December 19, 2025

Medtronic, Inc.
Ryan Peterfeso
Sr. Regulatory Affairs Specialist
8200 Coral Sea St. NE
Mounds View, Minnesota 55112

Re: K253409
Trade/Device Name: C320LBB Delivery System (C320LBBS45), C320LBB Delivery System (C320LBBS48), C320LBB Delivery System (C320LBBL45), C320LBB Delivery System (C320LBBL48)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 3, 2025
Received: November 3, 2025

Dear Ryan Peterfeso:

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,

JESSICA L. BATISTA -S

Digitally signed by JESSICA L. BATISTA -S
Date: 2025.12.19 17:12:36 -05'00'

Jessica Batista Bertolini
Acting Assistant Director
Division of Cardiac
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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)*
K253409

Device Name
C320LBB Delivery System (C320LBBS45), C320LBB Delivery System (C320LBBS48), C320LBB Delivery System (C320LBBL45), C320LBB Delivery System (C320LBBL48)

Indications for Use *(Describe)*
This non-therapeutic delivery system is intended to aid in the introduction and placement of cardiac leads into the right chambers of the heart. The leads are implanted in patients who are indicated for a cardiac implantable electronic device (CIED) for treatment of heart rhythm disorders. Refer to the respective CIED instructions for use for details about the types of heart rhythm abnormalities or patient conditions treated by each type of CIED.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Date Prepared:	September 30, 2025
Submitter:	Medtronic, Inc. Medtronic Cardiac Rhythm Management 8200 Coral Sea Street N.E. Mounds View, MN 55112 Establishment Registration Number: 2182208
Contact Person:	Ryan Peterfeso Senior Regulatory Affairs Specialist Medtronic Cardiac Rhythm Management 8200 Coral Sea Street N.E. Mounds View, MN 55112 Phone: 763.526.1013 Fax: N/A Email: ryan.r.peterfeso@medtronic.com

General Information

Trade Name:	**C320LBB Delivery System (C320LBBS45), C320LBB Delivery System (C320LBBS48), C320LBB Delivery System (C320LBBL45), C320LBB Delivery System (C320LBBL48)**
Common Name:	Catheter Delivery System
Regulation Number:	21 CFR 870.1250
Product Code:	DQY
Classification:	Class II
Classification Panel:	Cardiovascular
Predicate Device:	C315 Delivery Catheter (K250558)

Device Description

The C320LBB delivery system is composed of a single-use, disposable, fixed-shape catheter with integrated hemostasis valve, two integrated radiopaque marker bands at the distal segment and a dilator. These components are used together to provide a flexible and hemostatic conduit for insertion of intravascular devices into the right chambers of the heart.

Indications for Use

This non-therapeutic delivery system is intended to aid in the introduction and placement of cardiac leads into the right chambers of the heart. The leads are implanted in patients who are indicated for a cardiac implantable electronic device (CIED) for treatment of heart rhythm disorders. Refer to the respective CIED instructions for use for details about the types of heart rhythm abnormalities or patient conditions treated by each type of CIED.

Substantially Equivalent Device

The C320LBB delivery system uses similar technology and has the same Indications for Use and similar function, materials and method of operation to the following predicate device:

- C315 Delivery Catheter (K250558, cleared March 27, 2025)

The C320LBB delivery system uses the braid and Vestamid material from the following reference device:

- Attain Select II + Sure Valve Catheter (K222873, cleared November 7th, 2022)

Summary of Technological Differences to the Predicate Device

The C320LBB delivery system has two distinct curve shapes (large and small) designed to reach the Left Bundle Branch Area (LBBA), which are different from the curve shapes available in the C315 delivery catheter product family. Along with the curve differences, there are also differences in the materials and dimensions between the subject device and predicate.

Summary of Non-Clinical Data

Device integrity testing was performed to support the equivalency of the C320LBB delivery system to the predicate device. Testing included mechanical, functional, and biocompatibility testing. The C320LBB delivery system met all specified design and performance requirements.

Summary of Clinical Data

No clinical investigation has been performed for this device. This section is not applicable.

Sterilization Validation

The C320LBB delivery system will be sterilized using a validated Ethylene Oxide (EtO) sterilization process.

Conclusion

The results of the verification and validation testing met the specified acceptance criteria and did not raise new or different questions of safety or effectiveness. Therefore, the C320LBB delivery system described in this submission results in a device that is substantially equivalent to the respective predicate.