

K190632 Latex Surgeon's Gloves Powder Free with protein content labeling claim of 50µg/dm² or less per glove of extractable proteinOct 24, 2019
226 days to decisionK190632 · Product code: **KGO** · General Hospital
Source: <https://www.510kdatabase.net/k190632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Surgeon's Gloves (KGO)
Date received	Mar 12, 2019
Decision date	Oct 24, 2019
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lenora Glove Pvt , Ltd.
Location	Coimbatore, IN
Contact	Antony Kurian
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Liberty Management Group , Ltd.
Contact	Manoj Zacharias

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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