January 17, 2025

Medtronic Ireland
Michelle Greaney
Senior Regulatory Affairs Specialist
Parkmore Business Park West
Galway, H91 VY19
Ireland

Re: K251970
Trade/Device Name: Sprinter Legend Rapid Exchange Balloon Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Percutaneous Transluminal Coronary Angioplasty (Ptca) Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: June 26, 2025
Received: December 18, 2025

Dear Michelle Greaney:

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,

Jenny R. Katsnelson -S

Digitally signed by Jenny R. Katsnelson -S
Date: 2026.01.17 17:15:13 -05'00'

for Lydia Glaw
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)*
K251970

Device Name
Sprinter Legend Rapid Exchange Balloon Dilation Catheter

Indications for Use *(Describe)*
The Sprinter Legend RX and OTW 1.25mm Balloon Dilatation Catheter is indicated as a pre dilatation catheter for enlarging coronary luminal diameters during PCI procedures.

The Sprinter Legend RX 1.5-4.0mm balloon dilatation catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The balloon dilatation catheter (balloon models 2.25 mm - 4.0 mm) is also indicated for post-delivery expansion of balloon expandable stents.

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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Traditional 510(k) Summary per 21 CFR 807.92

Submitter: Medtronic Ireland
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Date Prepared: January 14, 2026

Trade Name: Sprinter Legend Rapid Exchange Balloon Dilatation Catheter

Common Name: Catheter

Device Classification: Class II

Classification Name: Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter

Classification Panel: Cardiovascular

Classification Regulation: 21 CFR 870.5100

Product Code: LOX

Predicate Device:

Predicate Device Clearance/Approval #	Predicate Device Name
P790017/S096	Sprinter Legend Rapid Exchange Balloon Dilatation Catheter (1.5 to 4.0mm)
K103095	Sprinter Legend Rapid Exchange Balloon Dilatation Catheter (1.25mm)
*On October 08th 2010, PTCA devices were reclassified to Class II in the U.S.	

Device Description:

Sprinter Legend Rapid Exchange Balloon Dilatation Catheter is a percutaneous transluminal coronary angioplasty (PTCA) device. The proximal end comprises of a luer hub, strain relief and a hypotube and stiffening wire subassembly (proximal shaft assembly). The distal end comprises of an inflatable balloon, dual lumen tip (guidewire lumen and the inflation lumen) and radiopaque marker bands. The distal shaft includes a hydrophilic coating to aid in device advancement to the target lesion. The guidewire lumen at the distal end enables the use of a 0.014" guidewire to position the device during use. Radiopaque balloon markers enable accurate placement at the target lesion. Exit markers on the proximal shaft indicate the exit of the balloon tip out of the guide catheter for brachial and femoral approaches.

Indication For Use:

1.25mm size	The Sprinter Legend RX and OTW 1.25 mm Balloon Dilatation Catheter is indicated as a pre dilatation catheter for enlarging coronary luminal diameters during PCI procedures.
1.5 to 4.0mm sizes	The Sprinter Legend RX 1.5-4.0mm balloon dilatation catheter is indicated for balloon dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. The balloon dilatation catheter (balloon models 2.25mm-4.0mm) is also indicated for post-delivery expansion of balloon expandable stents.

Comparison to Predicate Devices:

The subject device is substantially equivalent to the predicate device, which is Medtronic's own legally market device, and have comparable safety and performance. There is no change in sterilization method, sterility assurance level and shelf life. The material difference does not introduce different questions of safety or effectiveness compared to the predicate, as demonstrated by the bench testing.

Summary of Non-Clinical Data:

The following non-clinical tests were performed to evaluate and demonstrate substantial equivalence between the subject device and the predicate device. The results confirmed that the devices are substantially equivalent. The following tests were performed:

Biocompatibility Evaluation (conducted per ISO 10993 standards):

- Chemical Characterization
- Toxicological Risk Assessment
- Cytotoxicity
- Acute Systemic Toxicity
- Hemocompatibility
  - Hemolysis
  - Complement Activation
  - Partial Thromboplastin Time (PTT)
  - Platelet/Leucocyte Count
- Sensitization
- Irritation
- Material Mediated Pyrogenicity

Performance Testing included:

- Exit Marker Locations
- Shaft OD (Outer Diameter) - Coated Hypotube
- Product Removal from the Hoop
- Product Interface testing
  - Looper
  - Y-Adaptors
  - Guide Catheters
  - Guidewires
- Delivery & Retraction Characterization (Track Assessment)
- PTFE Particulate Characterization Testing
- PTFE Durability Characterization

All test results met the acceptance criteria, which are consistent with the predicate device, demonstrating that the subject device meets established performance specifications and is suitable for its intended use.

Summary of Clinical Data:

No clinical testing was required for this 510(k) submission.

Conclusion from Data:

The differences between the subject device and predicate device have been evaluated through non-clinical testing, which demonstrates that the subject device is substantially equivalent to the predicate device.