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JUN 13 2014

Nucletron B.V.
Waargelder 1
3905 TH Veenendaal
The Netherlands

Phone:(+31) 318-557-133
Fax: (+31) 629-031-313

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

Submitter of 510(k):

Company name:	Nucletron B.V.
Establishment Registration number:	9611894
Address:	Nucletron B.V. Waargelder 1 3905 TH Veenendaal The Netherlands
Phone:	(+31) 318-557-133
Fax:	(+31) 629-031-313
Correspondent:	Leo Hovestadt Quality Assurance and Regulatory Affairs leo.hovestadt@elekta.com

Device Name:

Trade/Proprietary Name:	Oncentra Brachy 4.4
Common/Usual Name:	Radiation therapy planning system
Classification	Class II
Classification Name:	System, planning, radiation therapy treatment 21 CFR 892.5050 Product Code: MUJ

Legally Marketed Device(s)
Our device is a modification of the legally marketed device:

Manufacturer	Device	510(k) #
Nucletron B.V.	Oncentra 4.2	K121448

Device description:

Oncentra Brachy 4.4 is a radiation therapy 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 Brachy 4.4 is a brachytherapy treatment planning only version of the Oncentra treatment planning system (Oncentra 4.2- K121448) and does not include Oncentra external beam treatment planning capabilities. Oncentra Brachy 4.4 includes all Oncentra software that is required for brachytherapy treatment planning which includes

- **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.
- **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.
- **Brachy Planning Module:** The Brachy Planning (BP) module handles execution of Brachytherapy dose calculations. The software allows reconstruction of the implant from external images, identification of the radioactive sources, optimization methods, displayed dose distributions and output of treatment times.
- **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 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.
- **Collapsed Cone Algorithm (ACE):** Is a model based dose calculation that has been implemented in accordance with the AAPM TG-186 recommendations for brachytherapy uniformity. This algorithm takes into account the effects of tissue heterogeneities (normal tissue, air and bone), shields and applicators within finite patient dimensions.

Intended Use:

Oncentra is radiation therapy 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 the Technical Characteristics

Oncentra Brachy 4.4 has the same technical characteristics as the legally marketed device (Oncentra 4.2) with the exclusion of external beam treatment planning software. There is no difference between the devices in the handling of images, planning brachytherapy treatments, analysis of the dose distribution or treatment plan output. A collapsed cone algorithm has been implemented to meet the AAPM TG 186 recommendations for brachytherapy uniformity; ACE (Advanced Dose calculation Engine) accounts for tissue heterogeneities, backscatter, attenuation, shielding and provides the user with a comparison of AAPM TG-43 and AAPM TG-186 based calculations.

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Summary of Non-clinical testing

Oncentra Brachy 4.4 met Nucletron verification and validation requirements for medical device software. This included traceable test cases for each requirement, identified risk, clinical scenarios and usability issues. All test cases were well documented with the results demonstrating all acceptance criteria were met and the software is determined to be safe and effective for clinical use.

Summary of Clinical testing

Oncentra Brachy 4.4 includes AAPM TG 186 as an evaluation method, which was clinically tested to ensure the implementation met clinical requirements and user expectations. All sites were in agreement that Oncentra Brachy 4.4 (including AAPM TG 186) was safe, effective and met clinical requirements.

Conclusion

Based on the technical characteristics and comprehensive testing it is determined that Oncentra Brachy 4.4 is safe, effective and meets clinical requirements.

May 20, 2014

Name John Lapre
Title President
Nucletron B.V.

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Nucletron B.V.
% Ms. Lu Anne Johnson
President
Capamed, Inc.
1917 29 ¾ Avenue
RICE LAKE WI 54868

June 13, 2014

Re: K132816
Trade/Device Name: Oncentra Brachy 4.4
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: May 20, 2014
Received: May 22, 2014

Dear Ms. Johnson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert A Ochs

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132816

Device Name: Oncentra Brachy 4.4

Indications for Use:

Oncentra is a radiation therapy 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___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 subpart D) (Part 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* Diagnostics and Radiological Health (OIR)

Robert A Ochs

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
510(k) K132816