

**K923976 AMBU SINGLE PATIENT USE PEEP VALVE**Jan 5, 1993  
151 days to decisionK923976 · Product code: **BYE** · Anesthesiology  
Source: <https://www.510kdatabase.net/k923976/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                            |
| Submission type       | Traditional   |
| Device classification | Attachment, Breathing, Positive End Expiratory Pressure (BYE) |
| Date received         | Aug 7, 1992   |
| Decision date         | Jan 5, 1993   |
| Days to decision      | 151 days  |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k923976/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 25, 2026