June 3, 2024

Medtronic, Inc.
Erin Roquemore
International Regulatory Affairs Specialist
710 Medtronic Pkwy NE
Minneapolis, Minnesota 55432

Re: K241259
Trade/Device Name: Amplatz™ Goose Neck Snare Kit
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MMX, DXE
Dated: May 3, 2024
Received: May 6, 2024

Dear Erin Roquemore:

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.

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,

Gregory W. O'connell -S
Digitally signed by Gregory W. O'connell -S
Date: 2024.06.03 15:39:37 -04'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241259

Device Name
Amplatz™ Goose Neck Snare Kit

Indications for Use *(Describe)*
The Amplatz Goose Neck Snare kit is intended for use in the cardiovascular system to retrieve and manipulate foreign bodies.

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

Applicant/ Submitter	Medtronic, Inc. 4600 Nathan Lane N Plymouth, MN 55442
Contact Person	Erin Roquemore International Regulatory Affairs Specialist Tel: 763-398-7657 Email: erin.p.roquemore@medtronic.com
Date Prepared	May 2024
Device Trade Name	Amplatz™ Goose Neck Snare Kit
Device Common Name	Intravascular Retrieval Devices
Classification Name	Percutaneous Retrieval Device
Regulation Number	21 CFR 870.5150
Classification	Class II
Classification Panel	Device, Percutaneous Retrieval
Product Code	MMX
Product Code	DXE
Predicate Device	Amplatz™ Goose Neck Snare Kit/Catheter
Predicate 510(k) Number	K972511
Device Description	The Amplatz Goose Neck Snare kit (Snare device) contains the snare, snare catheter, snare introducer, and torque device. The snare is made of a nitinol cable and a gold-plated tungsten loop. The preformed snare loop can be introduced through catheters without risk of snare deformation because of the snare's superelastic construction. The snare catheter contains a platinum-iridium, radiopaque marker band.
Indications for Use	The Amplatz Goose Neck Snare kit is intended for use in the cardiovascular system to retrieve and manipulate foreign bodies.
Comparison of Technological Characteristics with the Predicate Device	The proposed device has the same characteristics as the predicate device, with the exception of the following modifications: • Indications for use - narrowed anatomical sites of intended use to cardiovascular system • Change in packaging dimensions • Updates to labeling to meet latest International Standards • Specification change for tensile force

Performance data The following performance data were provided in support of substantial equivalence determination:

- **Biocompatibility**
  - ISO MEM Elution Using L-929 Mouse Fibroblast Cells
  - ISO Guinea Pig Maximization Sensitization Test
  - ISO Intracutaneous Irritation Test
  - ISO Acute Systemic Injection Test
  - ISO Materials Mediated Rabbit Pyrogen
  - ASTM Hemolysis Assay - Direct Contact Method
  - Complement Activation SC5b-9 Assay
  - ISO Standard Thrombogenicity in Canine
  - ISO Standard Thrombogenicity in Ovine

- **Design Verification**
  - Snare Catheter Length
  - Snare Catheter OD
  - Snare Catheter Tip OD
  - Guide Catheter Compatibility

- **Packaging Validation**
  - Visual Inspection (Gross Physical Damage to Package System)
  - Visual Inspection (Label Legibility and Adhesion)
  - Visual Inspection (Carton)
  - IFU / eIFU Leaflet (Legibility)
  - Visual Inspection (Device)
  - Visual Inspection (Sterile Barrier Seal Integrity and Width)
  - Package Integrity (Bubble Test)
  - Peel-Open/Aseptic Presentation
  - Seal Strength Test

- **Shelf Life**
  - Catheter Visual Inspection
  - Snare Catheter Tip Configuration
  - Snare Catheter ID and OD
  - Snare Catheter Length
  - Snare OD
  - Functional
  - Catheter Shaft Tensile Strength
  - Hub Bond Tensile Strength
  - Snare Catheter Tip OD
  - Guide Catheter Compatibility

- **Sterilization**
  - Sterilization validation per ISO 11135, overkill half cycle approach
  - Sterilization Residuals Testing

Animal testing was not required for the determination of substantial equivalence.
Clinical testing was not required for the determination of substantial equivalence.

The testing conducted demonstrates that all acceptance criteria were met, and the device meets product specifications.

Conclusion Based on the same general intended use, technological characteristics, and substantially equivalent safety and performance profile as demonstrated by the testing in this submission, Medtronic, Inc. concludes the proposed Amplatz Goose Neck Snare Kit to be substantially equivalent to the predicate Amplatz Goose Neck Snare Kit.