

K040485 MAXAIR SURGICAL HELMET SYSTEMOct 18, 2004
236 days to decisionK040485 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k040485/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Feb 25, 2004
Decision date	Oct 18, 2004
Days to decision	236 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bio-Medical Devices, Inc.
Location	Irvine, CA, US
Contact	NICK HERBERT
510(k) history	7 submissions · 7 cleared · 1994-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k040485/> 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 22, 2026