

**K211153 Inomax DSIR**Apr 20, 2023  
731 days to decisionK211153 · Product code: **MRN** · Anesthesiology  
Source: <https://www.510kdatabase.net/k211153/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Apr 19, 2021
Decision date	Apr 20, 2023
Days to decision	731 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	David Trueblood
510(k) history	4 submissions · 4 cleared · 2020-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mallinckrodt Hospital Products, Inc.</b>
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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