DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 9 2003

Ms. Christine Castleberry
RA & QA Manager
Nuclear Associates
120 Andrews Road
HICKSVILLE NY 11801

Re: K030066
Trade/Device Name: Cal/Rad Mark VI/VDC-505 Dose Calibrator, Model 34-165
Regulation Number: 21 CFR 892.1360
Regulation Name: Radionuclide dose calibrator
Regulatory Class: II
Product Code: 90 KPT
Dated: May 29, 2003
Received: June 3, 2003

Dear Ms. Castleberry:

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 Section 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 the 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" (21CFR Part 807.97) you may obtain. 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

510(k) Number (if known): K030066

Device Name: Cal/Rad Mark VI / VDC-505 Dose Calibrator

Indications For Use:

The Mark VI Dose Calibrator is designed to measure the amount of radioactive material in vials, syringes and capsules. It is used to measure the amount of activity used to prepare radiopharmaceutical kits, measure the activity in syringes of radiopharmaceuticals prior to injection and to quantify the activity remaining in the syringe following injection. It is indicated for use in the preparation of radiopharmaceuticals and verification of the activity prior to patient administration.

Data related to the factory calibration is stored in the chamber. This standardizes the response of each ion chamber, allowing each chamber to report the same amount of electric current for the same radiation source. The isotopic calibration factors are stored in the control/readout unit. The ion chamber current is processed using the isotopic calibration factors stored in the control unit in order to determine the amount of radioactive material present.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

David A. Legorreta

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K030066

Prescription Use ✓