FDA 510(k) Premarket Notification

K894365 SINGLE PATIENT USE DISPOSABLE MANUAL RESUSCITATOR

CLEARED

Oct 6, 1989
84 days to decision

K894365 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k894365/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Jul 14, 1989
Decision date	Oct 6, 1989
Days to decision	84 days
Third-party review	No

APPLICANT

Company	**Puritan Bennett Corp.**
Location	Mchenry, IL, US
Contact	MARSHALL SMITH
510(k) history	110 submissions · 101 cleared · 1976-2007