

K061901 INO THERAPEUTICS INOMAX DS (DELIVERY SYSTEM), MODEL 10003Dec 14, 2006
162 days to decisionK061901 · Product code: **MRN** · Anesthesiology
Source: <https://www.510kdatabase.net/k061901/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Apparatus, Nitric Oxide Delivery (MRN) |
| Date received | Jul 5, 2006 |
| Decision date | Dec 14, 2006 |
| Days to decision | 162 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061901/> 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