

**K945482 DISPOSABLE, CPAP OXYGEN MASK**Sep 19, 1995  
315 days to decisionK945482 · Product code: **BYG** · Anesthesiology  
Source: <https://www.510kdatabase.net/k945482/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Oxygen (BYG)
Date received	Nov 8, 1994
Decision date	Sep 19, 1995
Days to decision	315 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Fvtnks</b>
Location	Indianapolis, IN, US
Contact	PAUL E DRYDEN
510(k) history	4 submissions · 4 cleared · 1994-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945482/> 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 26, 2026