December 19, 2025

Nucletron B.V.
Loes Vloet-Emonts
Regulatory Affairs Engineer o BL-Q Brachy
3900 Ax Veenendaal, P.O. Box 930
Waardgelder 1
Veenendaal, 3905TH
Netherlands

Re: K251037
Trade/Device Name: Rectal Applicator
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote controlled radionuclide applicator system
Regulatory Class: Class II
Product Code: JAQ
Dated: November 26, 2025
Received: November 26, 2025

Dear Loes Vloet-Emonts:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lora D. Weidner, Ph.D.
Assistant Director
Radiation Therapy Team
DHT8C: Division of Radiological
Imaging and Radiation Therapy Devices
OHT8: Office of 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)*
K251037

Device Name
Rectal Applicator

Indications for Use *(Describe)*
The Rectal Applicator is intended for brachytherapy for treatment of rectal and anal cancer in combination with Elekta HDR and PDR remote controlled afterloaders.

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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TRADITIONAL 510(K) SUMMARY (21 CFR § 807.92)

I. SUBMITTER

Nucletron B.V.
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The Netherlands

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Establishment Registration #: 3002807741

510(k) Number: K251037

Date prepared: 19 December 2025

II. DEVICE

Trade Name: Elekta Rectal Applicator

Product Classification: Class II

Common Name: Rectal Applicator

Regulation Number: 21 CFR § 892.5700

Classification Name: System, Applicator, Radionuclide, Remote-Controlled

Product Code: JAQ

III. PREDICATE DEVICE

Predicate Device #: K041715

Predicate Trade Name: INTRACAVITARY MOULD APPLICATOR SET

IV. DEVICE DESCRIPTION

In brachytherapy the first treatment step is to position a brachytherapy applicator in or on the patient in order to reach the target volume. The second step is to determine the desired positions and dwell times of the source within the applicator to encompass the target volumes as good and optimal as possible, creating a treatment plan.
The Rectal Applicator is an applicator for brachytherapy procedures indicated for treatment of

rectal and anal cancer. The device is used in hospitals.

The Rectal Applicator has eight channels to guide a radioactive source or another accessory (e.g. check cable or marker) through the channel to a certain position. Transfer Tubes can be connected to the proximal end of the channels. The Transfer Tubes can be connected to Elekta HDR and PDR remote controlled afterloaders (Flexitron HDR/MicoSelectron digital / V2).

The applicator can be inserted free-hand or using the Insertion Tool. The Insertion Tool can be removed after the insertion or can stay in place during the treatment.

After the insertion of the applicator, the Fixation Element can be used for immobilization (using the Applicator clamp). The Fixation Element can be fixated to the applicator using the Fixation Clip.

Parts included in this 510(k):
- Rectal Applicator
- Fixation Element
- Fixation Clip
- Insertion Tool

Rectal Applicator

The Rectal Applicator is a flexible, cylindrical applicator containing eight flexible channels which can be used to optimize the target dose. In case of asymmetric tumors (which is mostly the case), only the needed channels can be loaded. When inserting the applicator under fluoroscopy (e.g., C-arm) in the sagittal or frontal plane, the integrated marker can be used to verify if the applicator has been inserted deep enough to cover the full target volume. The centimeter length markings on the applicator can be used as indications for the insertion depth. The markings can not be used for determining the most distal dwell position.

The Rectal Applicator is a sterile (EO), single use device mainly made of silicone material including an adhesive and silicone ink (centimeter scale). The applicator will come in direct contact with comprised mucosa (max. 24 h). The Rectal Applicator is classified as MR conditional.

Fixation Element and Fixation Clip

The Fixation Element can be placed on the applicator before or after insertion of the applicator. The Fixation Clip fixates the Fixation Element on the applicator and the design of the Fixation Element facilitate the possibility to immobilize the applicator to the CT/MR Applicator Clamp.

The Fixation Element and Clip are made of PPSU white and will come in indirect contact with intact skin (max. 24 h) and are MR Safe.
The Fixation Element and Fixation Clip are reusable and can be reprocessed using cleaning (manual or automated) and moist heat sterilization.

