

K211044 Sublime Radial Access 018 RX Dilatation CatheterJun 16, 2021
69 days to decisionK211044 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k211044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Angioplasty, Peripheral, Transluminal (LIT)
Date received	Apr 8, 2021
Decision date	Jun 16, 2021
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Creagh Medical Ltd. (A Wholly Owned Subsidiary of Surmodics,
Location	Ballinasloe, IE
Contact	Holly Ramirez
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211044/> 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