

K970352 SMARTVAC SMOKE EVACUATION SYSTEMNov 4, 1997
278 days to decisionK970352 · Product code: **FYD** · General HospitalSource: <https://www.510kdatabase.net/k970352/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Apparatus, Exhaust, Surgical (FYD)
Date received	Jan 30, 1997
Decision date	Nov 4, 1997
Days to decision	278 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Isomedix Operations, Inc.
Location	Libertyville, IL, US
Contact	MARY MCNAMARA-CULLINANE, RAC
510(k) history	2 submissions · 2 cleared · 1995-1997

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