

K211953 Disposable Sterilized Latex Surgical GlovesMay 25, 2022
336 days to decisionK211953 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k211953/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jun 23, 2021
Decision date	May 25, 2022
Days to decision	336 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Jiangxi Kemei Medical Apparatus & Instruments Group Co., Ltd.
Location	Nanchang, CN
Contact	Jenny Huang
510(k) history	3 submissions · 3 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Shanghai Mind-Link Business Consulting Co., Ltd.
Contact	Alice Huang

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211953/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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