

**K110344 INOMAX DSIR (DELIVERY SYSTEM)**Jun 24, 2011  
140 days to decisionK110344 · Product code: **MRN** · Anesthesiology  
Source: <https://www.510kdatabase.net/k110344/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Feb 4, 2011
Decision date	Jun 24, 2011
Days to decision	140 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ino Therapeutics</b>
Location	Middleton, WI, US
Contact	LARRY LEPLEY
510(k) history	8 submissions · 8 cleared · 2005-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110344/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 24, 2026