FDA 510(k) Premarket Notification

K911261 ERA 2000A

CLEARED

May 31, 1991
70 days to decision

K911261 · Product code: **BTL** · Anesthesiology
Source: https://www.510kdatabase.net/k911261/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Powered (resuscitator) (BTL)
Date received	Mar 22, 1991
Decision date	May 31, 1991
Days to decision	70 days
Third-party review	No

APPLICANT

Company	**Neotronics, Inc.**
Location	Mchenry, IL, US
Contact	JOE LAMBARDO
510(k) history	2 submissions · 2 cleared · 1980-1991