

K201339 The NOxBOXi Nitric Oxide Delivery SystemJun 19, 2020
30 days to decisionK201339 · Product code: **MRN** · Anesthesiology
Source: <https://www.510kdatabase.net/k201339/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	May 20, 2020
Decision date	Jun 19, 2020
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Praxair, Inc.
Location	Tonawanda, NY, US
Contact	Dave Loflin
Website	http://www.praxair.com
510(k) history	2 submissions · 2 cleared · 2005-2020

Praxair, Inc. is a leading global industrial gases and engineering company with a manufacturing facility in Tonawanda, US. The company specializes in gas supply systems and related technologies across multiple industrial sectors. Praxair has received FDA 510(k) clearances from total submissions. The company's regulatory focus is entirely concentrated on Anesthesiology devices, with clearances spanning from 2005 to 2020. This represents a historical record of FDA regulatory activity; the company has not received clearances in more than five years. Praxair's cleared Anesthe...

REGULATORY CONSULTANT

Consulting firm	Emergo Global Consulting, LLC
Contact	Sarah Marie Fitzgerald

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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Device record: <https://www.510kdatabase.net/k201339/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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