

K081691 INOMAX DS (DELIVERY SYSTEM)Aug 28, 2008
72 days to decisionK081691 · Product code: **MRN** · AnesthesiologySource: <https://www.510kdatabase.net/k081691/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Jun 17, 2008
Decision date	Aug 28, 2008
Days to decision	72 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ino Therapeutics, LLC
Location	Clinton, NJ, US
Contact	DAVID TRUEBLOOD
510(k) history	5 submissions · 5 cleared · 2007-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081691/> 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