

K960778 ISOLAIR APR TYPE N95May 9, 1996
73 days to decisionK960778 · Product code: **MSH** · General Hospital
Source: <https://www.510kdatabase.net/k960778/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Respirator, Surgical (MSH)
Date received	Feb 26, 1996
Decision date	May 9, 1996
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Louis M. Gerson Co., Inc.
Location	MA, US
Contact	JOSEPH Z ZDROK
510(k) history	8 submissions · 8 cleared · 1980-2006

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