FDA 510(k) Premarket Notification

K093922 INOMAX DS

CLEARED

Apr 15, 2010
114 days to decision

K093922 · Product code: **MRN** · Anesthesiology
Source: https://www.510kdatabase.net/k093922/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Nitric Oxide Delivery (MRN)
Date received	Dec 22, 2009
Decision date	Apr 15, 2010
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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