Nucletron
AN ELEKTA COMPANY

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

Phone:(+31) 318-557-133
Fax: (+31) 318 557 118

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

SEP 2 6 2013

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. Waardgelder 1 3905 TH Veenendaal The Netherlands
Phone:	(+31) 318-557-133
Fax:	(+31) 318 557 118
Correspondent:	Jeroen Schuurman Project Manager jeroen.schuurman@elekta.com

Device Name:

Trade/Proprietary Name:	Esteya
Common/Usual Name:	Electronic Brachytherapy System
Classification	Class II
Classification Name:	X-Ray radiation therapy system 21 CFR 892.5900 Product Code: JAD

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

Manufacturer	Device	510(k) #
iCAD Inc	Axxent® Electronic Brachytherapy System	K122951
Nucletron B.V.	Valencia Skin Applicator Set	K073107
Topex Inc.	Topex SRT 100 Superficial Radiation Therapy System	K063456

Device description:

The Esteya Electronic Brachytherapy System is designed for High Dose Rate (HDR) brachytherapy treatment of skin surface lesions. The Esteya Electronic Brachytherapy System utilizes a mobile treatment unit with an isotope free small 69.5 kV X-ray source that focuses the treatment dose directly to the skin lesion with the aid of a shielded surface applicator. This technique provides a uniform dose to the underlying tissue within minutes. The small X-ray source is activated by the

treatment control panel that is located adjacent to the treatment area where the operator is protected from radiation exposure during the patient treatment. The Esteya Electronic Brachytherapy dedicated computer system provides fractionated treatment times, plan approval, patient information and treatment reports in a protected database which is administrator controlled. The quality of the X-ray source output is measured on a daily basis with a dedicated quality assurance device that is connected directly to the treatment unit. This quality assurance check ensures consistent and accurate electronic brachytherapy treatment.

Intended Use:
The Esteya electronic brachytherapy system is intended to deliver x-ray radiation for surface brachytherapy procedures. Typical applications include treatment for Basal Cell Carcinoma, Squamous Cell Carcinoma, Kaposi 's sarcoma, Merkel Cell Cardinoma, Lentigo Maligna, Lentigo Maligna Melanoma, Keloids and Cutaneous Lymphomas (B and T cell).

Summary of the Technical Characteristics
Esteya Electronic Brachytherapy System and the predicate devices are designed to provide radiation therapy treatment of skin surface lesions. This treatment is performed with a radiation source and skin surface applicator which provides a uniform dose distribution to underlying tissue.

The Esteya Electronic Brachytherapy System and the predicate devices are nearly identical in design, technology and functionality. The differences between the devices are minimal and include additional features integrated into the Esteya Electronic Brachytherapy System to improve safety and effectiveness. The similarities in design and technology are the basis and reason for substantial equivalence of the Esteya Electronic Brachytherapy System to the legally marketed predicate devices.

Summary of Non- clinical testing
Esteya Electronic Brachytherapy System has been tested to meet the product requirements, electrical and mechanical safety standards, and clinical expectations. Testing was performed in accordance with defined test cases with clearly defined acceptance criteria and included bench testing, functional testing, testing to recognized standards, sterility and biocompatibility testing. In addition, external testing of the applicable standards was performed by certified independent laboratories.

Summary of Clinical testing
Clinical testing was performed to compare the treatment output, dose distribution and clinical acceptance of the Esteya Electronic Brachytherapy System as compared to the Nucletron Valencia Skin Applicator Set (K073107). The results of the clinical testing clearly demonstrated substantial equivalence of the Esteya Electronic Brachytherapy System.

Conclusion
The Esteya Electronic Brachytherapy System is substantially equivalent to the cleared predicate devices.

Name John Lapre'
Title President
Nucletron B.V.

July 1st 2013
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 3/4 Avenue
RICE LAKE WI 54868

September 26, 2013

Re: K132092
Trade/Device Name: Esteya
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: II
Product Code: JAD
Dated: July 2, 2013
Received: July 12, 2013

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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael D. O'Hara 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): K132092

Device Name: Esteya

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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* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K132092