

K212586 Amazing+Feb 17, 2022
185 days to decisionK212586 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212586/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Aug 16, 2021
Decision date	Feb 17, 2022
Days to decision	185 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212586/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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