

**K242578 EVOLVE Nitric Oxide Delivery System**Jan 3, 2025  
127 days to decisionK242578 · Product code: **MRN** · AnesthesiologySource: <https://www.510kdatabase.net/k242578/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Aug 29, 2024
Decision date	Jan 3, 2025
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Mallinckrodt Manufacturing, LLC</b>
Location	Madison, WI, US
Contact	Jennifer Brett
510(k) history	4 submissions · 4 cleared · 2020-2025

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