

K962286 2505 FACE MASK, TIE STRING / ANTI-FOG / FACE SHIELD

Oct 7, 1996
115 days to decision

K962286 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k962286/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 14, 1996
Decision date	Oct 7, 1996
Days to decision	115 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Berkley Medical Resources, Inc.
Location	Uniontown, PA, US
Contact	PAUL ZELLNER
510(k) history	2 submissions · 2 cleared · 1996-1997

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k962286/> 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 6, 2026