

K905002 SINGLE USE MANUAL RESUSCITATORSMar 29, 1991
142 days to decisionK905002 · Product code: **BTM** · AnesthesiologySource: <https://www.510kdatabase.net/k905002/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilator, Emergency, Manual (resuscitator) (BTM) |
| Date received | Nov 7, 1990 |
| Decision date | Mar 29, 1991 |
| Days to decision | 142 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Custom Medical, Inc. |
| Location | Mchenry, IL, US |
| Contact | GREGORY T POPP |
| 510(k) history | 3 submissions · 3 cleared · 1983-1991 |

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