K073107

Nucletron

NUCLETRON B.V.
Waardgelder 1 3905 TH Veenendaal
P.O. Box 930 3900 AX Veenendaal
The Netherlands
Phone +31 318 557133
Fax +31 318 550485

DEC 07 2007

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:	Valencia Skin 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	Leipzig Applicator Set	K953946

7.1 Description of Modified Device

The Valencia Skin Applicator Set as described in this submission is designed as an accessory to the Nucletron remote afterloading equipment, microSelectron and is intended for surface Brachytherapy procedures.

The Valencia Skin Applicator is placed over the treatment area. The applicator is then attached to the afterloader (treatment head), using transfer tubes. 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 afterloader and the clinical staff verify that the applicator is properly

attached prior to the treatment. 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 applicator is disconnected from the attached transfer tubes, and removed from the patient.

The device is the same as the legally marketed predicate device cited. The only change is that the device is equipped with a fixed flattening filter that provides a flat homogeneous isodose pattern. The Valencia Skin 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:

Valencia Skin Applicator Set is intended for surface Brachytherapy procedures involving the Nucletron remote afterloading equipment: mHDR.

Summary of technological considerations:

The Valencia Skin Applicator Set is substantially equivalent to the cleared predicate device, Leipzig Applicator Set, 510(k)#: K953946.

Name: Erik Agterhuis
Title: Manager Product Marketing
Nucletron B.V.
Veenendaal, The Netherlands

25-04-2007
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 07 2007

Ms. Lisa Dimmick
Director Quality Assurance & Regulatory Affairs
Nucletron Corporation
8671 Robert Fulton Drive
Columbia, MD 21046

Re: K073107
Trade/Device Name: Valencia Skin Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Control Radionuclide Applicator System
Regulatory Class: II
Product Code: JAQ
Dated: November 2, 2007
Received: November 5, 2007

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 (PMA), 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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

Device Name Valencia Skin Applicator Set

Indications for Use The Valencia Skin Applicator Set is intended for surface Brachytherapy procedures involving the Nucletron remote afterloading equipment: mHDR.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073107