

K915817 TECNOL FLUIDSHIELD INFECTION CONTROL MASKJan 27, 1993
394 days to decisionK915817 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k915817/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 30, 1991
Decision date	Jan 27, 1993
Days to decision	394 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Tecnol Medical Products, Inc.
Location	Fort Worth, TX, US
Contact	RUTH L JONES
510(k) history	21 submissions · 18 cleared · 1992-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k915817/> 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 July 5, 2026