

**K250459 DMRX 100ml Empty Container Solution**Apr 18, 2025  
59 days to decisionK250459 · Product code: **KPE** · General Hospital  
Source: <https://www.510kdatabase.net/k250459/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Container, I.v. (KPE)
Date received	Feb 18, 2025
Decision date	Apr 18, 2025
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	DMRX 250ml Empty Container Solution; DMRX 500ml Empty Container Solution; DMRX 1000ml Empty Container Solution

**APPLICANT**

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Company	<b>Technoflex Sas.</b>
Location	Bidart, FR
Contact	Dominique Saint Ellier
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mdi Consutants, Inc.</b>
Contact	Vaibhav Rajal

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

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