Insertion Tool

The Insertion Tool fits into the center cavity of the applicator and will make the applicator rigid to insert the rectal applicator into the rectum.

The Insertion Tool, made of PPSU white and glass fiber reinforced composite, is considered to be non-body contacting and can be reprocessed using cleaning (manual or automated) and moist heat sterilization.

V. INTENDED USE / INDICATIONS for USE

The Rectal Applicator is intended for brachytherapy for treatment of rectal and anal cancer in combination with Elekta HDR and PDR remote controlled afterloaders.

VI. INDICATIONS for USE COMPARISON

The Indications for Use of the subject device is for rectal and anal cancer.
The Rectal Applicator indications for use are significant equivalent to the one cleared under predicate device K041715 as described in IFU 090705ENG-04. While the language has been simplified and clarified, these refinement does not alter the fundamental indications for use. The anal cancer is introduced which requires the same placement of the applicator via the anal canal into the rectum. Only difference is in the treatment volume which may overlap but will be overall closer to the end of the gastrointestinal tract. The device placement is the same, the fixation is the same, the duration of insertion is the same, only difference may be in the dwell positions which may overlap but in general will be closer to the end of the gastrointestinal tract.
There may be differences in relation to the response to radiation, but this is not related to the use of the applicator. The prescribed dose, timing and fractionation are at the discretion of the treating physician Therefore, the device maintains the same indications for use as the predicate, aligning with the criteria for substantial equivalency.
Validation activities for the Rectal Applicator supports that the device is as safe and as effective as the predicate device cleared in K041715 and maintains the substantial equivalency as the predicate device.

VII. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The vast majority of technological characteristics are the same between the subject device and predicate device, however, there are some differences in technical characteristics summarized in the table below:

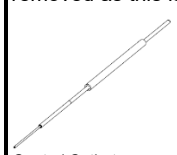
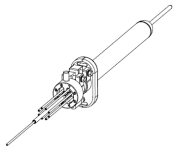
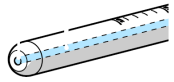
Table 1: Summary of Technological Similarities and Differences

Item category description	Item Identifier	**Predicate Devices** Intracavitary Mould Applicator Set **(K041715)**	**Subject Device** Rectal Applicator	**Comparison of subject device to predicate devices in their current state**	
Device description Clinical equivalence	Device description	The Intracavitary Mold Applicator Set is developed for the Elekta remote afterloading equipment and is intended for intracavitary rectal brachytherapy procedures. The main shape of the applicator is a cylinder, the intracavitary mold, which has the flexibility to follow the shape of the colon wall. This gives an optimal situation for clinical brachytherapy treatment (in all places the distance to the colon wall is equal) and also considers patient comfort (pain is minimized). In the cylinder there are 8 catheters for guiding the radioactive source of the afterloader. If desired, an additional central catheter can be placed. A support block can be used to fixate the applicator. The product is delivered partly in a sterile packaging and partly in a non-sterile packaging.	The applicator is a flexible applicator withy eight integrated treatment catheters to guide a radioactive source to the dwell positions. The dwell positions in the treatment catheters help to optimize the target dose. For example, only some of the treatment catheters need to have active dwell positions for asymmetrical tumors. The applicator is delivered sterile. Sterile-delivered are for single use only. The insertion tool, fixation element and fixation clip are delivered non-sterile, are reusable, and must be sterilized before use.	Significant Equivalent	The device description of the Rectal Applicator is similar as the device description included in K041715. Both devices are described as a flexible applicator with 8 channels and is delivered in a sterile state. The additional devices are delivered non-sterile. The Rectal Applicator and the device cleared under K041715 have the same shape, function, intended use, clinical workflow and clinical use. Furthermore, during the initial risk assessment where the difference between both devices is evaluated, it is concluded that the proposed changes to the Rectal Applicator do not introduce unacceptable risks. Therefore, it is concluded that the changes in the device description are considered non-significant.
	Anatomical sites	Intracavitary, rectum via anal canal	Intracavitary, rectum via anal canal	Identical	No changes have been made to the anatomical sites since K041715 clearance.
	Indications for use	The Intracavitary Mold Applicator Set is intended for intracavitary brachytherapy procedures involving Nucletron remote afterloading equipment.	The Rectal Applicator is intended for brachytherapy for treatment of rectal and anal cancer in combination with Elekta HDR and PDR remote controlled afterloaders.	Significant Equivalent	The Rectal Applicator intended purpose is significant equivalent to the one cleared under predicate device K041715. While the language has been simplified and clarified, these refinements does not alter the fundamental intended use. The modifications are intended sole to enhance user understanding without impacting the device clinical application or purpose. Therefore, the device maintains the same intended use as the predicate, aligning with the criteria for substantial equivalency.
Device	User	Qualified physicians,	Qualified physicians,	Identical	No changes have been made to the user since K041715 clearance.

