Nucletron B.V.
℅ Kiran Jose
Regulatory Affairs Senior Engineer
3900 Ax Veenendaal, P.O. Box 930
Waardgelder 1
Veenendaal, Utrecht 3905 TH
NETHERLANDS

January 11, 2022

Re: K213942
Trade/Device Name: Esteya
Regulation Number: 21 CFR 892.5900
Regulation Name: X-ray radiation therapy system
Regulatory Class: Class II
Product Code: JAD
Dated: December 10, 2021
Received: December 17, 2021

Dear Kiran Jose:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Julie Sullivan, Ph.D.
Chief
Nuclear Medicine and Radiation Therapy Branch
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213942

Device Name

Esteya

Indications for Use *(Describe)*

The Esteya is intended to deliver X-ray radiation for superficial radiotherapy procedures and surface brachytherapy. Applications include treatment for Basal Cell Carcinoma, Squamous Cell Carcinoma, Kaposi's Sarcoma, Merkel Cell Carcinoma, Lentigo Maligna, Lentigo Maligna Melanoma, Keloids and Cutaneous Lymphomas (B and T cell).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY (21 CFR § 807.92)

I. SUBMITTER

	Nucletron B.V. 3900 Ax Veenendaal, P.O. Box 930 Waardgelder 1 Veenendaal, Utrecht NL, 3905 TH
Contact:	Kiran Jose Regulatory Affairs Senior Engineer
Establishment Registration #:	9611894
510(k) Number:	K213942
Date Prepared:	10 December 2021

II. DEVICE

Trade Name:	Esteya
Product Classification:	Class II
Common Name:	Superficial Radiation Therapy System and Electric Brachytherapy System
Regulation Number:	21 CFR § 892.5900
Regulation Description:	X-ray radiation therapy system
Product Code:	JAD

III. PREDICATE DEVICES

Primary Predicate: K132092 – Esteya Electronic Brachytherapy System

Secondary Predicate: K150037 – Sensus Healthcare Superficial X-ray Radiation Therapy System with Ultrasonic Imaging Capabilities (SRT-100 Vision)

IV. INTENDED USE / INDICATIONS FOR USE

The Esteya is intended to deliver X-ray radiation for superficial radiotherapy procedures and surface brachytherapy. Applications include treatment for Basal Cell Carcinoma, Squamous Cell Carcinoma, Kaposi's Sarcoma, Merkel Cell Carcinoma, Lentigo Maligna, Lentigo Maligna Melanoma, Keloids and Cutaneous Lymphomas (B and T cell).

V. DEVICE DESCRIPTION

The Esteya is designed for high dose rate treatment of skin surface lesions. The Esteya 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 dedicated computer system of Esteya 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 & superficial radiotherapy treatment.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

The Esteya System is substantially equivalent to the predicate devices, Esteya Electronic Brachytherapy System (K132092) and SRT-100 Vision (K150037). Other than the addition of superficial radiotherapy capability as an additional indication for use, there is no functional difference between the Esteya System versus the previously cleared Esteya Electronic Brachytherapy System.

The technological characteristics are substantially equivalent to the predicate device; the clarification of the intended use statement does not affect the fundamental scientific technology or raise different questions of safety or effectiveness of the device. The device safety and performance have been addressed by non-clinical testing in conformance with predetermined performance criteria, FDA guidance, clinical use and recognized consensus standards. The results of verification and validation as well as conformance to relevant safety standards demonstrate that the Esteya System meets the established safety and performance criteria and is substantially equivalent to the predicate devices.

VII. SUMMARY OF PERFORMACE TESTING (NON-CLINICAL)

The Esteya 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 blocompatibility testing. In addition, external testing of the applicable standards was performed by certified independent laboratories. The below table contains the performance information to meet the intended use of the device.

Performance	**Data**
Fractionated treatment capabilities	✓
Source to Skin Distance (SSD)	60 mm
80% of the dose at a depth of:	3 mm
Dose Rate at skin surface	3 Gy/m
Maximum width of treatment surface (diameter of treatment area)	30 mm
PDD curves demonstrate a sharp falloff of dose to protect underlying tissue	✓
Accelerating potential (V)	69.5 kvp
Tube current (A)	0.5,1,1.6 mA
Tube power (W)	112
Flattening Filter in the tube	✓
Range of applicator diameters (mm)	Standard: 0, 10, 15, 20, 25, 30 Mini set: 10, 15, 20
Treatment applicator in contact with skin surface	✓
Contact material with skin surface	PPSU
Applicator Shielding	Densimet

VIII. SUMMARY OF PERFORMACE TESTING (CLINICAL)

No animal or clinical tests were performed to establish substantial equivalence with the predicate devices. The performance data demonstrate that the Esteya System is as safe and effective and performs as well as the predicate devices.

IX. SUBSTANTIAL EQUIVALENCE CONCLUSION

The Esteya System has the same intended use as the predicate devices. Any technological differences do not raise new questions of safety or effectiveness. Performance testing, along with verification and validation activities demonstrate that the Esteya System is as safe and effective and performs as well as the predicate devices. Therefore, the Esteya System is substantially equivalent to the predicate devices.