

K143213 INOmax DSIR Plus MRIJul 10, 2015
242 days to decisionK143213 · Product code: **MRN** · Anesthesiology
Source: <https://www.510kdatabase.net/k143213/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Nov 10, 2014
Decision date	Jul 10, 2015
Days to decision	242 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ino Therapeutics/Ikaria
Location	Madison, WI, US
Contact	Robert Bovy
510(k) history	2 submissions · 2 cleared · 2013-2015

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