

K143480 Euphora Rapid Exchange Balloon Dilatation CatheterApr 2, 2015
115 days to decisionK143480 · Product code: **LOX** · Cardiovascular
Source: <https://www.510kdatabase.net/k143480/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheters, Transluminal Coronary Angioplasty, Percutaneous (LOX)
Date received	Dec 8, 2014
Decision date	Apr 2, 2015
Days to decision	115 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	John Kilmartin
Website	https://www.medtronic.com
510(k) history	209 submissions · 208 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...

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