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Nucletron

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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Special 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 807.92(c)

Submitter of 510(k):

Company name:	Nucletron Corporation
Registration number:	1121753
Address:	7080 Columbia Gateway Drive Columbia, MD 21046-2133
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	OTP 1.2
Common/Usual Name:	Radiation Therapy Planning System
Classification Name:	Accessory to Radiotherapy Device
Classification:	21Cfr892.5050 Class II

Legally Marketed Device(s)
Our device is substantially equivalent to the legally marketed predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	TheraPlan Plus	K970236

Description:

The Oncentra Treatment Planning (OTP 1.2) system is radiation treatment planning software designed to analyze and plan radiation treatments in three dimensions for the purpose of treating patients with cancer. The treatment plans provide estimates of dose distributions expected during the proposed treatment, and may be used to administer treatments after review and approval by qualified medical personnel.

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OTP 1.2 is uses externally acquired medical images and user input. The OTP software is based on a modular client/server design, with the treatment planning functions divided into "Activities".

OTP 1.2 contains the following Activities:

- Anatomy Module:
  - Structure Definition
  - Target Definition
  - Image Registration
- Beam Module
- Connectivity Module:
  - DICOM Import / Export
- Dose Module
- Evaluation Module:
  - Plan Evaluation
  - Volume Rendering

In addition, various system utilities are available.

The software runs on a Windows XP platform.

Intended use:

The modified device has the same intended use as the legally marketed predicate device cited:

OTP is radiation treatment planning software designed to analyze and plan radiation treatments in three dimensions for the purpose of treating patients with cancer.

Summary of technological considerations:

OTP is substantially equivalent to the cleared predicate device, TheraPlan Plus, 510(k)#: K970236.

T J. Bt

April 15, 2003

Name: Tim Bateman
Title: Business Segment Manager
Nucletron B.V.
Veenendaal, The Netherlands

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2003

Ms. Lisa Cole Dimmick
Director of Regulatory Affairs
Nucletron Corporation
8671 Robert Fulton Drive
COLUMBIA MD 21046

Re: K031349
Trade/Device Name: OTP 1.2
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charge-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: July 14, 2003
Received: July 16, 2003

Dear Ms. Dimmick:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number K031349

Device Name OTP 1.2

Indications for Use OTP is radiation treatment planning software designed to analyze and plan radiation treatments in three dimensions for the purpose of treating patients with cancer.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

David R. Segars

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031349