510(K) SUMMARY

Item category description	Item Identifier	**Predicate Devices** Intracavitary Mould Applicator Set **(K041715)**	**Subject Device** Rectal Applicator	**Comparison of subject device to predicate devices in their current state**	
description		trained in brachytherapy techniques	trained in brachytherapy techniques		
Clinical equivalence Technical equivalence	Use environment/location of use	The device is used in the hospitals by trained professionals	The device is used in the hospitals by trained professionals	Identical	No changes have been made to the Use environment/location of use since K041715 clearance.
	Intended population	No age restrictions, but fertility preservation may be a reason to choose an alternative treatment.	The device is suitable for patients weighing at least 37.5 kg (82.7 lbs) due to the potential exposure to levels of ethylene oxide (EO) and ethylene chlorohydrin (ECH) that may exceed established carcinogenic and teratogenic safety thresholds.	Significant change	There are restriction in the patient population for the Rectal Applicator compared to predicate device K041715. While the restriction related to patient population is added due to the Biological Safety Evaluation. this does not alter the fundamental intended use and the device clinical application or purpose. It is important that one or more qualified physicians consider all the characteristics of the patient, such as age, stage of the disease, and alternative or concurrent treatments, to identify if the benefit-risk analysis supports the application of brachytherapy.
	Compatibility with other devices	microSelectron Digital	Flexitron HDRwith Flexitron Transfer Tubes for 6F Flexibles microSelectron Digital (previous name: microSelectron V3) and microSelectron V2 with microSelectron Transfer Tubes for 6F Flexibles. Oncentra Brachy X-Ray Markers 6F 400 mm (3-10) CT markers 400 mm, Green CT/MR Applicator Clamp with Base Plate CT/MR Applicator Clamp with Axle Lubricant Endocavity balloon	Significant Equivalent	Improvement of documentation, no changes to compatibility with other devices. microSelectron Digital is the substantial equivalent legally market device for the Flexitron HDR as included in K070574.
	Picture			n.a.	-

