

K972849 ISOSAFE EARLOOP PROCEDURE MASK (BLUE, YELLOW)May 28, 1998
300 days to decisionK972849 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k972849/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 1, 1997
Decision date	May 28, 1998
Days to decision	300 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Cypress Medical Products, Ltd.
Location	Mc Henry, IL, US
Contact	ANTHONY L GIACCIO
510(k) history	26 submissions · 19 cleared · 1989-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972849/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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