

K970448 PCM 2000Apr 30, 1997
83 days to decisionK970448 · Product code: **MSH** · General Hospital
Source: <https://www.510kdatabase.net/k970448/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respirator, Surgical (MSH)
Date received	Feb 6, 1997
Decision date	Apr 30, 1997
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary
Other names	ISOLAIR APR MODEL 2735

APPLICANT

Company	Tecno! Medical Products, Inc.
Location	Fort Worth, TX, US
Contact	RUTH JONES
510(k) history	21 submissions · 18 cleared · 1992-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k970448/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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