

K231973 Polyisoprene Powder Free Black Colour Radiation Attenuating Surgical GloveSep 29, 2023
88 days to decisionK231973 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k231973/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jul 3, 2023
Decision date	Sep 29, 2023
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ineo Tech Sdn Bhd
Location	Bandar Kassia, MY
Contact	Pierre Hoerner
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231973/> 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 25, 2026