

K034015 EARLOOP PROCEDURE MASKFeb 20, 2004
58 days to decisionK034015 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k034015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 24, 2003
Decision date	Feb 20, 2004
Days to decision	58 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medipack Medical Packaging Mfg. Co.
Location	Mc Henry, IL, US
Contact	ANTONIO L GIACCIO
510(k) history	2 submissions · 2 cleared · 1999-2004

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