

**K974068 PFR95 PARTICULATE FILTER RESPIRATOR AND SURGICAL MASK REGULAR SIZE, PFR95 PARTICULATE FILTER RESPIRATOR AND SURGICAL**Dec 22, 1997  
55 days to decisionK974068 · Product code: **MSH** · General Hospital  
Source: <https://www.510kdatabase.net/k974068/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respirator, Surgical (MSH)
Date received	Oct 28, 1997
Decision date	Dec 22, 1997
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tecnol Medical Products, Inc.</b>
Location	Fort Worth, TX, US
Contact	RUTH JONES
510(k) history	21 submissions · 18 cleared · 1992-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k974068/>; 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 5, 2026