

K202401 Powder Free NR Latex Surgical Glove (Sterile) with Protein content labelling claims 50ug/dm2 or less per glove of extractable ProteinFeb 17, 2021
180 days to decisionK202401 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k202401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgeon's Gloves (KGO)
Date received	Aug 21, 2020
Decision date	Feb 17, 2021
Days to decision	180 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Eco Medi Glove Sdn. Bhd.
Location	Kamunting Perak, MY
Contact	Suresh Kumar
510(k) history	15 submissions · 15 cleared · 2014-2024

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