DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2001

Ms. Christine G. Castleberry
Nuclear Associates
100 Voice Road
P.O.Box 349
CARLE PLACE NY 11514-0349

Re: K010417
Model 34-162, CAL/RAD MARK IV
DOSE Calibrator
Dated: November 19, 2000
Received: February 12, 2001
Regulatory Class: II
21 CFR §892.1360/Procode: 90 KPT

Dear Ms. Castleberry:

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.
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): K010417

Device Name: CAL/RAD MARK IV, DOSE CALIBRATOR, Model # 34-162

Indications For Use:

The model 34-162, CAL/RAD Mark IV Dose Calibrator, is designed for daily QA requirements. It is used to verify the accuracy of delivered patient dose in a Nuclear Lab.

Both the ionization chamber and the control unit are microprocessor controlled, resulting in two 'intelligent' systems, which communicate with each other using a communication link.

The control unit commands the chamber to perform action. In most cases, this means the request to send dose measurement values. Calibration factors for most of the used isotopes can be set on the control unit and are sent to the ionization chamber. This Calibration factor will be shown on the LCD-display at all times when measuring. The factor for Tc-99m has been predefined and is the default factor at power-up.

The chamber itself has no information on isotopes. The chamber is able to calculate proper activity values by means of the calibration factors sent to it by the control unit. The calibration of the system can be performed in five steps.

The data needed for the proper calibration of an ionization chamber is stored only in the memory of the ionization chamber itself, which makes it possible to exchange different chambers and control units without having to perform a new calibration.

The ionization chamber is equipped with non-volatile memory, with the advantage that all the parameters that are set by the user will be remembered even if the power is disconnected over longer periods of time.

(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 _____

(Optional Format 1-2-96)

David A. Segarra

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010417