

K240410 EVOLVE Nitric Oxide Delivery SystemMay 28, 2024
106 days to decisionK240410 · Product code: **MRN** · AnesthesiologySource: <https://www.510kdatabase.net/k240410/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Feb 12, 2024
Decision date	May 28, 2024
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Malinckrodt Manufacturing, LLC
Location	Madison, WI, US
Contact	Jennifer Brett
510(k) history	1 submissions · 1 cleared · 2024-2024

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