

K191898 Sterile Latex Powder-Free Surgical GlovesDec 18, 2019
155 days to decisionK191898 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k191898/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Jul 16, 2019
Decision date	Dec 18, 2019
Days to decision	155 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Modern Healthcare Corp.
Location	Hsin-Chu City, TW
Contact	Ke-Min Jen
510(k) history	3 submissions · 3 cleared · 2007-2020

REGULATORY CONSULTANT

Consulting firm	Chinese-European Industrial Research Society
Contact	Ke-Min Jen

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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