

K092344 LAC-MAC INNERBLOC LR SURGICAL GOWNSDec 17, 2009
135 days to decisionK092344 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k092344/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Gown, Surgical (FYA)
Date received	Aug 4, 2009
Decision date	Dec 17, 2009
Days to decision	135 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Lac Mac, Ltd.
Location	Austin, TX, US
Contact	JEFFREY O STULL
510(k) history	6 submissions · 6 cleared · 2003-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092344/> 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 June 20, 2026