



# Nucletron

MAY 6 1998

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

K980629

TBN MKT VSS 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: VSS, Virtual Simulation System  
Common/Usual Name: Radiation therapy virtual simulation system  
Classification Name: Radiation Therapy Simulation System,  
21 CFR 892.5840 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) # |
|----------------------|---------------|----------|
| Picker International | ACQSIM        | K923851  |
| GE Medical Systems   | Advantage Sim | K951830  |
| Nucletron            | PLATO         | K964206  |

**d. Description**

VSS virtual simulation described in this submission is a software package for the virtual simulation of radiation therapy plans. VSS is installed and runs on a PLATO radiation therapy treatment planning system workstation.

Nucletron's VSS provides the virtual simulation capabilities required to define anatomical volumes and geometric treatment beams for radiation therapy treatment simulation. The 3D patient model is based on CT images and is displayed in single or multiple image windows. Treatment beams are simulated using surface rendering and digitally reconstructed radiographs.

The system uses CT images either from a DICOM 3 compatible scanner or from the PLATO treatment planning system patient database. Previously defined anatomical structures and beams can be read from the PLATO patient database. All anatomical structures and beams can be stored in the PLATO patient database or sent to a DICOM RT compatible system.

When connected to a Nucletron Simulix radiation therapy simulator, VSS allows the planned beam parameters to be downloaded directly to the Simulix simulator for automatic set-up. The user can initiate the real-time transfer of actual simulator position to update the field parameters on VSS. VSS can be used to display the live image intensifier image, viewed on the same screen as the beam's eye view and planar image(s). A direct comparison of the CT-based treatment plan with the actual set-up on the Simulix, prior to patient treatment, can be made to verify the geometric beam parameters and set-up conditions.

**e. Intended use**

Virtual simulation with VSS is intended to be used to prepare geometric and anatomical data relating to a proposed radiation therapy treatment prior to dosimetry planning on a treatment planning system. Complex 3D volumes and field geometries can be visualised for plan preparation.

When connected to a Nucletron Simulix radiation therapy simulator, the simulation of the planned treatment fields can be aided by automated set-up on the Simulix simulator. Adjustments made on the Simulix can be reviewed on the virtual simulation system screen. A direct comparison of the CT-based treatment plan with the actual set-up on the Simulix, prior to patient treatment, can be made to verify the geometric beam parameters and set-up conditions.

**f. Summary of technological considerations**

The VSS is substantially equivalent to the predicate devices. It allows the use of CT images for the definition of anatomical volumes and the simulation of radiation treatment beams.

T.J. Bateman

11 Feb. 1998

Name: T.J. Bateman

Date

Title Product Manager

Nucletron bv

Veenendaal

Netherlands



MAY 6 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Ralph E. Shuping, Sc.D.  
Regulatory Affairs Manager  
Nucletron Corporation  
7080 Columbia Gateway Drive  
Columbia, MD 21046-2133Re: K980629  
VSS Virtual Simulation System  
Dated: February 17, 1998  
Received: February 18, 1998  
Regulatory class: II  
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Shuping:

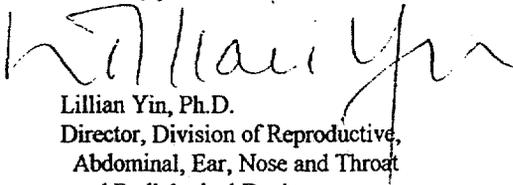
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Statement of indications for use

510(k) Number (if known): K980629

Device Name: VSS Virtual Simulation System

Indications for Use: Virtual simulation with VSS is intended to be used to prepare geometric and anatomical data relating to a proposed radiation therapy treatment prior to dosimetry planning on a treatment planning system. Complex 3D volumes and field geometries can be visualised for plan preparation.

When connected to a Nucletron Simulix radiation therapy simulator, the simulation of the planned treatment fields can be aided by automated set-up on the Simulix simulator. Adjustments made on the Simulix can be reviewed on the virtual simulation system screen. A direct comparison of the CT-based treatment plan with the actual set-up on the Simulix, prior to patient treatment, can be made to verify the geometric beam parameters and set-up conditions.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  OR Over the Counter Use   
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David C. Seymour  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K980629