FDA 510(k) Premarket Notification

K984085 RITEFLO SPACER

CLEARED

Aug 5, 1999
262 days to decision

K984085 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k984085/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Nov 16, 1998
Decision date	Aug 5, 1999
Days to decision	262 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Aeromax Technologies, Inc.**
Location	Phoenix, AZ, US
Contact	ALLAN M WACHTER
510(k) history	1 submissions · 1 cleared · 1999-1999