

K230304 Polyisoprene Surgical GlovesAug 9, 2023
187 days to decisionK230304 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k230304/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Feb 3, 2023
Decision date	Aug 9, 2023
Days to decision	187 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Puyang Linshi Medical Supplies Co., Ltd.
Location	Puyang, CN
Contact	Catherine Liu
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Shanghai Truthful Information Technology Co., Ltd.
Contact	Boyle Wang

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/k230304/> 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