Nucletron BV
℅ Rigo Meens
Head of QA
Waardgelder 1
Veenendaal, Utrecht 3905 TH
THE NETHERLANDS

July 16, 2020

Re: K201272
Trade/Device Name: Geneva
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: Class II
Product Code: JAQ
Dated: March 20, 2020
Received: May 12, 2020

Dear Rigo Meens:

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,

For

Thalia T. Mills, Ph.D.
Director
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

A4. Indications for Use Statement

See next page

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: *0613012020*
See *PRA Statement below.*

510(k) Number *(if known)*

K201272

Device Name
Geneva

Indications for Use *(Describe)*

The device is intended for intracavitary brachytherapy for cancer treatment of the cervix and the endometrium. Optional needles can be placed for interstitial brachytherapy.

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

X Prescription Use (Part 21 CFR 801 Subpart D) O 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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"An agency may not conduct or sponsor, and a *person is not required to respond to,* a *collection of information unless* it *displays* a *currently valid OMB number."*

A5. 510(k) Summary

See next pages

510(k) Summary **20 March 2020**

Submitter of 510(k):

Company name:	Nucletron B.V.
Registration number:	611894
Address:	Waardgelder 1, 3905 TH Veenendaal, The Netherlands
Phone:	+31 318 557 133
Correspondent:	Leidimar Guararima

Device Name:

Trade/Proprietary Name:	Geneva
Common/Usual Name:	Brachytherapy Applicator
Classification Name:	Remote controlled radionuclide applicator system
Classification:	21CFR892.5700, Class II
Product code:	JAQ

Legally Marketed Device(s)

Our device is substantially equivalent to the following legally marketed predicate device:

Manufacturer	Device	510(K)#	Device classification
Nucletron B.V.	Utrecht Interstitial CT/MR Applicator Set	K091154	Class II

The Geneva is a gynecological applicator for intracavitary brachytherapy with the option for interstitial brachytherapy treatment. It can be used for the treatment of the cervix and endometrium. The applicator consists of tubes and ovoids, guiding the radioactive source of the afterloader to the target volume. Compatible components can be combined to reach a wide range of target areas.

Indications for use:
The device is intended for intracavitary brachytherapy for cancer treatment of the cervix and the endometrium. Optional needles can be placed for interstitial brachytherapy.

The indications for use for the Geneva are identical to the indications for use of the legally marketed above-mentioned predicate device.

Summary of technological considerations:
The subject device and the predicate devices are intended to provide a path for the isotope source to travel to the target volume. The devices are used in the hospital by qualified physicians. Geneva is used in the same anatomical sites as the predicate device and is made of the same materials.
The devices are compatible with Nucletron remote afterloader systems and accessories. Section C provides an overview of the similarities and differences of Geneva with the predicate device.

The subject device is tandem and ovoid type applicator with compatible interstitial needles. Geneva is identical in principle technology, clinical function and technical and biological characteristics to the predicate device. The device design fits in the same

clinical workflow as the predicate device. As a result, it is determined that the Geneva is substantially equivalent to the legally marketed predicate device.

Summary of testing:
Bench testing was performed at a hospital site, under simulated clinical conditions and with the involvement of clinical personnel but excluding the delivery of treatment to patients. Experienced users reviewed the device design and executed validation tests. The test results demonstrated the suitability of the device to its intended use and user needs and demonstrated clinical acceptance of the device.
Usability testing demonstrated that the device can be used by the intended users, under simulated clinical conditions, without serious use errors or problems.
Validation of reprocessing processes and biological evaluation was performed. The device can be used in the MR, CT, X-ray and US environments. Bench testing (similar to bench testing done to the Legally Marketed Device) shows that the device meets its performance requirements.

The results of the testing provided in this submission adequately demonstrate that the Geneva performs as defined in the requirements, meets clinical expectations and is safe and effective for clinical use.

Conclusion:
As a result, it was determined that Geneva is substantially equivalent in intended use, function, design and technological characteristics to the legally marketed predicate device.