FDA 510(k) Premarket Notification

K963910 HEART NEBULIZER #100609

CLEARED

Dec 16, 1996
77 days to decision

K963910 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k963910/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Sep 30, 1996
Decision date	Dec 16, 1996
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Vortran Medical Technology 1, Inc.**
Location	Mchenry, IL, US
Contact	GORDON A WONG
510(k) history	28 submissions · 28 cleared · 1984-2021