FDA 510(k) Premarket Notification

K901623 AMBU OXYGEN REGULATOR

CLEARED

Apr 26, 1990
20 days to decision

K901623 · Product code: **CAN** · Anesthesiology
Source: https://www.510kdatabase.net/k901623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Regulator, Pressure, Gas Cylinder (CAN)
Date received	Apr 6, 1990
Decision date	Apr 26, 1990
Days to decision	20 days
Third-party review	No

APPLICANT

Company	**Flotec, Inc.**
Location	Indianapolis, IN, US
Contact	C KLOPSTAD
510(k) history	2 submissions · 2 cleared · 1990-1997