FDA 510(k) Premarket Notification

K082566 MARK 5 NUVO LITE OCSI AND STD

CLEARED

Dec 3, 2008
90 days to decision

K082566 · Product code: **CAW** · Anesthesiology
Source: https://www.510kdatabase.net/k082566/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Generator, Oxygen, Portable (CAW)
Date received	Sep 4, 2008
Decision date	Dec 3, 2008
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Nidek Medical Products, Inc.**
Location	Birmingham, AL, US
Contact	JENNIFER MCWILLIAMS
510(k) history	12 submissions · 12 cleared · 1988-2020