

**K213775 Glovatex™ White Latex Gloves, Glovanil™ Blue Nitrile Gloves**Apr 24, 2022  
143 days to decisionK213775 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k213775/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Dec 2, 2021
Decision date	Apr 24, 2022
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Avecena Gloves Sdn Bhd</b>
Location	Negeri Sembilan, MY
Contact	Mohd Aswad bin Ramli
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Medcer Uluslararası Medikal Belgelendirme Anonim Sirketi</b>
Contact	Mehmet Fatih Ormeci

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213775/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 27, 2026