

**K943254 SCIPOTEX POWDER FREE SURGICAL GLOVES
(BEADED)**Mar 7, 1995
244 days to decisionK943254 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k943254/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jul 6, 1994
Decision date	Mar 7, 1995
Days to decision	244 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Wembley Rubber Products (M) Sdn Bhd
Location	Kuala Lumpur, Malaysia, MY
Contact	ONG GHEE CHEE
510(k) history	61 submissions · 61 cleared · 1990-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k943254/> 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