

**K180007 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter**Apr 19, 2018  
107 days to decisionK180007 · Product code: **LIT** · Cardiovascular  
Source: <https://www.510kdatabase.net/k180007/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Jan 2, 2018
Decision date	Apr 19, 2018
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Creagh Medical, Ltd.</b>
Location	North Reading, MA, US
Contact	Shane Costello
510(k) history	5 submissions · 5 cleared · 2010-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180007/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 30, 2026