

**K925185 ISOLAIR 2 FLUID RESIST
SURG/PROCE/CONE/EARLOOP MAS**Feb 3, 1994
477 days to decisionK925185 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k925185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 14, 1992
Decision date	Feb 3, 1994
Days to decision	477 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k925185/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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