

**K851556 OP-FACE MASK(MASQUE DE CHIRUGIE)**Apr 30, 1985  
14 days to decisionK851556 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k851556/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Apr 16, 1985
Decision date	Apr 30, 1985
Days to decision	14 days
Third-party review	No

**APPLICANT**

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Company	<b>Roseburg SA</b>
Location	Washington, DC, US
Contact	CHAMBORD
510(k) history	24 submissions · 23 cleared · 1985-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k851556/>, 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 22, 2026