

**K223102 Tegamen Nitrile Examination Gloves**Mar 15, 2023  
166 days to decisionK223102 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k223102/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 30, 2022
Decision date	Mar 15, 2023
Days to decision	166 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>M/S Tegamen Safety Products Private Limited</b>
Location	Alwar, CA
Contact	Manmohan Gulati
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Arora 297 Consultancy</b>
Contact	Avinash K. Arora

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223102/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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