K992434

JAN 13 2000

Nucletron

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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 ITP
Common/Usual Name:	Radiation therapy treatment planning system
Classification Name:	Radiation Therapy Simulation System, accessory to.

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) #
NOMOS Corp.	Peacock Plan	K940663
General Electric	Target Series 2	K841997
Nucletron	PLATO RTS	K964206

K992434

d. Description

PLATO ITP as described in this submission is a software package which is used to optimize multi-leaf collimator (MLC) positions or partial attenuation block shapes for intensity modulated external beam radiation therapy (IMRT). ITP is installed and runs on a PLATO radiation therapy planning system workstation.

Nucletron's PLATO ITP software uses previously defined anatomical structures and beams from the PLATO database to construct a 3D patient model used in the optimization process. The 3D patient model is based on CT images and is displayed in single or multiple image windows. The software also uses the treatment machine beam data from the PLATO radiation therapy planning system database.

The user defines the desired dose to be delivered to the target and the maximum dose to be delivered to the surrounding structures. Priority values are entered to weight the optimization calculations according to the importance of reaching the dose objectives for the target and other structures. After the user starts the optimization, the software calculates the required MLC or partial attenuation block shapes needed to achieve the dose objectives. This is done for each beam simultaneously and the resulting dose distribution and DVH are displayed in real-time. Once the optimization is complete, the dose distribution and DVH curves are displayed for the user to evaluate. If the user is not satisfied with the results of the optimization, the input parameters can be modified (dose constraints and priority values) and the optimization repeated.

The optimized plan can be saved for final dose calculation using PLATO RTS. Plans that have not been recalculated using PLATO radiation therapy planning system cannot be used for patient treatment. After final dose calculation, the resulting treatment plan can be exported to a DICOM RT Plan compatible system for treatment delivery.

e. Intended use

PLATO ITP is intended to optimize multi-leaf collimator (MLC) positions or partial attenuation block shapes for intensity modulated external beam radiation therapy (IMRT) prior to final dosimetry planning on PLATO RTS external beam planning.

Once the optimization is complete, the dose distribution and dose-volume histogram curves are displayed for the user to evaluate. The optimized plan can be saved for final dose calculation and plan output using PLATO RTS.

f. Summary of technological considerations

The PLATO ITP software is substantially equivalent to the predicate devices. It allows optimization of beam intensity for muli-leaf collimators and partial attenuation blocks.

T.J. Bateman

Name: T. J. Bateman
Title: Product Manager
Nucletron BV
Veenendaal, The Netherlands

7/7/99
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 17 2000

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

Re: K992434
PLATO ITP (Inverse Treatment Planning)
Regulatory Class: II /21 CFR 82.5700
Product Code: 90 MUJ
Dated: October 14, 1999
Received: October 15, 1999

Dear Dr. Shuping:

This letter corrects our substantially equivalent letter of January 13, 2000 regarding the PLATO ITB (Inverse Treatment Planning).

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 Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 continue 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

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Statement of intended use

Device Name: PLATO ITP

Intended use

PLATO ITP is intended to optimize multi-leaf collimator (MLC) positions or partial attenuation block shapes for intensity modulated external beam radiation therapy (IMRT) prior to final dosimetry planning on PLATO RTS external beam planning.

Once the optimization is complete, the dose distribution and dose-volume histogram curves are displayed for the user to evaluate. The optimized plan can be saved for final dose calculation and plan output using PLATO RTS.

Prescription use

The PLATO ITP is intended to be used for medical procedures on patients to be prescribed and performed by a suitably trained and certified medical professional.

T.J. Bateman — 7/7/99

Name: T. J. Bateman
Title: Product Manager
Nucletron BV
Veenendaal, The Netherlands

Date

David C. Dejoy
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991434

Prescription Use ✓
(Per 21 CFR 801.109)

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