FDA 510(k) Premarket Notification

K261759 Euphora Rapid Exchange (RX) Balloon Dilatation Catheter

CLEARED

Jul 27, 2026
60 days to decision

K261759 · Product code: **LOX** · Cardiovascular
Source: https://www.510kdatabase.net/k261759/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	May 28, 2026
Decision date	Jul 27, 2026
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Ireland**
Location	Shoreview, MN, US
Contact	Sarah Grant
510(k) history	8 submissions · 8 cleared · 2006-2026