FDA 510(k) Premarket Notification

K991788 SALTER LABS PEP DEVICE

CLEARED

Aug 6, 1999
73 days to decision

K991788 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k991788/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	May 25, 1999
Decision date	Aug 6, 1999
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Salter Labs**
Location	Mchenry, IL, US
Contact	DUANE KAZAL
510(k) history	48 submissions · 48 cleared · 1978-2017