FDA 510(k) Premarket Notification

K970991 DATEX ENGSTOM MANUAL RESUSCITATOR

CLEARED

Jun 16, 1997
89 days to decision

K970991 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k970991/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Mar 19, 1997
Decision date	Jun 16, 1997
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Promedic, Inc.**
Location	Indianapolis, IN, US
Contact	PAUL E DRYDEN
510(k) history	16 submissions · 14 cleared · 1995-2014