

K932133 EYSOTEKApr 29, 1994
361 days to decisionK932133 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k932133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 3, 1993
Decision date	Apr 29, 1994
Days to decision	361 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Isotech Corp.
Location	Wethersfield, CT, US
Contact	RONALD E VLIET
510(k) history	2 submissions · 2 cleared · 1994-1994

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