

Premarket Notification

**Nucletron Sonographic Planning of Oncology Treatments (SPOT)**

Date: July 1, 1999

K992303

**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

## 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: Sonographic Planning of Oncology Treatments (SPOT)  
 Common/Usual Name: 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
LIS, Inc	LIS 6000A	K961403

**d. Description**

Sonographic Planning of Oncology Treatments (SPOT) as described in this submission is a software package which utilizes the acquisition of 2D ultrasound images and 3D reconstruction of the ultrasound images for treatment planning of brachytherapy procedures. This software runs on a Windows NT workstation.

Nucletron Sonographic Planning of Oncology Treatments (SPOT) software initially acquires 2D ultrasound images and generates 3D ultrasound image processing for definition of the treatment volume. These images are utilized for reconstructing the target volume of the brachytherapy implant, needles placement, defining the location of the radioactive sources within the implant, identifying a reference point, i.e. dose points, anatomical points. Once the treatment volume is identified and the implant is reconstructed 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 Sonographic Planning of Oncology Treatments (SPOT) software can export the treatment data to the Nucletron remote afterloading system and the PLATO Brachytherapy Planning System via a network. The Sonographic Planning of Oncology Treatments (SPOT) 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.

Nucletron' Sonographic Planning of Oncology Treatments (SPOT) 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, utilizing a 3D ultrasound imaging cube, with Sonographic Planning of Oncology Treatments (SPOT) is intended for use with brachytherapy procedures, i.e. intercavitary, interstitial, intraluminal, 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.

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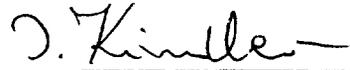
**Nucletron Sonographic Planning of Oncology Treatments (SPOT)**

**Date: July 1, 1999**

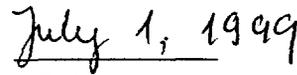
With remote afterloading brachytherapy treatment planning the Sonographic Planning of Oncology Treatments (SPOT) program exports the treatment data, i.e. treatment times to the remote afterloader. With manual brachytherapy treatment planning the program exports treatment data regarding, source loading, 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 treatment planning software modules.

**f. Summary of technological considerations**

The Sonographic Planning of Oncology Treatments (SPOT) 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.



\_\_\_\_\_  
Name J. Kindlein  
Title Product Manager  
Nucletron BV  
Veenendaal  
The Netherlands



\_\_\_\_\_  
Date



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 27 2000

Ralph Shuping, Sc.D.  
Regulatory Affairs Manager  
Nucletron Corporation  
7080 Columbia Gateway Drive  
Columbia, MD 21046

Re: K992303  
Sonographic Planning or Oncology Treatments (SPOT)  
Dated: January 18, 2000  
Received: January 18, 2000  
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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.  
Captain, USPHS  
Director, Division of Reproductive,  
Abdominal, and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure(s)

**Statement of indications for use**

510(k) Number (if known): \_\_\_\_\_

Device Name: Sonographic Planning of Oncology Treatments (SPOT)

**Indications for Use:**

Brachytherapy planning, utilizing 3D Ultrasound Imaging, Sonographic Planning of Oncology Treatments (SPOT) is intended for use with Brachytherapy procedures, i.e. intercavitary, interstitial, intraluminal, 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. From this information the patient can be treated with radioactive sources.

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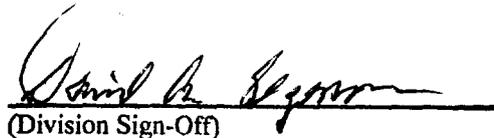
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over the Counter Use \_\_\_\_\_

(Optional Format 1-2-96)



(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K992303