510(K) SUMMARY

Item category description	Item Identifier	**Predicate Devices** Intracavitary Mould Applicator Set **(K041715)**	**Subject Device** Rectal Applicator	**Comparison of subject device to predicate devices in their current state**	
	Dimensions	Diameter: 20 mm Applicator length (silicone part): 280 mm	Diameter: 20 mm Applicator length (silicone part): 320 mm Applicator length (incl. catheters): 410.0 mm	Significant Equivalent	The overall dimensions are similar than the predicate device cleared in K041715. Usability validation shows no impact on the usability for the dimension change. Therefore, the change in dimensions is considered non-significant.
	Shore of material	40 Shore A	40 Shore A	Identical	-
	Amount of channels	8 lateral channels 1 central catheter Tip of catheter slightly curved	8 lateral channels Catheters straight / parallel	Significant Change	8 parallel channels along the circumference, are the same as the compared to the device cleared in K041715. The central catheter is an optional item for the intracavitary mold applicator. The central catheter is removed as this is not used for rectum.  *Central Catheter*  *Central Catheter placed in the Intracavitary Mold Applicator*  *Intracvitary Mold Applicator*  *Rectal Applicator* The catheter shape does not have an effect on the applicator shape. The diameter of the cylinder and the distribution of the source channels in the cylinder are not changed compared to the Intracavitary Mold Applicator. There is a small difference in the tip of the applicator. In the Rectal Applicator, the source channels are completely straight and parallel to each other. In the Intracavitary Mold Applicator, the distal end of the catheters are slightly converging. However, the source cannot reach the very end of the catheter. As a result, the possibilities for treatment planning are considered substantially equivalent, as supported by verification and validation activities. .
	Distance of lateral channels to outer surface	3.5 mm	3.5 mm	Identical	No changes have been made to the distance of lateral channels to outer surface since K041715 clearance.
Technical equivalence Materials	Dead-end space (First dwell position (FDP) to tip)	12.6 mm	9.3 mm	Significant Equivalent	The overall dead-end space (FDP to tip) is changed slightly; however verification & validation activities and usability assessment were used to support significant equivalent when compared to the predicate device cleared in K041715 .
	Channel numbering/identification	channel numbering as a separate component	Identification of the treatment catheter with a longer channel guide	Significant Equivalent	An exterior longer channel guide has been added to facilitate identification of the catheter with the integrated marker. Verification & validation activities and usability assessment were used to support substantial equivalence to the predicate device.

510(K) SUMMARY

Item category description	Item Identifier	**Predicate Devices** Intracavitary Mould Applicator Set **(K041715)**	**Subject Device** Rectal Applicator	**Comparison of subject device to predicate devices in their current state**	
	Immobilization	Yes, by support block	Yes, utilizing a fixation element and fixation clip	Significant Equivalent	The immobilization approach for the subject device has been simplified (fewer components, no tools needed for immobilization, no metal components). Verification & validation activities and usability assessment were used to support substantial equivalence to the predicate device.
	Additional component: Insertion tool	Yes, three versions (including a metal version)	Yes (one version, non-metal)	Significant Equivalent	Instead of 3 different insertion tools (metal, non- metal of different diameters) utilized for the predicate, the subject device 1 non-metal version will be the provided. This is an optional tool. Verification & validation activities were used to support substantial equivalence to the predicate device.
	Kink protection	Yes, as a separate component	Yes, integrated in design of the cylinder	Significant Equivalent	Kink protection is integrated with the mold in new design. Verification & validation activities were used to support substantial equivalence to the predicate device.
	Verifying insertion depth	Using the metal plate in the applicator tip	Using integrated marker	Significant Equivalent	The subject device includes an integrated marker, while the predicate device used a metal plate in the applicator tip. The integrated marker is on the distal dwell position and intended for depth verification and positioning. Verification & validation activities and usability assessment were used to support substantial equivalence to the predicate device.
	Dosimetry	- Asymmetric dosimetry by lateral channels - Distance by silicon bougie - No shielding Additional distancing by endorectal balloon (third party)	- Asymmetric dosimetry by lateral channels - Distance by silicon bougie - No shielding Additional distancing by endorectal balloon (third party)	Identical	No changes have been made to the dosimetry since K041715 clearance.
	Sterility	Intracavitary Mold: Single Use, Sterile Support Block: Reusable, Nonsterile Number Tag Ring: Reusable, Nonsterile Insertion Tool: Reusable, Nonsterile Screwdriver: Reusable, Nonsterile	Rectal applicator: Single Use, Sterile Fixation Element: Reusable, Non-sterile Fixation Clip: Reusable, Non-sterile Insertion tool: Reusable, Non-sterile	Significant Equivalent	No changes to the classification of the device (single use, sterile) and Components/Accessories (reusable, non-sterile)
	Sterilization method for single use items	EO	EO	Identical	No changes have been made to the sterilization method since K041715 clearance.
	Sterilization method for reusable items:	Support Block: Moist heat Number Tag Ring: Moist heat	Fixation Element: Moist heat Fixation Clip: Moist heat Insertion tool: Moist heat	Identical	No changes have been made to the reprocessing method since K041715 clearance.

