MAY - 8 2001

K010472

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h)

1. **Submitter:**

Thomson & Nielsen Electronics Ltd.
25B Northside Rd.
Ottawa, ON K2H 8S1
Canada

Contact : Norma Thomson
Phone : (613) 596-4563
Fax : (613) 596-5243

Prepared March 3, 2001

2. **Common or Usual Name:** MOSFET 20

Proprietary Name : Patient Dose Verification System

Classification Name: Instrument, Therapeutic Accelerator Accessory

Manufactured By :

Thomson & Nielsen Electronics Ltd.
25E Northside Rd.
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3. **Predicate Device** Nuclear Associates
Model 37-702 and 37-703 PC Rainbow

4. **Device Description**

The TN-RD-50 System comprises a combination of one reader, from one to four bias supplies and from one to twenty dosimeters. The dosimeters are plugged into the bias supply and placed on the patient during irradiation. After the procedure, the bias supply is plugged into the reader and a readout is obtained. The dosimeters are metal oxide semiconductor field effect transistors, or MOSFETs. The active region is a tiny area measuring 0.2X0.2mm at the end of a thin, flexible lead.

5. **Indication for Use**

The device is intended for use during radiation therapy in verifying the occurrence of radiation dose on the skin of a patient. The system is intended for the verification of the output of radiation producing devices.

6. **Comparison with Predicate Device :** Both systems use diffused silicon semiconductor sensors, contained in bolus material, and externally applied to a patient to measure radiation. Any differences in the application of the diffused semiconductor technology between the two devices are not believed to affect the efficacy nor safety in use. It is the opinion of Thomson & Nielsen that the TN-RD-50 is substantially equivalent to the predicate device and does not represent any new potential safety concerns.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2001

Ms. Norma Thomson
Executive Vice President
Thomson/Nielson Electronic Ltd.
25B Northside Rd.
Ottawa, Ontario
CANADA K2H 8S1

Re: K010472
Patient Dose Verification System, Model TN-RD-50
Dated: February 15, 2001
Received: February 20, 2001
Regulatory Class: II
21 CFR §892.5050/Procode: 90 IYE

Dear Ms. Thomson:

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,

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 (s)

510(k) Number (if known): K010472

Device Name: Patient Dose Verification System

Indications For Use:

To provide dosimetry or to detect the dose delivered to a patient during therapeutic radiation procedures. This is a surface device used on the skin of the patient. The system is intended for the verification of the output of radiation producing devices.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010472