K041715

MAR 1 4 2005

Nucletron

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

As required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	8671 Robert Fulton Drive Columbia, MD 21046
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	Intracavitary Mould Applicator Set
Common/Usual Name:	Remote Afterloading for Intracavitary Brachytherapy applications
Classification Name:	Remote controlled radionuclide applicator system accessory
Classification:	21Cfr892.5700 Class II

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	Miami Vaginal Applicator Set	K953946

Description:

The Nucletron Intracavitary Mould Applicator Set as described in this submission is designed as an accessory to the Nucletron remote afterloading equipment and is intended for Intracavitary Brachytherapy procedures.

The device consists of a disposable silicone cylinder, with eight radial placed catheters to the surface of the cylinder, which is inserted Intracavitary into the target volume, i.e. the rectum. The cylinder is fixated, by using an applicator clamp. Once fixated, the insertion tool and the filling wires are removed, which protected the catheters from kinking during transport. The number tag ring aids in the identification of the afterloader channels. Optional a disposable central catheter can be placed.

X-ray catheters or CT markers are inserted into the applicator for visualisation. Radiographic images, planar films or transverse slices, i.e. CT, MR is obtained to determine the precise location of the applicator within the body. This information is then used for Brachytherapy treatment planning purposes.

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

For the first treatment the Intracavitary Mould Applicator Set is attached to the afterloader (treatment head), using transfer tubes. When the applicator is attached, a check cable run is performed to ensure that the applicator is properly attached and that there are no obstructions, which will interrupt treatment. After the check cable run, the radioactive source will step through the applicator to deliver the prescribed dose of radiation.

After the treatment the Intracavitary Mould Applicator Set is disconnected from the attached transfer tubes. When the course of treatment is completed the Intracavitary Mould Applicator Set is removed from the patient.

The device uses similar (implantable) materials as in the legally marketed predicate device cited the Freiburger Flap. The device uses similar implant techniques respect to the legally marketed predicate device cited the Miami Vaginal Applicator Set.

The Intracavitary Mould Applicator Set is used as an accessory to the Nucletron microSelectron.

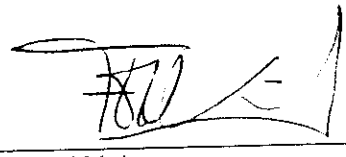
Intended use:

The modified device has the same intended use as the legally marketed predicate device cited:

The Intracavitary Mould Applicator Set is intended for Intracavitary Brachytherapy procedures involving Nucletron remote afterloading equipment.

Summary of technological considerations:

The Intracavitary Mould Applicator Set is substantially equivalent to the cleared predicate device, Miami Vaginal Applicator Set, 510(k)#: K953946.



14-6-2004

Name: Frits van Krieken
Title: Business Segment Manager
Nucletron B.V.
Veenendaal, The Netherlands

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2005

Ms. Lisa Cole Dimmick
Director of Regulatory Affairs
Nucletron Corporation
8671 Robert Fulton Drive
COLUMBIA MD 21046

Re: K041715
Trade/Device Name: Intracavitary Mould Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: March 1, 2005
Received: March 2, 2005

Dear Ms. Dimmick:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

Indications for Use Statement

510(k) Number	K041715
Device Name	Intracavitary Mould Applicator Set
Indications for Use	The Intracavitary Mould Applicator Set is intended for use with Nucletron remote afterloading equipment for intracavitary rectal brachytherapy procedures. The applicator set provides a means of delivering the prescribed radiation dose to the treatment area.

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)

Marvin Boston

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041715