

**K962654 COMPLEAT SURGICAL MASK**Jan 27, 1997  
203 days to decisionK962654 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k962654/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 8, 1996
Decision date	Jan 27, 1997
Days to decision	203 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carl Parker Associates, Inc.</b>
Location	Hauppauge, NY, US
Contact	ANDREW PARKER
510(k) history	7 submissions · 7 cleared · 1987-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k962654/> 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 July 6, 2026