4/2/99

Premarket Notification
Nucletron microSelectron-HDR classic with TCS
Date : 31 August, 1998

K983115

Nucletron

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

PKG MKT mHDR 510k

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: Treatment Control Station - microSelectron-HDR classic Upgrade, Remote Afterloading System

Classification Name: Remote Control Radionuclide Applicator System
21 CFR 892.5700 Class II.

c. Legally Marketed Predicate Device(s)

Our Device is substantially equivalent to the legally marketed predicate devices cited in the table below.

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Manufacturer	Device	510(k) #
Nucletron	microSelectron-HDR classic	K864210
Nucletron	microSelectron-HDR	K953946

d. Description

The Treatment Control Station (TCS) described in this submission is a software and hardware package which replaces the current Treatment Control Unit (TCU) for the microSelectron-HDR classic.

The TCS is windows based software and runs on a PC based computer system. TCS will allow the user to program a treatment and monitor a treatment in progress. TCS will come together with a Treatment Control Panel, which takes care of the secondary timing and providing hardware independent "Start", "Interrupt" button and source location indicators.

The TCS user obtains authorization for parts of the functionality depending on the user name and password.

Treatment data can either be entered manually, based on a standard plan, based on a previously fraction or imported from the Nucletron Treatment Planning System (PLATO).

Prior and after treatment completion an extensive report is generated providing full details of how the patient will be and is treated.

A detailed description including principles of operation and other information necessary to understand the device is provided in Section 3.

e. Intended use

The indications for use for the Treatment Control Station - microSelectron-HDR classic Upgrade are:

Remote Afterloading Brachytherapy Unit for interstitial, intracavitary, intraluminal, including bronchial, endovascular (PARIS IDE), intraoperative and surface applicator treatments.

f. Summary of technological considerations

The Treatment Control Station - microSelectron-HDR classic Upgrade is substantially equivalent to the predicate devices. It allows the use of an enhanced user interface to program a treatment and monitor a treatment in progress.

31-08-98

Name: P.Krechting Date

Title Product Manager

Nucletron bv

Veenendaal

Netherlands

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 Manger
Nucletron Corporation
7080 Columbia Gateway Drive
Columbia, Maryland 21046

Re: K983115
Treatment Control Station (TCS)
MicroSelectron HDR Classic Upgrade
Dated: January 14, 1999
Received: January 19, 1999
Regulatory Class: II
21 CFR 892.5700/Procode: 90 JAQ

Dear Dr. Schuping:

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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PKG MKT mHDR 510k

Statement of intended use

Device Name: Treatment Control Station - microSelectron-HDR classic Upgrade, remote afterloading system

Intended use

The indications for use for the Treatment Control Station - microSelectron-HDR classic Upgrade are:

Remote Afterloading Brachytherapy Unit for interstitial, intracavitary, intraluminal, including bronchial, endovascular (PARIS IDE), intraoperative and surface applicator treatments.

Prescription use

The Treatment Control Station - microSelectron-HDR classic Upgrade is intended to be used for medical procedures on patients to be prescribed and performed by a suitably trained and certified medical professional.

31-08-98

Name P. Krechting Date
Title Product Manager
Nucletron BV
Veenendaal
Netherlands

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983115