FDA 510(k) Premarket Notification

K950206 FISONEB(R) II

CLEARED

Jan 27, 1995
9 days to decision

K950206 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k950206/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Jan 18, 1995
Decision date	Jan 27, 1995
Days to decision	9 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fisons Corp.**
Location	Mchenry, IL, US
Contact	JOAN M WOODCOOK
510(k) history	3 submissions · 3 cleared · 1977-1995