

**K260043 Smart Reactors Camouflage Coated Extracorporeal  
Cardiopulmonary Tubing Set (SR180C)**Feb 23, 2026  
47 days to decisionK260043 · Product code: DWF · Cardiovascular  
Source: <https://www.510kdatabase.net/k260043/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF)
Date received	Jan 7, 2026
Decision date	Feb 23, 2026
Days to decision	47 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Smart Reactors</b>
Location	Galway, IE
Contact	Mark Brassil
Website	<a href="https://smartreactors.com">https://smartreactors.com</a>
510(k) history	1 submissions · 1 cleared · 2026-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Psephos Biomedica</b>
Contact	Robin Stephens

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260043/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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