July 24, 2026

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

Re: K262383
Trade/Device Name: LumenCare Azure
Regulation Number: 21 CFR 892.5700
Regulation Name: Remote Controlled Radionuclide Applicator System
Regulatory Class: Class II
Product Code: JAQ
Dated: July 13, 2026
Received: July 13, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K262383

Please provide the device trade name(s).

LumenCare Azure

Please provide your Indications for Use below.

The LumenCare Azure is intended for intraluminal brachytherapy and is used for treatment of the lung or other lumen, e.g. bronchus and bile duct.

The LumenCare Azure is designed to fit in the working channel of an endoscope.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)

K262383

SPECIAL 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: K132874

Date prepared: 13 July 2026

II. DEVICE

Trade Name: LumenCare Azure

Product Classification: Class II

Common Name: LumenCare Azure

Regulation Number: 21 CFR § 892.5700

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

Product Code: JAQ

III. PREDICATE DEVICE

Predicate Device #: K132874

Predicate Trade Name: LumenCare Azure Set F6, 150cm,
LumenCare Azure Set 5F, 150 cm
LumenCare Azure Set 5F, 140 cm

IV. DEVICE DESCRIPTION

The device will function as catheter for intraluminal brachytherapy treatments. This type of applicator is commonly used for brachytherapy for lumen type body sites.
The device will consist of a plastic catheter which can be fed into a lumen directly or via a biopsy channel of an endoscope to bring the catheter to the treatment area in the required body site.
With the use of an adapter the catheter can be connected directly to an afterloader.
The LumenCare Azure can be used:

- During a complete imaging, planning and treatment cycle.
- In combination with the following afterloaders:
  - microSelectron HDR
  - Flexitron HDR/Cobalt
- In combination with Oncentra Brachy or Oncentra Prostate treatment planning software.

The LumenCare Azure is available in 5F diameter and in two different lengths (140cm, 150cm) with a round tip. The catheter can be used for image based planning, i.e. X-ray (with markers).
The LumenCare Azure is specifically manufactured for the Elekta/Nucletron remote afterloaders. The catheter is connected to the afterloader with an adapter.
Insertion of the catheter can be done directly into a lumen or with an insertion guidance for example an endoscope. To avoid kinking a guide wire is recommended to be used, which is inserted in the catheter before insertion into the lumen.
When the catheter is in position the endoscope is removed gently while holding the catheter in position with the guide wire.
After removal of the endoscope the catheter will be immobilized and the guide wire removed.
The guide wire is not part of the applicator and not delivered with the applicator.

Figure 1 Illustration of the LumenCare Azure

The subject device has the same technological characteristics as the predicate device, except for the packaging configuration.
The modification consists of a change to a single pouch sterile barrier system. No changes were made to:

- device materials
- design or functional characteristics
- sterilization modality
- clinical performance

The modification does not alter the fundamental scientific technology of the device.

V. INTENDED USE / INDICATIONS for USE

The LumenCare Azure is intended for intraluminal brachytherapy and is used for treatment of lung or other lumen, e.g. bronchus and bile duct. The LumenCare Azure is designed to fit in the working channel of an endoscope.

VI. INDICATIONS for USE COMPARISON

The intended use of the device is identical to that of the predicate device cleared under K132874.

VII. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE

The subject device has the same technological characteristics as the predicate device, except for the packaging configuration.
The modification mainly consists of a change to a single pouch sterile barrier system.
No changes were made to:

- device materials
- design or functional characteristics
- sterilization modality
- clinical performance

The device remains compatible with the same imaging modalities (CT, X-ray, and cone beam imaging) as the predicate device.
The modifications do not alter the fundamental scientific technology of the device.

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). Performance testing was conducted to evaluate the effect of the packaging modification on device safety and effectiveness.

Risks associated with the packaging change were identified and mitigated. Identified risks included:

- loss of sterility
- packaging damage during transport and storage

Verification and validation activities were designed to confirm that these risks are adequately controlled and that no new risks were introduced.

<u>1. Packaging Validation</u>

- Packaging integrity testing performed per:
  - ASTM F88 (seal strength)
  - ASTM F1929 (dye penetration)
  - ASTM F2096 (bubble emission)
- Objective: Confirm sterile barrier integrity of the single pouch system
- Result:
  - All acceptance criteria met
  - No seal failures or integrity breaches observed

<u>2. Transport Simulation Testing</u>

- Conducted per ASTM D4169 distribution testing

- Simulated real-world shipping and handling conditions
- Objective: Ensure packaging withstands distribution stresses
- Result:
  - Packaging maintained integrity post-testing
  - No damage impacting sterile barrier function observed

3. Accelerated Aging / Shelf-Life Testing

- Conducted per ASTM F1980
- Simulated 5-year shelf life (accelerated aging at elevated temperature)
- Acceptance Criteria:
  - Maintenance of packaging integrity
  - No material degradation affecting performance
- Result:
  - Packaging and device met all dimensional and integrity requirements after aging
  - No degradation impacting functionality or sterility

4. Sterile Barrier System Validation

- Pouch sealing process validated in accordance with:
  - ISO 11607-1
  - ISO 11607-2
- Validation included:
  - Process Characterization Study (PCS)
  - Operational Qualification (OQ)
  - Performance Qualification (PQ)
- Result:
  - Sealing processes demonstrated reproducibility and consistency
  - All sterile barrier system requirements met predetermined acceptance criteria

5. Sterilization Validation

- The package system was evaluated
  - Ethylene oxide (EO) sterilization validation conducted per ISO 11135
  - Included evaluation of the new pouch configuration
- Outcome:
  - Sterility Assurance Level (SAL) of 10^{-6} achieved
  - EO/ECH residuals within allowable limits
  - Packaging system compatible with sterilization process
  - Sterility risk are effectively mitigated

Summary of Results

All testing was successfully completed with no failures, deviations, or unresolved issues. Results demonstrate that:

- identified risks were effectively mitigated
- sterile barrier integrity is maintained
- packaging withstands transport and shelf life conditions
- no new hazards or increased risks were introduced

IX. SUSTANTIAL EQUIVALENCE CONCLUSION

The performance testing, conducted within a risk management framework, demonstrates that the change to a single pouch packaging configuration does not adversely affect the safety or effectiveness of the device. All identified risks have been appropriately controlled and verified, and no new risks were introduced.

The subject device remains substantially equivalent to the predicate device, as the modification:

- maintains sterility and device integrity
- preserves imaging compatibility and performance
- does not introduce new or increased risks
- does not affect intended use or technological characteristics

Therefore, the subject device is considered substantially equivalent to the predicate device.