April 16, 2026

Abbott Medical
Katee Perez Anderson
Regulatory Affairs Specialist
6901 Preston Rd.
Plano, Texas 75024

Re: K253907
Trade/Device Name: Disposable Radiofrequency Cannula
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: December 5, 2025
Received: December 5, 2025

Dear Katee Perez Anderson:

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,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.04.16 14:37:43 -04'00'

for Jaime Raben, Ph.D.
Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine Devices
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. | K253907 |

Please provide the device trade name(s).

Disposable Radiofrequency Cannula

Please provide your Indications for Use below.

The Disposable Radiofrequency Cannulas, in combination with approved compatible generators and electrodes, are indicated as an aid in the management of pain in the peripheral nervous system. Examples include facet denervation, trigeminal rhizotomy, and related functional neurosurgical procedures. These are single-use-only products.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

# 510(k) Summary

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|---|---|
| **510(k) Number:** | K253907 |
| **510(k) Type:** | Traditional 510(k) |
| **Date Prepared:** | December 5, 2025 |
| **Manufacturer Name & Address:** | Abbott Medical<br>5050 Nathan Lane North<br>Plymouth, MN, 55442 USA |
| **Primary Correspondent:** | Katee Perez Anderson<br>Regulatory Affairs Specialist<br>(945) 256 9915<br>katee.perez@abbott.com |
| **Secondary Correspondent:** | Jenna Roycraft<br>Associate Director Regulatory Affairs<br>(972) 526 4645<br>jenna.roycraft@abbott.com |

## Device Information

| | |
|---|---|
| **Trade Name:** | Disposable Radiofrequency Cannula |
| **Common Name:** | Radiofrequency lesion probe |
| **Class:** | II |
| **Classification Name:** | 882.4725 Radiofrequency lesion probe |
| **Product Code:** | GXI |
| **Predicate Device 510(k)s:** | K090955 (Smith & Nephew RF Cannulae) (Primary),<br>K000073 (Mercury Medical Disposable Radiofrequency Cannula),<br>K042375 ([Technomed] Disposable Cannula), |
| **Reference Device 510(k):** | K242841 (Disposable RF Electrode) |
| **Device Description:** | Abbott Medical Radiofrequency (RF) Cannulas, also called needles, are part of the Radiofrequency Ablation (RFA) system. The RFA System is used to create heat lesions on nerves by interrupting the pain signals generated from the target nerve. The Disposable RF Cannula is a small hollow needle, with a layer of insulation and an exposed, sharp tip. During clinical use, the Cannula is inserted parallel to the targeted nerve, the stylet |

is removed and discarded. An electrode, or probe, connected to the RF generator is inserted through the Cannula, which sends radiofrequency waves through the uninsulated portion, or active tip, to the targeted nerve which lesions the targeted nerve. A dispersive grounding pad provides a return path for the applied RF current.

The RF Cannulas consists of a stylet, stylet cap, hub, and needle shaft. The subject device is a product family made of three model types; the Classic, Select and SMK Cannulas; which differ in hub material, hub design and insulation material, and vary in shaft length, active tip length, and gauge size. The RF Cannula is provided as sterile (using ethylene oxide) and is a single-use product.

**Indications for Use:** The Disposable Radiofrequency Cannulas, in combination with approved compatible generators and electrodes, are indicated as an aid in the management of pain in the peripheral nervous system. Examples include facet denervation, trigeminal rhizotomy, and related functional neurosurgical procedures. These are single-use-only products.

## Comparison of Characteristics with the Predicate Devices

Abbott Medical is submitting this traditional 510(k) seeking market clearance for the Disposable RF Cannula including cumulative design changes that have been made since latest clearances (K090955, K000073, K042375) and proposed changes that are being made to the device. The subject device and predicate devices have different indication for use but the same intended use, which is for lesioning of neural tissue in the nervous system by allowing access to the targeted nerve site and directing RF energy to the targeted nerve site. The difference in indications for use does not change the intended use. The indications for use has been updated to align with the indications for use statement of the compatible IonicRF Generator and the Disposable RF Electrode, since the subject device must be used together with these devices in order to treat patients with neural pain.

The subject device and predicate device have similar technological characteristics. Any differences between the subject device and predicate devices do not raise different questions of safety and effectiveness as confirmed by performance testing, biocompatibility testing, sterilization validation, packaging validation, and shelf-life validation, which is also comparable to the reference device. Therefore, Abbott has determined the Disposable RF Cannula to be substantially equivalent to the predicate devices.

## Non-Clinical Testing Summary

Non-clinical testing was performed to confirm that the physical, electrical, and biological properties of the Disposable RF Cannulas met all the performance requirements and specifications. The following testing was provided in support of the substantial equivalence determination:

- Biocompatibility: The Disposable RF Cannula was evaluated per ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-12, ISO 10993-18, and ISO 10993-23. Testing included cytotoxicity, sensitization, irritation, and acute systemic toxicity.
- EMC and Electrical Safety: The Disposable RF Cannula was evaluated per IEC 60601-1, 60601-1-2, and 60601-2-2. Testing included assessment of the electrical safety of the device.

- Performance Testing: The Disposable RF Cannula was tested to verify the subject device meets product requirements for performance. Applicable standards include ISO 7864, ISO 9626, ISO 80369-7, and ISO 6009.
- Sterilization: The Disposable RF Cannula was tested to verify the subject device meets SAL $10^{-6}$ according to ISO 11135.
- Packaging and Shelf-Life: The Disposable RF Cannula packaging was tested to verify the packaging meets product requirements and maintains its integrity during conditions normally encountered during sterilization, handling, shipping, and storage. To verify the shelf-life and package integrity, the effects of aging on the device packaging were evaluated through accelerated aging testing. Applicable standards include ASTM F2825, and ASTM D4169.

## Clinical Testing

Based on substantial equivalence to the predicate device and results of testing, clinical studies were not required to establish substantial equivalence of the Disposable RF Cannula.

## Substantial Equivalence Conclusion

Based on comparison of intended use and technical characteristics, the Disposable RF Cannula is substantially equivalent to the predicate devices. The results of testing confirm that the subject device meets all requirements and specifications. Any differences in the subject and predicate devices do not raise new types of questions of safety and effectiveness. Therefore, the Disposable RF Cannula is substantially equivalent to the predicate devices.