510(K) SUMMARY

Item category description	Item Identifier	**Predicate Devices** Intracavitary Mould Applicator Set **(K041715)**	**Subject Device** Rectal Applicator	Comparison of subject device to predicate devices in their current state	
		Insertion Tool: Moist heat Screwdriver: Moist heat			
	Principles of operation	The applicator's source channels guide the radioactive source of the afterloader to the place where treatment is to be applied	The applicator's source channels guide the radioactive source of the afterloader to the place where treatment is to be applied	Identical	No changes have been made to the principles of operation since K041715 clearance.
	Imaging modalities	CT & X-Ray	CT & MR & X-Ray	Significant Change	The Rectal Applicator is labeled MR conditional and the included Accessories/Components (Insertion Tool, Fixation Element, Fixation Clip) are labeled MR safe. MR Safety and Compatibility Assessment (Force Testing, Torque Testing, RF Heating Testing, Image Artifact Testing) were used to support updates to the labeling.
	Shelf life	Intracavitary Mold: 5 years The reusable products don't carry a shelf life but have an expected lifetime of 3 years	Rectal Applicator: 3 years; Insertion Tool, Fixation Element, Fixation Clip: 3 years or 300 reprocessing cycles (whatever comes first)	Significant Equivalent	Verification & validation activities including assessment of reprocessing (for reusable parts) and packaging support the shelf life of the Rectal Applicator and its reusable parts (Fixation Clip, Fixation Element, Insertion Tool).
	Material Silicone cylinder	Cap and Base: Silopren LSR 404 of Bayer 40+5 Shore A	Cap and Base: Silicone	Significant Equivalent	Changes to the material and the biological safety evaluation were assessed according to the requirements of EN ISO 10993-1: 2020 and ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Biological evaluation of medical devices – Evaluation and testing in a risk management process.*
	Material catheter	PA11/PUR	Polyamide	Significant Equivalent	Changes to the material and the biological safety evaluation were assessed according to the requirements of EN ISO 10993-1: 2020 and ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Biological evaluation of medical devices – Evaluation and testing in a risk management process.*
	Material holder	POM White Ti 6AL-4V	PPSU	Significant Equivalent	Changes to the material and the biological safety evaluation were assessed according to the requirements of EN ISO 10993-1: 2020 and ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Biological evaluation of medical devices – Evaluation and testing in a risk management process.*
	Material Insertion Tool	Ø 4 mm: AISI 303 Ø 8 mm: PPSU White Ø 10 mm: PPSU White	Grip: PPSU Rod: Glas Fiber reinforced epoxy	Significant Equivalent	Changes to the material and the biological safety evaluation were assessed according to the requirements of EN ISO 10993-1: 2020 and ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Biological evaluation of medical devices – Evaluation and testing in a risk management process.*
	Material immobilization block	PPSU White Ti 6AL-4V	PPSU	Significant Equivalent	Changes to the material and the biological safety evaluation were assessed according to the requirements of EN ISO 10993-1: 2020 and

Item category description	**Item Identifier**	**Predicate Devices** Intracavitary Mould Applicator Set **(K041715)**	**Subject Device** Rectal Applicator	**Comparison of subject device to predicate devices in their current state**	
					ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Biological evaluation of medical devices – Evaluation and testing in a risk management process.*
Materials Manufacturing equivalence	Materials in contact with the body	Cylinder, catheter (skin), immobilization block (skin)	Cylinder, catheter (skin), immobilization block (skin)	Significant Equivalent	Changes to the materials and the biological safety evaluation were assessed according to the requirements of EN ISO 10993-1: 2020 and ISO 10993-1:2018 *Biological evaluation of medical devices – Part 1: Biological evaluation of medical devices – Evaluation and testing in a risk management process.*
	Packaging	Double pouch	Single Pouch	Significant Equivalent	The predicate Intracavitary Mould Applicator Set used a double pouch for the single use device, while the subject Rectal Applicator uses a single pouch for the single use device. Verification & validation activities (including packaging integrity) were used to support the change in packaging.

