FDA 510(k) Premarket Notification

K230052 Inogen Rove 6

CLEARED

Jun 30, 2023
175 days to decision

K230052 · Product code: **CAW** · Anesthesiology
Source: https://www.510kdatabase.net/k230052/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Jan 6, 2023
Decision date	Jun 30, 2023
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inogen, Inc.**
Location	Goleta, CA, US
Contact	Sandra LeClair
510(k) history	4 submissions · 4 cleared · 2004-2024