

K964206

JUN 20 1997

**SUMMARY OF 510(K)
SAFETY AND EFFECTIVENESS DATA
PLATO 3D Radiation Therapy Planning System, External Beam Planning RTS V2
and RTS 3D V2**

October 17, 1996

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PLATO External Beam Planning RTS V2 and RTS 3D V2

Trade/Proprietary Name: RTS-2 3-D Radiation Treatment Planning System

Common Name: 3-D Radiation Therapy Planning System

Classification Name: Medical Charged Particle Radiation Therapy System
21 CFR 892.5050 (Class II)

Substantial Equivalence: Nucletron PLATO Radiation Therapy Planning System
510(k) K 921991

ADAC Pinnacle 3 APEX
510(k) K 951581

Siemens Treatment Management System (TMS)
510(k) K 953391

Device Description:

The PLATO 3-D Treatment Planning System described in this submission is a computer-based external beam and brachytherapy treatment planning system for clinical radiation therapy applications.

Based on an individual patient's anatomical information obtained from radiographs, CT or MRI scans, a treatment setup or source configuration, including insertion times for brachytherapy, is defined and the resultant dose distribution is calculated. These calculations rely on physical algorithms describing the radiation transport process which finally leads to dose deposition inside a patient's anatomy.

Treatment set-up, or source parameters, are changed until the corresponding dose distribution are clinically acceptable. The operator performing the treatment planning forms part of the PLATO Radiation Treatment Planning System. The prescribed treatment is then administered to the patient, utilizing medical linear accelerators, cobalt units, afterloaders, or manual techniques.

The PLATO 3-D Treatment Planning System is modular in structure and consists of the following main features which are depicted in the attached system overview diagram.

RTS - A module for External Beam planning

EVAL 2.0 - An evaluation module for combination of external and brachytherapy planning using evaluation tools;

IPS-CT - Imports images from CT, MRI, radiographs and outlining features;

MLC - Multileaf Collimator

Device Intended Use:

As indicated above, the PLATO 3-D Treatment Planning System is used to prepare individual treatment plans for cancer patients undergoing therapeutic radiation treatment. The system can be applied for external photon and electron therapy.

PLATO External Beam Planning RTS V2 and RTS 3D V2 has equivalent intended uses as its predecessor PLATO RTS V1. This device is used for external beam radiation therapy treatment planning for localization and treatment planning of malignant and benign lesions of patients.

Treatment of cancer may require use of external radiation beams from an external source, Teletherapy unit coordinates of beam placement including gantry angle, field size, and shape along with accurately calculated predicted dose computation, are necessary in present day planning for radiotherapy. The ability to calculate both coplanar and noncoplanar beams to a highly accurate level is desirable by the industry. PLATO RTS V 2 allows for the accuracy and speed to clinically facilitate this need. The recent use of linear accelerator Multileaf Collimators for field shaping is desired and supported by RTS V2.

Safety and Effectiveness

The PLATO Treatment Planning System is manufactured by Nucletron B.V. in The Netherlands that is officially registered as an ISO 9001 manufacturer. Accordingly, the system described herein will be manufactured in accordance with the ISO 9001 requirements, GMP regulations, and other applicable European standards.

The operator is provided with a comprehensive User's Manual, accompanied by an Instruction Manual, which provides the operator with a detailed tutorial. Nucletron employs a knowledgeable staff of clinical application specialists to complement the written documentation provided to the user. Such assistance is available during initial start-up and at other times when requested by the user. On-going training programs and seminars for users are conducted by Nucletron on a continual basis.

Nucletron's prior experience with treatment planning systems provides an extensive background in such devices and ensures that all systems are safe and effective as represented.

Software is designed in accordance with prescribed specifications, and detailed test plans ensure software integrity through definitive verification and validation procedures. A concept of "user-friendliness", safe, and effective operation is a top priority in all design and manufacturing efforts by Nucletron.

Conclusion:

The FDA 510K certification pre-market notification for the RTS 2 product contains adequate information and data to enable the determination of substantial equivalence with the documentation summarized in this submission.

- Nucletron's RTS 2 is subject to internal performance standards as defined by product design specifications.
- The RTS 2 external beam planning software will be developed and ongoing monitored to adhere to standards specified by Nucletron, Good Manufacturing Practices and ISO 9001 requirements.
- The information for users contains comprehensive instructions and documentation to ensure safe and effective use.
- Product Specifications and performance levels are substantially equivalent to other products currently cleared by FDA for marketing in the U.S. Function and Dose calculation parameters have been tested and will be retested before actual product release.
- Close evaluation of other equivalent predicate devices demonstrates that RTS 2 is safe and effective for marketing.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 20 1997

Randolph Hemingway
Nucletron Corporation
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Columbia, MD 21046

Re: K964206
Plato RTS-2 3D Radiation Therapy Treatment
Planning System
Dated: March 30, 1997
Received: March 30, 1997
Regulatory class: II
21 CFR 892.5050/Procode: 90 IYE

Dear Mr. Hemingway:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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/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

510(k) Number (if known): K964206

Device Name: PLATO External Beam Planning System RTS V2 & RTS 3D V2

Indications For Use;

PLATO 3-D Treatment Planning System is used to prepare individual treatment plans for cancer patients undergoing therapeutic radiation treatment. The system is utilized to develop plans for external photon and electron therapy.

PLATO External Beam Planning RTS V2 and RTS 3D V2 has intended uses equivalent to its predecessor PLATO RTS V1. This device is used for external beam radiation therapy treatment planning for localization and treatment planning of malignant and benign lesions of patients.

Treatment of cancer may require use of external radiation beams from an external source. Teletherapy unit coordinates of beam placement including gantry angle, field size, and shape along with accurately calculated predicted dose computation, are necessary in present day planning for radiotherapy. The ability to calculate both coplanar and noncoplanar beams to a highly accurate level is desirable by the industry. PLATO RTS V 2 allows for accuracy and speed to clinically facilitate this need. The recent use of linear accelerator Multileaf Collimators for field shaping is desired and supported by RTS V2.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

William A. Segrom
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K964206

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use