Justification for substantial equivalence for difference in the amount of channels:
The Elekta Rectal Applicator features:

a) 8 lateral channels and the catheter is straight
b) Imaging modalities for CT & MR & X-Ray

8 parallel channels along the circumference, are the same as the compared to the device cleared in K041715. The central catheter (central channel) is removed as it's not used for rectum. The catheter shape does not have an effect on the applicator shape.
The diameter of the cylinder and the distribution of the source channels in the cylinder are not changed compared to the Intracavitary Mold Applicator.
There is a small difference in the tip of the applicator. In the Rectal Applicator, the source channels are completely straight and parallel to each other. In the Intracavitary Mold Applicator, the distal end of the catheters are slightly converging. However, the source cannot reach the very end of the catheter. As a result, the possibilities for treatment planning are similar.
The verification and validation activities for the Rectal Applicator supports that the device is as safe and as effective as the predicate device cleared in K041715 and maintains the substantial equivalency as the predicate device.

Justification for substantial equivalence for difference in Imaging modalities:
The Rectal Applicator has an integrated most distal dwell position marker and radiopaque catheters. X-ray markers and CT markers can be used with the Rectal Applicator. With the Intracavitary Mold Applicator only X-ray markers can be used.
The Rectal applicator is suitable for use in an MR environment. Most metallic / conductive parts have been removed from the design, only the integrated metallic marker is left. The marker is small. The potential risk introduced by this marker is evaluated in the MRI Safety Assessment. Potential hazards caused by interactions of the metallic integrated marker and the MR environment are assessed and based on this evaluation, the Rectal Applicator is classified as MR conditional.
The verification and validation activities for the Rectal Applicator supports that the device is as safe and as effective as the predicate device cleared in K041715 and maintains the substantial equivalency as the predicate device.
There are no novel forms of technology introduced in this premarket notification.

VIII. SUMMARY OF PERFORMANCE TESTING (NON-CLINICAL)

Development, verification and validation activities have been carried out in accordance with design controls as required by FDA's Quality System Regulation (21 CFR § 820.30), applicable ISO 13485 Quality Management System requirements, ISO 14971 Risk Management requirements and other FDA recognized consensus standards (either full or partial applicable).
Basic safety and essential performance of the Elekta Rectal Applicator have been satisfied through conformance with the applicable general, particular and collateral safety and essential performance standards for medical devices listed below.

Standards	
Standard No.	**Standard Title**
IEC 60601-2-17 Edition 3.0 2013-11	Medical electrical equipment Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading-equipment
ISO 20417	Medical Devices – Information to be supplied by the manufacturer

Standards	
Standard No.	**Standard Title**
First Edition 2021-04 Corrected version 2021-12	
ISO 15223-1 Fourth Edition 2021-07	Medical Devices – Symbols to be used with information supplied by the manufacturer – Part 1: General Requirements
ISO 17664-1 First Edition 2021-07	Medical Devices – Information to be supplied by the manufacturer
ASTM F2503	Standard Practice for Marking Medical Devices and Other Items for safety in Magnetic Resonance Environment
ASTM D4169-16	Standard Practice for Performance Testing of Shipping Containers and Systems
ASTM F2503-23	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
ASTM F88-21	Standard Test Method for Seal Strength of Flexible Barrier Materials
ASTM F1886-16	Standard Test Method for Determing Integrity of Seals for Flexible Packaging by Visual Inspection
ASTM F1929-15	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by dye Penetration
ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
ASTM F2096-11	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
ASTM F3208-20	Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices
ISO 11607-1:2019	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming sealing and assembly processes
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
ISO 10993-5:2009	Biological Evaluation of Medical Devices: Test for in vitro cytotoxicity
ISO 10993-7:2008	Biological Evaluation of Medical Devices: Ethylene Oxide Sterilization Residuals
ISO 10993-10:2021	Biological Evaluation of Medical Devices: Test for Irritation and Skin Sensitization
ISO 10993-11: 2017	Biological Evaluation of Medical Devices: Test for systemic toxicity
ISO 10993-18:2020	Biological Evaluation of Medical Devices: Chemical characterization of medical device materials within a risk management process
ISO 10993-23:2021	Biological Evaluation of Medical Devices: Test for irritation
ISO 11135:2014/A1:2018	Sterilization of health-care products - Ethylene oxide - Requirements for the development validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of Annex E Single batch
ISO 17665-1:2006/(R)2013	Sterilization of health care products -- Moist heat -- Part 1: Requirements for the development validation and routine control of a sterilization process for medical devices

