

K222930 Evolve Nitric Oxide Delivery SystemDec 6, 2023
436 days to decisionK222930 · Product code: **MRN** · Anesthesiology
Source: <https://www.510kdatabase.net/k222930/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Sep 26, 2022
Decision date	Dec 6, 2023
Days to decision	436 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mallinckrodt Manufacturing, LLC
Location	Madison, WI, US
Contact	David Trueblood
510(k) history	4 submissions · 4 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	Mallinckrodt Hospital Products, Inc.
Contact	David Trueblood

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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