K081281 pg. 1 of 3

Nucletron

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

MAY 20 2008

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
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Phone:	410-312-4100
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Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

Modified Device Name:

Trade/Proprietary Name:	Oncentra MasterPlan 3.1
Common/Usual Name:	Radiation Therapy Planning System
Classification Name:	System,Planning,Radiation Therapy Treatment
Classification:	21Cfr892.5050 Class II

Legally Marketed Device(s)

Our modified device is based on the legally marketed device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	OTP 1.2	K031349
Nucletron B.V	PLATO Brachytherapy 14.0	K983343

Description

The Oncentra MasterPlan 3.1 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.

Oncentra MasterPlan 3.1uses externally acquired medical images and user input. The Oncentra MasterPlan 3.1software is based on a modular client/server design, with the treatment planning functions divided into "Activities".

Oncentra MasterPlan 3.1 contains the following Activities:

- **Anatomy Module:**
  The Anatomy Modeling (AM) module is an advanced contouring package for defining structures (ROIs) related to the patient anatomy and target volumes for treatment planning. The AM allows the user to create and edit image registration between image series so that image fusion tools can be utilized.
- **Beam Module**
  The Beam Modelling (BM) module handles specification of the beam shapes and other manipulation of the treatment plan.
- **Connectivity Module:**
  The Connectivity Module (CM) module handles all forms of DICOM data input to the Oncentra Brachy system from external sources, and data output from the system to external sources.
- **Dose Module**
  The Dose Modelling (DM) module handles execution of External Beam dose calculations.
- **Optimizer Module**
  The Oncentra Optimizer (OM) module handles execution of treatment plan optimization. This activity will result in an optimized treatment plan for which the final dose calculation must be performed by DM.
- **Brachy Planning Module**
  The Brachy Planning (BP) module handles execution of Brachytherapy dose calculations.
- **Evaluation Module:**
  The Evaluation Module (EM) handles the necessary tools for evaluating one treatment plan that has a calculated Dose result. EM supports the same tools as BM but in a read-only mode. Tools that are not read-only like new/delete beams, field shaping, edit MLC, apply/remove wedges, etc. are not supported in EM.
- **Evaluator Module**
  The Oncentra Evaluator (EVAL) handles the necessary tools for evaluating and comparing multiple treatment plans and dose summation of two or more plans for a selected case. The user may also select a candidate plan and approve the plan for treatment. The EVAL is a read-only activity with the exception of the plan approval function.
- **Volume Rendering**
  The Volume Rendering (VR) module handles visualization of plans and their corresponding dose in 3D. No plan related data is modified in this module.

In addition, various system utilities are available.

The software runs on a Windows XP platform.

Intended use:

The Oncentra MasterPlan system is a 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.

Summary of technological considerations:

Oncentra MasterPlan 3.1 is substantially equivalent to the cleared predicate devices:

Manufacturer	Device	510(k) #
Nucletron BV	OTP 1.2	K031349
Nucletron B.V	PLATO Brachytherapy 14.0	K983343

Name: Paul van den Biggelaar
Title: Director Oncentra
Nucletron B.V.
Veenendaal, The Netherlands

February 26 2008
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nucletron Corporation
% Mr. Jay Yoriyuki Kogoma
Senior Staff Engineer
Intertek Testing Services NA, Inc.
2307 East Aurora Rd., Unit B7
TWINSBURG OH 44087

MAY 20 2008

Re: K081281
Trade/Device Name: Oncentra MasterPlan 3.1
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: May 5, 2008
Received: May 6, 2008

Dear Mr. Kogoma:

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 such 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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	K081281
Device Name	Oncentra MasterPlan 3.1
Indications for Use	The Oncentra MasterPlan system is a 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.

Prescription Use ___X___ (Part 21 CFR 801 subpart D) AND/OR Over-The-Counter Use_____ (Part 21 CFR 801 subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081281