

**K111343 CROSSTEX ISOFLUID PLUS SURGICAL EARLOOP
MASK-BLUE, CROSSTEX ISOFLUID PLUS FOGFREE
SURGICAL EARLOOP FACE MASK-BLUE, CROSS**Oct 6, 2011
146 days to decisionK111343 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k111343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 13, 2011
Decision date	Oct 6, 2011
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Crosstex International, Inc.
Location	Minneapolis, MN, US
Contact	RICHARD M ORMSBEE
510(k) history	2 submissions · 2 cleared · 2010-2011

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