Standards	
Standard No.	**Standard Title**
ISO 14971:2019	Medical devices - Applications of risk management to medical devices
IEC 62366-1: 2015+AMD1:2020	Medical Devices – Part 1: Application of usability engineering to medical devices including Amendment 1
ISO 11138-1:2017	Sterilization of health care products- Biological indicators – Part 1: General Requirements
ISO 11138-2:2017	Sterilization of health care products- Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes
ISO 11737-1:2018	Sterilization of health care products. Microbiological methods- Part 1: Determination of a population of microorganisms on products
AAMI TIR12: 2020	Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
ANSI AAMI ST98:2022	Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices
ANSI AAMI ST79:2017	Comprehensive guide to steam sterilization and sterility assurance in health care facilities
ANSI AAMI ST72:2019	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing

The verification of the performance of the Elekta Rectal Applicator was conducted to confirm that design outputs meet their design inputs.
The results are as follows:

- All requirements have been verified and met
- All risk control measures have been correctly implemented
- No issues were found

The verification results confirm that design outputs meet their design inputs.
The results of verification and validation activities as well as conformance to relevant standards demonstrate that the device meets the safety and performance criteria. It is concluded that the major technological characteristics are substantially equivalent to the predicate device and the differences do not raise new questions of safety and effectiveness compared to the predicate.

The following performance data were provided in support of the substantial equivalence determination.

<u>Performance testing</u>

- Dose distribution
- Euler Kink Force
- Device radiation resistance
- Compatibility to other devices
- Immobilization characteristics
- Visibility on CT image modalities
- Magnetic Resonance Environment marking / MRI Safety Assessment
- Visibility on X-Ray image modalities

Biocompatibility testing / Animal testing

To demonstrate the biological safety of the rectal applicator, in relation to the nature of body contact and contact duration, a series of biocompatibility studies (including animal studies) were conducted to comply to the ISO 10993-1. The following tests have been performed:

- ISO 10993-5L2009 Cytotoxicity
- ISO 10993-23:2021 Irritation
- ISO 10993-11:2017 Acute and subacute systemic toxicity
- ISO 10993-10:2021 Sensitization
- USP, General Chapter ,151, Pyrogenicity
- ISO 10993-7:2008 EO/ECH residues mediated toxicity

All biocompatibility tests have been performed under GLP and passed the requirements. The results demonstrate that the device meets the safety and performance criteria. It is concluded that the major technological characteristics are substantially equivalent to the predicate device and the differences do not raise new questions of safety and effectiveness compared to the predicate.

Usability testing

All through the design process of the Rectal Applicator (including Fixation Element, Fixation Clip and Insertion Tool) the usability activities have been performed:

- Customer interviews
- Review of post-production information from predicate device
- Formative usability evaluation
- Summative usability evaluation
- Risk Management

Based on the results of these activities compliance to IEC 62366-1:2015 is demonstrated and it is concluded that the Rectal Applicator is safe and effective for the intended users, uses and use environments.

IX. SUSTANTIAL EQUIVALENCE CONCLUSION

All changes whether significant or non-significant have been evaluated to ensure that the Elekta Rectal Applicator remains substantially equivalent to the predicate device. Comprehensive testing and risk assessments were conducted to confirm that these changes do not impact the safety or effectiveness of the device for its intended use. Supporting data demonstrates that the Elekta Rectal Applicator is as safe and effective as the predicate device. Therefore, it is concluded that the Elekta Rectal Applicator is considered to be substantially equivalent to the Intracavitary Mould Applicator Set (K041715). Differences in materials, catheter structure and fixation mechanisms do not raise new safety or effectiveness concerns.