

K222993 Flexylon Surgical Powder Free Gloves with Low Dermatitis Potential Claim, Green Tested For Use with 13 Chemotherapy Drugs

Aug 18, 2023
324 days to decisionK222993 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k222993/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Sep 28, 2022
Decision date	Aug 18, 2023
Days to decision	324 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement
Other names	Flexylon Surgical Powder Free Gloves with Low Dermatitis Potential Claim, White Tested For Use with 32 Chemotherapy Drugs

APPLICANT

Company	Sentienx Sdn Bhd
Location	Kulim, MY
Contact	Sahrudin Shah Bin Abu Bakar
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Tg Medical USA (Inc)
Contact	David Lim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222993/> 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 27, 2026