

**K880534 ZEPHYR**Sep 6, 1988  
210 days to decisionK880534 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k880534/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 9, 1988
Decision date	Sep 6, 1988
Days to decision	210 days
Third-party review	No

**APPLICANT**

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Company	<b>Racal Health &amp; Safety, Inc.</b>
Location	Frederick, MD, US
Contact	NANCY L BODIE
510(k) history	3 submissions · 2 cleared · 1988-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k880534/>; 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