FDA 510(k) Premarket Notification

K963793 OPTIVENT

CLEARED

Apr 16, 1997
205 days to decision

K963793 · Product code: **CAF** · Anesthesiology
Source: https://www.510kdatabase.net/k963793/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nebulizer (direct Patient Interface) (CAF)
Date received	Sep 23, 1996
Decision date	Apr 16, 1997
Days to decision	205 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Health Care Products, Inc.**
Location	Cedar Grove, NJ, US
Contact	LAUREN R ZIEGLER
510(k) history	1 submissions · 1 cleared · 1997-1997