FDA 510(k) Premarket Notification

K863026 PULMANEX TM (MODIFICATION)

CLEARED

Aug 26, 1986
15 days to decision

K863026 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k863026/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Aug 11, 1986
Decision date	Aug 26, 1986
Days to decision	15 days
Third-party review	No

APPLICANT

Company	**Life Design Systems, Inc.**
Location	Mchenry, IL, US
Contact	GILBERT M KIRK
510(k) history	29 submissions · 29 cleared · 1982-1992