K121448

JUL 2 2012

Nucletron

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

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 21 CFR 807.92

1. SUBSCRIBERS NAME & ADDRESS

Company name:	Elekta Inc. D/B/A Nucletron Corporation
Registration number:	1121753
Address:	7 St. Paul Street, Suite 1660 Baltimore, Maryland 21202
Phone:	770-670-2548
Fax:	770-729-1585
Correspondent:	Thomas Valentine VP QA/RA, Elekta Inc. D/B/A Nucletron Corporation
Date:	May 1, 2012

2. MODIFIED DEVICE NAME- CLASSIFICATION:

Trade/Proprietary Name:	Oncentra 4.2
Common/Usual Name:	Radiation Therapy Planning System
Classification Name:	System,Planning,Radiation Therapy Treatment
Classification:	21Cfr892.5050 Class II

3. PREDICATE DEVICE IDENTIFICAITON

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

Manufacturer	Device	510(k) #
Nucletron BV	Oncentra MasterPlan 3.1	K081281
Nucletron BV	PLATO Brachytherapy 14.0	K983343

4. OVERALL DESCRIPTION OF ONCENTRA 4.2

Oncentra 4.2 is an update of *Oncentra MasterPlan 3.1*- they are the same product with same technological characteristics. The technical description described below is part of both *Oncentra 4.2* and *Oncentra MasterPlan 3.1*.

1. Overview

The Oncentra 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.

The system is intended for use by qualified medical personnel in radiotherapy clinics, suitably trained by Nucletron staff (or other competent people) in using the system. In addition to radiotherapy, the users must be trained in general Windows usage – Nucletron does not provide specific training or documentation concerning standard Windows functionality.

The Oncentra system should be configured locally and maintained by radiation physicists. It is a requirement that the person responsible for the local configuration has been suitably trained in configuring and maintaining the system.

2. Primary Operating Functions

The following table shows the general Primary Operating Functions (POF) for the system, respectively workflow descriptions and which actor that is most probably to perform the workflow. The POF have been identified in the Action Error Analysis (AEA) for Oncentra. Changes to this table must be motivated by the changes or additions to the AEA.

POF	Workflow Description	Actor
A. System Installation	The system (server/client) is installed or upgraded to a new version.	Medical Engineers
B. Manage Treatment Unit and Physics Data	The treatment unit parameters and data are installed, configured, updated and checked.	Physicists
C. Prescription	Dose is prescribed; fractionation and treatment protocol are decided.	Physicians
D. Define anatomy	Target and risk structures are defined on the planning CT images. Structures (ROI) are contoured based on the information from the physician.	Physicians Radiation therapists Physicists
E. Approve structures	The defined structure set is approved.	Physicians
F. Create plan	The prescription is interpreted and a treatment plan developed.	Radiation therapists Physicists
G. Evaluate plan	The plan is evaluated according to the prescribed dose for the contoured structures.	Physicians
H. Approve plan	The physicians approve a plan for treatment.	Physicians

I. Export plan	The plan is exported to the treatment unit verification system	External beam: Physicians Brachy: Radiation therapists Physicists
J. Validate plan	The treatment plan is validated before treatment delivery through independent calculations and measurements.	Physicists

3. Activities

Oncentra 4.2 uses externally acquired medical images and user input. The *Oncentra 4.2* software is based on a modular client/server design, with the treatment planning functions divided into "Activities".

Oncentra 4.2 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 Modeling (BM) module handles specification of the beam shapes and other manipulation of the treatment plan.

- **Plan Manager**
  The Plan Manager activity allows the user to create a new, or modify an existing, external beam treatment plan for photon beams. The activity provides tools for manual, and, if applicable, automatic, manipulation of beam geometries and modifiers

- **Connectivity Module:**
  The Connectivity Module (CM) module handles all forms of DICOM data input to the Oncentra MasterPlan 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 7 and XP platform.

5. SUBSTANTIAL EQUIVALENCE

The functionality for the Oncentra 4.2 is equivalent to its predicate device K081281 in safety and effectiveness. The fundamental technical characteristics are the same to those of the predicate device and are listed on the comparison charts provided in this 510 (k) submission.

5.1 Dosimetric validation – Brachy

The dosimetric accuracy for brachy dose calculations has for earlier releases been evaluated by the physics team. Comparisons have been made between Oncentra Brachy releases and Plato version 14.3.5, phantom measurements, and data published in the TG-43 report [*[1] AAPM TG-43 Rivard MJ, Coursey BM, DeWerd LA, Hanson WF, Huq MS, Ibbott GS, Mitch MG,Nath R and Williamson JF. (2004). Update of AAPM task group no. 43 report: a revised AAPM protocol for brachytherapy dose calculations. Med. Phys. 31, pp.633-674.]*

The accuracy of applicator shielding calculations was validated by comparisons with the established Plato planning system

No changes have been made to the brachytherapy dose calculations, therefore only a comparison with the previous version has been performed to verify consistency.

The results are well within expectable error margins and the dose calculations are deemed good for clinical use.

5.2 Dosimetric validation - External Beam

The base dose calculation algorithms of Oncentra have not been updated for this version. Comparison of results with those from earlier versions has been made to ensure that no unexpected changes have taken place.

The results are well within expectable error margins and the dose calculations are deemed good for clinical use.

6. INTENDED USE:

The legally marked predicate device *Oncentra MasterPlan 3.1* (K081281) has the same intended use as the modified device cited:

Oncentra 4.2
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.

7. CLINICAL USAGE OF ONCENTRA 4.2

Oncentra 4.2 is to be used in radiotherapy. Most patients are cancer patients who will receive radiotherapy treatment. There are also other conditions which can be treated with radiotherapy such as AVM Arteriovenus Malformations, Keloids (scars), and after removal of osteophytes (bone spurs) among others. - Patient population → all ages and genders.

Name: John Lapre
Title: Vice President Research & Development
Nucletron B.V.
Veenendaal, The Netherlands

May 30, 2012
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUL 2 2012

Mr. Thomas Valentine
Vice President, Quality and Regulatory Affairs
Elekta Inc. D/B/A Nucletron Corporation
7 St. Paul Street, Suite 1660
BALTIMORE MD 21202

Re: K121448
Trade/Device Name: Oncentra 4.2
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: May 11, 2012
Received: May 15, 2012

Dear Mr. Valentine:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121448

Device Name: Oncentra 4.2

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Prescription Use _____X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K121448