July 27, 2000
Received: August 9, 2000
Regulatory class: II
21 CFR 892.5730/Procode: 90 KXK
21 CFR 892.5700/Procode: 90 JAQ

Dear Mr. Powers:

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 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). 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) 594-4639. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002446

Device Name: Sun Nuclear Corporation Model 1008 Re-Entrant Well Chamber

Indications For Use:

The 1008 is a well type re-entrant chamber designed for application with brachytherapy source strength measurement. The chamber is hermetically sealed, therefore there is no air density correction requirement.

An MQA (Measurement Quality Assurance) program should be implemented immediately upon receipt of any ion chamber which is to be used for clinical measurements.

The first step in MQA is to measure the axial response (sweet spot) and the response to a long lived isotope such as a Cs-137 tube source which can be dedicated to periodic constancy measurements. Ideally, this would be done before sending the unit to a calibration laboratory. Then after calibration, the initial tests can be repeated to verify that no change has occurred during shipping. This will validate the calibration. Subsequent measurements with the constancy source will assure the long term stability of the calibration.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002446

(Optional Format 1-2-96)