

**K924216 AMBU SILICONE RESUSCITATOR INFAN/CHILD
W/OPEN RESO**Sep 16, 1992
43 days to decisionK924216 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k924216/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilator, Emergency, Manual (resuscitator) (BTM) |
| Date received | Aug 4, 1992 |
| Decision date | Sep 16, 1992 |
| Days to decision | 43 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Ambu, Inc. |
| Location | Walker, MI, US |
| Contact | DAVID LEE |
| 510(k) history | 33 submissions · 33 cleared · 1984-2005 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k924216/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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