

K091357 MICROCOOL SURGICAL GOWN, BREATHABLE HIGH PERFORMANCE KC400Aug 10, 2009
94 days to decisionK091357 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k091357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Gown, Surgical (FYA)
Date received	May 8, 2009
Decision date	Aug 10, 2009
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kimberly-Clark Corp.
Location	Mchenry, IL, US
Contact	DAVID M LEE
Website	http://www.Kimberly-Clark.com
510(k) history	104 submissions · 103 cleared · 1978-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091357/> 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 24, 2026