FDA 510(k) Premarket Notification

K960401 ULTIMATE SEAL

CLEARED

Jun 20, 1996
143 days to decision

K960401 · Product code: **KGB** · Anesthesiology
Source: https://www.510kdatabase.net/k960401/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Oxygen, Non-rebreathing (KGB)
Date received	Jan 29, 1996
Decision date	Jun 20, 1996
Days to decision	143 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Hans Rudolph, Inc.**
Location	Mchenry, IL, US
Contact	KEVIN RUDOLPH
510(k) history	11 submissions · 11 cleared · 1979-2008