

K212597 Amazing+ Latex Examination Powder Free GlovesMay 28, 2022
285 days to decisionK212597 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k212597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 16, 2021
Decision date	May 28, 2022
Days to decision	285 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Amazing Rubber Products Pvt, Ltd.
Location	Cochin, IN
Contact	Jayasankar S
510(k) history	4 submissions · 4 cleared · 2022-2022

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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