



Food and Drug Administration
10903 New Hampshire Avenue
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Nucletron B.V.
% Ms. Lizette van de Streek
RA Engineer and Export Control Specialist
Waardgelder 1
3905 TH Veenendaal
THE NETHERLANDS

June 23, 2015

Re: K151272
Trade/Device Name: Henschke Titanium Applicator Set
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: II
Product Code: JAQ
Dated: May 12, 2015
Received: May 13, 2015

Dear Ms. van de Streek:

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,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style. A faint, large watermark of the letters "FDA" is visible in the background behind the signature.

For

Robert Ochs, Ph.D.
Acting 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): K151272

Device Name: Henschke Titanium Applicator Set

Indications for Use: The Henschke Titanium Applicator Set is designed for treatment of the cervix and endometrium

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 subpart D) (Part 21 CFR 801 subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)



510(k) Summary

12 May 2015

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
Fax: +31 318 557 118
Correspondent: Lizette van de Streek

Device Name:

Trade/Proprietary Name: Henschke Titanium Applicator Set
Common/Usual Name: Intracavitary 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 predicate device cited in the table below:

Manufacturer	Device	510(k) #
Nucletron B.V.	HENSCHKE APPLICATOR SET (included in 510(k) for MICROSELECTRON-HDR VERSION 2)	K953946

Description:

The Henschke Titanium Applicator Set is a modification of the Henschke Applicator Set (K953946). It is intended for intracavitary brachytherapy and is used for cancer treatment of the cervix and endometrium.

The Henschke Titanium Applicator Set is a gynecological applicator for Brachytherapy procedures. The applicator uses an intrauterine tube and two colpostat tubes. A colpostat cap can be placed on each colpostat tube.

The tubes guide the radioactive source of the afterloader to the location where treatment is to be applied. Transfer tubes are required to connect the applicator to the afterloader.

With the adjustable cervical stopper, the intrauterine tube-length can exactly be fitted to the patient's anatomy. The intrauterine tube has adjustment centimeter-markings.

The device is compatible with Nucletron afterloaders.

The applicator is made of Titanium and PPSU, to minimize distortion on CT imaging. This enables conformal treatment planning with the use of CT images.

Indications for use:

The Henschke Titanium Applicator Set is intended for intracavitary brachytherapy and is used for cancer treatment of the cervix and endometrium.

The indications for use of the modified Henschke Titanium Applicator Set are the same as the indications for use of the predicate device.

Summary of technological considerations:

The Henschke Titanium Applicator Set is used by the same users as the predicate device, at the same location and the general operating principle is the same. The device is used for the same anatomical sites and insertion techniques. The sterilization method does not change.

The device its environmental specifications are changed; the device can now also be used in combination with CT imaging by changing the device materials to a type of material that has been used in other legally marketed devices within the same classification regulation.

These differences do not affect the similarity in principal technology, function and operational characteristics of the devices. As a result, it is determined that the Henschke Titanium Applicator is substantially equivalent to the predicate device.

Summary of testing:

Henschke Titanium Applicator Set has been tested to meet the product requirements, requirements from (safety) standards and clinical expectations. Verification covers functional verification 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 results of the testing provided in this submission adequately demonstrate that the Henschke Titanium Applicator Set performs as defined in the requirements, meets clinical expectations and is safe and effective for clinical use.

Conclusion:

Nucletron considers the Henschke Titanium Applicator Set to be substantially equivalent to legally marketed predicate device through the data and information presented. No safety or effectiveness issues were identified.
