FDA 510(k) Premarket Notification

K130605 INOMAX DSIR (DELIVERY SYSTEM)

CLEARED

May 2, 2013
56 days to decision

K130605 · Product code: **MRN** · Anesthesiology
Source: https://www.510kdatabase.net/k130605/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Mar 7, 2013
Decision date	May 2, 2013
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k130605/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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