

**K962443 N95 FILTERING FACEPIECE**Jan 3, 1997  
193 days to decisionK962443 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k962443/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 24, 1996
Decision date	Jan 3, 1997
Days to decision	193 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Survivair, Inc.</b>
Location	Lake Forest, IL, US
Contact	GRACE HOLLAND
510(k) history	2 submissions · 2 cleared · 1997-2007

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k962443/> 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 June 28, 2026