K082642

NUCLETRON B.V.
Waardgelder 1 3905 TH Veenendaal
P.O.Box 930 3900 AX Veenendaal
The Netherlands
Phone +31 318 557133
Fax +31 318 550485

NOV - 7 2008

Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 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:	8671 Robert Fulton Drive Columbia, MD 21046
Phone:	410-312-4100
Fax:	410-312-4197
Correspondent:	Lisa Dimmick Director Assurance & Regulatory Affairs

New Device Name:

Trade/Proprietary Name:	Oncentra RT Viewer 1.0.
Common/Usual Name:	Radiation Therapy Viewer
Classification Name:	System, Planning, Radiation Therapy Treatment
Classification:	21Cfr892.5050 Class II

Legally Marketed Device(s)
Our new device is based on the legally marketed device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron BV	MasterPlan 3.1	K081281

Description:
RT Viewer provides tools for analysis of single and summed plans, and for comparison of several alternative plans. All image series and all RT objects (Structure Set, Plans, RT Images and Dose) in the study can be displayed and explored.

RT Viewer is principally a read-only activity and produces no new data or modifications to the data for the study and the plan(s).

Single Plan Evaluation
- Display of plan dose in original, reconstructed planar and 3D images.
- Display of dose as a sequence of objects.
- Inspection and comparison of individual objects for a plan in a study.
- Display of DVH in individual and total mode to view contributions from total plan or individual beams.
- Display of DVH statistics.

Plan Comparison
- Side-by-side display of a plan for selected plans in a study, shown as a sequence of objects.
- Comparison of DVH and dose statistics for plans in a study.

Plan Summation
- Summation of dose distributions for plans and display of summed dose.
- Display of DVH in individual and total mode to view contributions from summed or individual plans.

The software runs on a Windows XP or VISTA platform.

Intended use:
The Oncentra RT Viewer is intended to be used for review and evaluation of DICOM based patient data by qualified specialists. It is used to load and display data generated by different DICOM modalities including, but not limited to: RT Image, RT Structure Set, RT Plan, RT Dose, CT, CR, MR, and PET.
It provides the user with a wide range of tools to compile, compare, and manipulate views and images. It enables super-positioning of geometrically related DICOM data.

Summary of technological considerations:
Oncentra RT Viewer 1.0 is substantially equivalent to the cleared predicate device.
The cleared predicate device, Oncentra MasterPlan 3.1, has a wide intended use than the new device Oncentra RT Viewer 1.0 which is merely a viewer.

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

2008-07-08
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 7 2008

Nucletron Corporation
% Mr. Daniel W. Lehtonen
Senior Staff Engineer – Medical Devices
Intertek Testing Services
2307 E. Aurora Rd., Unit B7
TWINSBURG OH 44087

Re: K082642
Trade/Device Name: Oncentra RT Viewer 1.0.
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: October 27, 2008
Received: October 28, 2008

Dear Mr. Lehtonen:

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 Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(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 Biometrics' (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,

Joyce M. Whang, Ph.D.
Acting 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 K082642

Device Name Oncentra RT Viewer 1.0.

Indications for Use

The Oncentra RT Viewer is intended to be used for review and evaluation of DICOM based patient data by qualified specialists. It is used to load and display data generated by different DICOM modalities including, but not limited to: RT Image, RT Structure Set, RT Plan, RT Dose, CT, CR, MR, and PET.

It provides the user with a wide range of tools to compile, compare, and manipulate views and images. It enables super-positioning of geometrically related DICOM data.

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

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082642