4/2/99

Premarket Notification
Nucletron Rotterdam Nasopharynx Mould Set
Date : 18, September 1998

K983337

Nucletron

NUCLETRON B.V.
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Department of Health and Human Services
Center of Device and Radiological Health
Office of Device Evaluation
Pre-Market Notification Section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

a. Submitter of 510(k)

Company name:	Nucletron Corporation
Registration #	1121753
Address:	7080 Columbia Gateway Drive Columbia, MD 21046-2133
Contact Person:	Ralph E. Shuping Regulatory Affairs Manager
Phone:.	410-312-4100
Fax:	410-312-4197

b. Device Name:

Trade/Proprietary Name:	Rotterdam Nasopharynx Mould Set
Common/Usual Name:	Remote Afterloading Intracavitary Nasopharynx Brachytherapy Applicator
Classification Name:	Accessory to remote afterloader 21 CFR 892.5700, Class II.

c. Legally Marketed Predicate Device(s)

Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Standard Nasopharyngeal Applicator Set	K953946

d. Description

The Nucletron Rotterdam Nasopharynx Mould as described in this submission is designed as an accessory to the Nucletron remote afterloading equipment: mHDR, mHDR-Classic and mPDR, for intracavitary nasopharynx brachytherapy procedures.

The Nucletron Rotterdam Nasopharynx Mould Set is inserted into the mouth and positioned within the nasopharynx cavity with the assistance of guidance tubes. Once in position, it is immobilized and treatment catheters are inserted. Radiographic images, planar films or transverse slices, i.e. CT, MR are obtained to determine the precise location of the applicator within the body. This information is then used for brachytherapy treatment planning purposes. When the treatment planning is completed the applicator is then attached to the Nucletron remote afterloading equipment (treatment head): mHDR, mHDR-Classic and mPDR, by the Nucletron transfer tubes. The transfer tubes lock into the open end of the applicator and the remote afterloading equipment (treatment head) prior to treatment. When the applicator is properly attached, a check cable run is performed to ensure that the applicator is properly attached and that there is no obstructions which will interrupt treatment. After the check cable run, the radioactive source will step through the applicator to deliver that prescribed dose of radiation. When the treatment is complete, the applicator is detached from the transfer tube and remote afterloading equipment. The applicator is then removed from the patient.

The applicator is a closed system to prevent the radioactive source from coming in contact with body fluids. The applicator does not control the treatment unit; it strictly provides a treatment path for the radioactive source. The Nucletron remote afterloading system and the clinical staff verify that the applicator is properly attached prior to treatment.

e. Intended use

Nucletron Rotterdam Nasopharynx Mould Set is intended for use with the Nucletron remote afterloading equipment: mHDR, mHDR-Classic and mPDR, for intracavitary nasopharynx brachytherapy procedures. The applicator provides a means of delivering the prescribed radiation dose to the treatment area. The applicator is a closed system to prevent the radioactive source from coming in contact with body fluids.

f. Summary of technological considerations

The Nucletron Rotterdam Nasopharynx Mould Set is substantially equivalent to the predicate device. It combines the functionality, components and design of the predicate device while incorporating a new material.

21-Sept-98

Name: L. A. Johnson
Title Product Manager
Nucletron BV
Veenendaal
Netherlands

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 1999

Ralph E. Shuping, Sc.D.
Regulatory Affairs Manager
Nucletron Corporation
7080 Columbia Gateway Dr.
Columbia, MD 21046

Re: K983337
Nucletron Rotterdam Nasopharynx Mould Set
Dated: January 18, 1999
Received: January 19, 1999
Regulatory class: II
21 CFR 892.5700/Procode: 90 JAQ

Dear Dr. Shuping:

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) 594-4613. 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 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Statement of intended use

Device Name: Rotterdam Nasopharynx Mould Set

Intended use

Nucletron Rotterdam Nasopharynx Mould Set is intended for use with the Nucletron remote afterloading equipment: mHDR, mHDR-Classic and mPDR, for intracavitary nasopharynx brachytherapy procedures. The applicator provides a means of delivering the prescribed radiation dose to the treatment area. The applicator is a closed system to prevent the radioactive source from coming in contact with body fluids.

Prescription use

The Nucletron Rotterdam Nasopharynx Mould Set is intended to be used for medical procedures on patients to be prescribed and performed by a suitably trained and certified medical professional.

21-Sept-98

Name L. A. Johnson
Date
Title Product Manager
Nucletron BV
Veenendaal
Netherlands

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983337