

K251970 Sprinter Legend Rapid Exchange Balloon Dilatation Catheter

Jan 17, 2026
205 days to decision

K251970 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k251970/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Jun 26, 2025
Decision date	Jan 17, 2026
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic, Ireland
Location	Shoreview, MN, US
Contact	Michelle Greaney
510(k) history	7 submissions · 7 cleared · 2006-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k251970/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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