

K904719 DISPOSABLE FACE MASKJan 2, 1991
76 days to decisionK904719 · Product code: **BYG** · AnesthesiologySource: <https://www.510kdatabase.net/k904719/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Oxygen (BYG)
Date received	Oct 18, 1990
Decision date	Jan 2, 1991
Days to decision	76 days
Third-party review	No

APPLICANT

Company	Tri/Bor Medical, Inc.
Location	Westtown, NY, US
Contact	KATHLEEN MIRESSI
510(k) history	5 submissions · 5 cleared · 1991-1991

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k904719/>; 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