

K093901 SURGICAL FACE MASKSep 10, 2010
262 days to decisionK093901 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k093901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 22, 2009
Decision date	Sep 10, 2010
Days to decision	262 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Epard Protective Products, Ltd.
Location	Mosely, VA, US
Contact	DARREN REEVES
510(k) history	1 submissions · 1 cleared · 2010-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k093901/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 20, 2026