

K203483 Medispo Rubber Surgical Gloves, Medispo Polyisoprene Surgical GlovesFeb 1, 2021
66 days to decisionK203483 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k203483/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Nov 27, 2020
Decision date	Feb 1, 2021
Days to decision	66 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	Shelley Li

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/k203483/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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