K092804

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

OCT – 8 2009

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:	Elaina Colby Manager Quality Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	MicroSelectron HDR Version 2
Common/Usual Name:	Afterloader
Classification Name:	Remote controlled radionuclide applicator system
Classification:	21Cfr892.5700 Class II
Product Code	JAQ

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	MicroSelectron HDR Version 2	K953946

Description:

The microSelectron-HDR is a remote afterloading system for high dose rate brachytherapy treatment using a single iridium-192 radioactive source.

The MicroSelectron-HDR delivers a radiation dose distribution conforming to treatment data, which is either, manually entered at the workstation or imported from a treatment planning system.

The modifications to the cleared device k953946 are:

- Increase of maximum source strength for treatment of patients from 10 Ci (aprox. 40.000 µGy.m²/h) to 12Ci (aprox. 48.000 µGy.m²/h).

Intended use:

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

The MicroSelectron HDR Version 2 is intended to enable an operator to apply, by remote control, a radionuclide source into the body (including Interstitial, Intracavitary, Intraluminal, Bronchial, Endovascular and Intra-operative) or to the surface of the body for radiation therapy.

Summary of technological considerations:

MicroSelectron HDR Version 2 is substantially equivalent to the previously cleared device (K953946) and to the microSelectron V3 (K061354).

Name: John Lapre
Title: Vice President R&D
Nucletron B.V.
Veenendaal, The Netherlands

Aug 28, 2009
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Elaina M. Colby
Manager, Quality Assurance & Regulatory Affairs
Nucletron Corporation
8671 Robert Fulton Drive
COLUMBIA MD 21046-2133

OCT – 8 2009

Re: K092804
Trade/Device Name: MicroSelectron HDR Version 2
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radio-nuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: September 10, 2009
Received: September 11, 2009

Dear Ms. Colby:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting 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	K092804
Device Name	MicroSelectron HDR Version 2
Indications for Use	The MicroSelectron HDR Version 2 is intended to enable an operator to apply, by remote control, a radionuclide source into the body (including Interstitial, Intracavitary, Intraluminal, Bronchial, Endovascular and Intra-operative) or to the surface of the body for radiation therapy.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092804