

K200389 INOmax DSIR PlusJun 17, 2020
120 days to decisionK200389 · Product code: **MRN** · Anesthesiology
Source: <https://www.510kdatabase.net/k200389/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Feb 18, 2020
Decision date	Jun 17, 2020
Days to decision	120 days
Third-party review	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

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