

K242419 018 Hydrophilic Coated OTW PTA Balloon Dilatation Catheter

Nov 15, 2024
92 days to decision

K242419 · Product code: **LIT** · Cardiovascular
Source: <https://www.510kdatabase.net/k242419/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Aug 15, 2024
Decision date	Nov 15, 2024
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Creagh Medical Ltd. Dba Surmodics, Inc.
Location	Ballinasloe, IE
Contact	Brendan McCormack
510(k) history	1 submissions · 1 cleared · 2024-2024

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k242419/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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