4/2/99

Premarket Notification
Nucletron PLATO Brachytherapy
Date : 20 September 1998

CONFIDENTIAL

K983343

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

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:	PLATO Brachytherapy (BPS v. 14.0)
Common/Usual Name:	PLATO Brachytherapy planning system
Classification Name:	Accessory to remote afterloader 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.

Manufacturer	Device	510(k) #
Nucletron BV	PLATO Brachytherapy Planning System	K915562
Nucletron BV	Nucletron Planning System	K911612

d. Description

PLATO Brachytherapy as described in this submission is a software package designed for treatment planning of brachytherapy procedures. This software runs on a PLATO radiation therapy treatment planning system workstation

Nucletron PLATO Brachytherapy software is capable of reconstructing the brachytherapy implant (i.e. radiographs, transverse slices, or 3D coordinates), defining the location of the radioactive sources within the implant, identifying a reference point, i.e. dose points, anatomical points. Once this data is entered the prescription dose is defined and the software program calculates treatment data, including dose distributions and treatment/implantation time.

The brachytherapy treatment planning session allows the physician to evaluate the implant prior to insertion of the radioactive sources in order to determine the most optimal dose distribution within the treatment volume. Once the physician approves the treatment plan the implant is loaded with radioactive sources manually or via the Nucletron remote afterloading equipment. The PLATO Brachytherapy software exports the treatment data to the Nucletron remote afterloading system via a floppy, program card or network. The PLATO Brachytherapy software does not control the treatment unit; it strictly exports treatment times and related information. The Nucletron remote afterloading system and the clinical staff verify this data input prior to treatment.

Nucletrons' PLATO Brachytherapy software includes remote afterloading radioactive source brachytherapy treatment planning and manual loaded radioactive source brachytherapy treatment planning. The program provides a variety of plan evaluation tools to assist in generating the most optimal dose distribution, i.e. dose volume histograms, dose verification points, dose profiles, etc.

e. Intended use

Brachytherapy planning with PLATO Brachytherapy is intended for use with brachytherapy procedures involving manual or remote afterloading radioactive sources. The software program provides the physician with anatomical and dosimetric information to determine the positioning and loading of the radioactive sources prior to insertion. The software also provides the treatment time and dose distribution for the specified loading. From this information the patient can be treated with radioactive sources.

With remote afterloading brachytherapy treatment planning the PLATO Brachytherapy program exports the treatment data, i.e. treatment times to the remote afterloader. With manual brachytherapy treatment planning the program exports treatment data regarding insertion/removal time, total dose in permanent implantation and dose distributions for patient records. With both types of software the dose grid is exported and can be evaluated in conjunction with the Nucletron PLATO External Beam treatment planning software.

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f. Summary of technological considerations

The PLATO Brachytherapy software is substantially equivalent to the predicate devices. It combines the functionality of the defined predicate devices into one user interface for brachytherapy treatment planning.

18-Sept-98

Name: L. A. Johnson
Title Product Manager
Nucletron BV
Veenendaal
Netherlands

Date

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 Manager
Nucletron Corporation
7080 Columbia Gateway Drive
Columbia, MD 21046-2133

Re: K983343
PLATO Brachytherapy (BPS v14.0)
Dated: January 7, 1999
Received: January 11, 1999
Regulatory class: II
21 CFR 892.5700/Procode: 90 MUJ

Dear Dr. Shuping:

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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Statement of intended use

Device Name: PLATO Brachytherapy

Intended use

Brachytherapy planning with PLATO Brachytherapy is intended for use with brachytherapy procedures, i.e. intercavitary, interstitial, intraluminal (including bronchial) and surface applicator treatments, involving manual or remote afterloading radioactive sources. The software program provides the physician with anatomical and dosimetric information (i.e. radiographs, transverse slices, or 3D coordinates) to determine the positioning and loading of the radioactive sources prior to insertion. The software also provides the treatment time and dose distribution for the specified loading. From this information the patient can be treated with radioactive sources.

With remote afterloading brachytherapy treatment planning the PLATO Brachytherapy program exports the treatment data, i.e. treatment times to the remote afterloader. With manual brachytherapy treatment planning the program exports treatment data regarding insertion/removal time, total dose in permanent implantation and dose distributions for patient records. With both types of software the dose grid is exported and can be evaluated in conjunction with the Nucletron PLATO External Beam treatment planning software.

Prescription use

The PLATO Brachytherapy (BPS v.14.0) is intended to be used for medical procedures on patients to be prescribed and performed by a suitably trained and certified medical professional.

Name L. A. Johnson
Title Product Manager
Nucletron BV
Veenendaal
Netherlands

18-Sept.-98
Date

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983343

Prescription Use ✓
(Per 21 CFR 801.109)