FDA 510(k) Premarket Notification

# K911971 MODIFIED SINGLE PATIENT USE DISP. MANUAL RESUSCIT.

**CLEARED**

Aug 9, 1991
98 days to decision

K911971 · Product code: **BTM** · Anesthesiology
Source: https://www.510kdatabase.net/k911971/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilator, Emergency, Manual (resuscitator) (BTM) |
| Date received | May 3, 1991 |
| Decision date | Aug 9, 1991 |
| Days to decision | 98 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

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