MAY 23 2002

K021286
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Nucletron

NUCLETRON B.V.
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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:	7080 Columbia Gateway Drive Columbia, MD 21046-2133
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	microSelectron®HDR - GENIE Afterloading System
Common/Usual Name:	Remote Controlled Afterloading System
Classification Name:	Radiotherapy Device
Classification:	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	K953946 microSelectron-HDR V2	K953946

K021286

Description:

The entry-level microSelectron®HDR - GENIE Afterloading System concerns a microSelectron-HDR (V2) with only three treatment channels. The operators console of the microSelectron®HDR - GENIE Afterloading System concerns a PC running dedicated Treatment Console Software which is similar as in the predicate device microSelectron-HDR (V2). In the microSelectron®HDR - GENIE Afterloading System there is on the operators console a second completely independent software program for radiotherapy treatment planning. Treatment plans are transferred from the radiotherapy treatment planning software to the Treatment Console Software by file transfer. It is the same as in the predicate device where treatment plans are transferred to the Treatment Console Software from radiotherapy treatment planning software running on a separate computer.
The radiotherapy treatment planning software is covered by a separate 510(k) submission.

Applicators and Transfer Tubes as available for microSelectron-HDR (V2) are also applicable for the microSelectron®HDR - GENIE Afterloading System.

The entry-level microSelectron®HDR - GENIE Afterloading System is a standalone device. Connection to a LAN is only for the purpose of File Transfer of Treatment Plan Files.

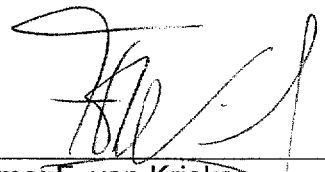
Intended use:

The Nucletron microSelectron®HDR - GENIE Afterloading System has the same intended use as the legally marketed predicate device cited:

This device is intended to enable an operator to apply, by remote control, a radionuclide source into the body or to the surface of the body for radiation therapy.

Summary of technological considerations:

The Nucletron microSelectron®HDR - GENIE Afterloading System is substantially equivalent to the cleared predicate device, microSelectron-HDR V2, 510(k)#: K953946.



10 APRIL 2002

Name: F. 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

MAY 23 2002

Ms. Lisa Dimmick
Director Quality Assurance
and Regulatory Affairs
Nucletron Corporation
7080 Columbia Gateway Drive
COLUMBIA MD 21046-2133

Re: K021286
Trade/Device Name: MicroSelectron® HDR - GENIE Afterloading System
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: 90 JAQ
Dated: April 10, 2002
Received: April 23, 2002

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 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/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

510(k) NUMBER (IF KNOWN): K021286

DEVICE NAME: MICROSELECTRON HDR-GENIE AFTERLOADING SYSTEM

INDICATIONS FOR USE:

The Nucletron microSelectron HDR - GENIE Afterloading System has the same intended use as the legally marketed predicate device cited.

This device is intended to enable an operator to apply, by remote control, a radionuclide source into the body or to the surface of the body for radiation therapy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K021286