FDA 510(k) Premarket Notification

K081691 INOMAX DS (DELIVERY SYSTEM)

CLEARED

Aug 28, 2008
72 days to decision

K081691 · Product code: **MRN** · Anesthesiology
Source: 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