DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 27, 2017

Nucletron B.V.
% Mr. Rudolf Vos
QA Engineer
Waardgelder 1
Veenendaal 3905 TH
THE NETHERLANDS

Re: K161688
Trade/Device Name: Advanced Gynecological Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: December 22, 2016
Received: December 29, 2016

Dear Mr. Vos:

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,

Michael D. O'Hara For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K161688

Device Name
Advanced Gynecological Applicator

Indications for Use *(Describe)*
The intended use of the Advanced Gynecological Applicator is intracavitary brachytherapy for cancer treatment of the cervix and endometrium. Optional needles can be placed for interstitial brachytherapy.

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.

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510(k) Summary

17 June 2016

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:	Rudolf Vos

Device Name:

Trade/Proprietary Name:	Advanced Gynecological Applicator
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 these legally marketed predicate devices:

Manufacturer	Device	510(k) #
Nucletron B.V.	Interstitial Ring CT/MR Applicator Set	K091154
Nucletron B.V.	Utrecht Interstitial CT/MR Applicator Set	K091154
Nucletron B.V.	MUPIT Applicator Set	K953946

Description:

The Advanced Gynecological Applicator is a gynecological applicator for intracavitary and interstitial brachytherapy treatment. It can be used it for treatment of the vagina, cervix and uterus. The applicator consists of tubes, caps and templates to place needles. Components can be combined to reach a wide range of target areas. The tubes and the needles, if used, guide the radioactive source of the afterloader to the target volume.

Indications for use:

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

The indications for use for the Advanced Gynecological Applicator are identical to the indications for use for the legally marketed Interstitial Ring CT/MR Applicator Set and the Utrecht Interstitial CT/MR Applicator Set.

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 trained professionals. The Advanced Gynecological Applicator is used in the same anatomical sites as the primary predicate device and is made of the same materials. The devices are compatible with Nucletron remote afterloader systems and accessories.

The subject device combines features from more predicate devices with the same intended use into a single device. It is a tandem and ovoid type applicator with interstitial needles. Together, two ovoids make a ring shape. The device includes a needle templates to place needles and intracavitary cylinders to treat the vaginal wall. The configuration of the needles through ovoids of the Advanced Gynecological Applicator differ from the predicate devices; some needles can be placed perpendicular to the ovoids and some are angled outwards (oblique).

These differences do not affect the similarity in principal technology, function and operational characteristics of the devices. The device design fits in the same clinical workflow as the primary predicate device. As a result, it is determined that the Advanced Gynecological Applicator is substantially equivalent to the legally marketed predicate devices.

Summary of testing:
Bench testing was performed at a hospital site, under clinical conditions and with the involvement of clinical personnel but excluding the delivery of treatment of patients. Experienced users reviewed the device design and executed validation tests. The test results demonstrated suitability of the device to its intended uses and clinical acceptance of the device.
Usability testing demonstrates that the device can be used by the intended users, under simulated clinical conditions, without serious use errors or problems.
Validation of sterilization processes and biological evaluation was performed. The device was tested for use in the MR and CT environment. Bench testing (similar to bench testing done to the Legally Marketed Device) shows that the device meets its performance requirements, and that the modified device performance is equivalent to the marketed devices.

The results of the testing provided in this submission adequately demonstrate that the Advanced Gynecological Applicator performs as defined in the requirements, in accordance with the recognized standards, meets clinical expectations and is safe and effective for clinical use.

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