

K193481 AeroNOx 2.0 Nitric Oxide Titration & Monitoring System

Mar 10, 2020
84 days to decisionK193481 · Product code: **MRN** · Anesthesiology
Source: <https://www.510kdatabase.net/k193481/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Dec 17, 2019
Decision date	Mar 10, 2020
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	International Biomedical
Location	Austin, TX, US
Contact	Amy Pieper
510(k) history	8 submissions · 8 cleared · 2014-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193481/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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