

K222620 Sterilized Latex Surgical GlovesMar 23, 2023
205 days to decisionK222620 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k222620/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Aug 30, 2022
Decision date	Mar 23, 2023
Days to decision	205 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Suzhou Colour-Way New Material Co., Ltd.
Location	Suzhou, CN
Contact	Yongping Xu
510(k) history	3 submissions · 3 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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