

K080484 INOMAX DS (DELIVERY SYSTEM), MODEL 10003Aug 6, 2008
166 days to decisionK080484 · Product code: **MRN** · Anesthesiology
Source: <https://www.510kdatabase.net/k080484/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Feb 22, 2008
Decision date	Aug 6, 2008
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ino Therapeutics
Location	Middleton, WI, US
Contact	DAVID TRUEBLOOD
510(k) history	8 submissions · 8 cleared · 2005-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k080484/> 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