

K113468 ELM PTA BALLON DILATATION CATHETERDec 20, 2011
28 days to decisionK113468 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k113468/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Nov 22, 2011
Decision date	Dec 20, 2011
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Creagh Medical, Ltd.
Location	North Reading, MA, US
Contact	MAUREEN O'CONNELL
510(k) history	5 submissions · 5 cleared · 2010-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113468/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026