

K980412 COLOURED POWDWR-FREE SURGICAL GLOVESApr 8, 1998
64 days to decisionK980412 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k980412/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Feb 3, 1998
Decision date	Apr 8, 1998
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kenwell International , Ltd.
Location	Karnataka, Karnataka, IN
Contact	SUSAN D GOLDSTEIN-FALK
510(k) history	5 submissions · 5 cleared · 1990-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k980412/> 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 5, 2026