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Section 1.6

510(k) Premarket Notification Summary of Safety and Effectiveness

Submitter Name:	Sun Nuclear Corporation
Submitter Address:	425-A Pineda Court Melbourne, FL 32940
Submitter Phone:	(321) 259-6862
Submitter Fax:	(321) 259-7979
Contact Person:	Jim Mixon, Quality Assurance Manager
Date Summary Prepared:	April 12, 2002
Trade Name:	Model 1133 IVD PC Version
Common Name:	Patient Radiation Dose Monitor
Classification Name:	Accelerator, Linear, Medical
Product Code:	90 IYE
Substantial Equivalence:	Model 1133 IVD K011332

Description

The Sun Nuclear Model 1133 rf-IVD (In-Vivo Dosimetry) is a system that measures the radiation output of a linear accelerator or a radioactive substance such as a Co-60 source, during the treatment of a patient. It has 3 detector inputs per detector pod, with only one detector pod usable at a time.

The radiation therapist connects the radiation detectors (diodes) to the Detector Module and then positions them on the patient in order to measure the radiation from the accelerator. The Detector Module communicates with the Base Station by radio frequency communication. The measurement data is then sent through a line to an optically isolated interface, then to the PC. The Detector Module and Base Station are battery powered.

The therapist leaves the treatment room. Dose measurement is then remotely started on the rf-IVD from the control room using the PC Software and then the radiation beam is turned on. When the beam turns off, the rf-IVD is stopped and the dose value is displayed. The rf-IVD display value is recorded or printed on an accessory printer. The therapist then enters the room and removes the detector from the patient.

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Intended Use:

The recorded rf-IVD measurement is a QA test that verifies the dose output during treatment from the radiation machine. The actual treatment plan is calculated in the Treatment Planning Computer (TPC – not part of the rf-IVD) which uses dosimetry data acquired from a NIST traceable calibrated ion chamber and 3D-water phantom. The plan output should also include the "expected" dose at the point of the rf-IVD detector placement. Then the measured rf-IVD dose and the expected TPC dose can be compared for verification. If the expected dose is not verified, the measured dose should not be used to adjust future treatments. Instead, an investigation should be conducted as to why the error occurred. Therefore, the rf-IVD offers a closed loop QA test of the implementation of the plan.

Summary of Technological Characteristics

Comparison of Model 1133 IVD PC Version to Marketed Device

The following table shows the common functions between the Sun Nuclear Model 1133 rf-IVD and the IVD PC Version. The function is stated in the left column, and the device column has a "x" if it includes the feature.

Function	IVD PC Version	rf-IVD Marketed Device
Measure diode radiation detectors	x	x
Display dose and dose rate in real time	x	x
Solid state measurement electrometers, microprocessor controlled	x	x
Electrometer design - unipolar, detector current to pulse count frequency	x	x
Measurement result printable	x	x
Selectable calibration configurations for different beams and detectors	x	x
Calibration storage in non-volatile memory	x	x
Measurement electrometer in treatment room (eliminates extension cables)	x	x
Password protection of calibration procedures	x	x
Suitable for total body treatment measurement	x	x

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EFFECTIVENESS:

The model 1133 IVD is an effective tool in the radiation oncology department. It offers the ability to perform closed loop quality assurance test of the radiation dose delivery to the patient without a significant burden to the therapist. The IVD can use diode detectors that are already present in the department's inventory; it only requires a calibration with these diodes. Because they are so small, the placement of the diode detector is easy for the therapist; and because there is no voltage on the diode detector, there is no electrical shock hazard. The dose measurement result is available instantly, allowing the therapist to compare with the physicist's expected dose and, while the patient is still setup for treatment, notifies physics for help in verification if there is an error noted. Since the IVD is not part of the treatment calculation or the treatment delivery system, it is totally independent and offers an effective method of testing the implementation of the desired treatment. With the operational features of the IVD, there is little effort on the part of the therapist except to: 1) place the detector, 2) click on a single "button" to start the measurement, 3) press the Stop"button" to get the final answer, 4) compare the measurement to the expected dose, 5) (optionally) print the results of the measurement for their records, and 6) remove the detector from the patient.

SAFETY FEATURE LIST FOR IVD

	FEATURE	PURPOSE
1.	Battery Operation	Eliminates risk of shock to the patient
2.	Auto shut off during charging	Eliminates risk of shock to the patient
3.	Uses diodes, no detector voltage	Eliminates risk of shock to the patient
4.	Optically isolated serial interface	Eliminates risk of shock to the patient when connected to PC
5.	Energy key calibration	Reduces chance of error by requiring only one key to start
6.	Password protected calibration	Prevents tampering with calibration values
7.	Displays only calibrated detectors	Prevents accidental recording of wrong detector
8.	Diagnostic power up test	Notifies user of system error (hardware and software)
9.	Low Battery indicator	Cautions user that complete measurement might not be possible
10.	Low Battery shut down	Prevents operation at low battery voltage

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 2002

Mr. William E. Simon
President
Sun Nuclear Corporation
425-A Pineda Court
MELBOURNE FL 32940-7508

Re: K021463
Trade/Device Name: IVD Model 1133 – PC Version Radiotherapy Dosimetry System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 IYE
Dated: May 2, 2002
Received: May 7, 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

K021463

Section 1.4

Indications for Use Statement

510(k) Number (if known)	~~K011332~~ - Special Submission
Device Name	IVD Model 1133 - PC Version
Indications for Use	The PC Version of the IVD Model 1133 has the same Indications for Use as the rf IVD submitted under K011332 which is quoted here:

Sun Nuclear's Model 1133 rf-IVD is a battery operated dosimetry system designed to measure the patient's dose during radiation therapy treatment.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✔ Over-The-Counter Use _____
(Per 21 CFR 801. 109)

David A. Jayson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K021463