

K110635 INOMAX DS(IR) (DELIVERY SYSTEM)Jun 23, 2011
111 days to decisionK110635 · Product code: **MRN** · Anesthesiology
Source: <https://www.510kdatabase.net/k110635/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Mar 4, 2011
Decision date	Jun 23, 2011
Days to decision	111 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ino Therapeutics, LLC/Db a Icaria
Location	Port Allen, LA, US
Contact	LARRY LEPLEY
510(k) history	2 submissions · 2 cleared · 2011-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110635/> Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026