

K952962 EZ-PERSONAL PROTECTION KITSep 27, 1995
93 days to decisionK952962 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k952962/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 26, 1995
Decision date	Sep 27, 1995
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Safetec of America, Inc.
Location	Buffalo, NY, US
Contact	ROBERT O DEAN
510(k) history	4 submissions · 3 cleared · 1995-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k952962/> 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 May 26, 2026