

K171251 014 Hydrophilic Coated PTA Balloon Dilatation Catheter

Sep 8, 2017
133 days to decision

K171251 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k171251/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Apr 28, 2017
Decision date	Sep 8, 2017
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Creagh Medical
Location	Ballinasloe, IE
Contact	Shane Costello
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k171251/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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