

K221748 Medispo Rubber Surgical Gloves, Medispo Polyisoprene Surgical GlovesSep 13, 2022
89 days to decisionK221748 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k221748/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jun 16, 2022
Decision date	Sep 13, 2022
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guilin Hbm Health Protections, Inc.
Location	Guilin, CN
Contact	Pu Lei
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Landlink Healthcare Technology (Shanghai) Co., Ltd.
Contact	Stuart Situ

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

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