

**K222715 Black Nitrile Powder Free Patient Examination Glove,  
Non Sterile**Dec 3, 2022  
86 days to decisionK222715 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k222715/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Polymer Patient Examination Glove (LZA)
Date received	Sep 8, 2022
Decision date	Dec 3, 2022
Days to decision	86 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Safeskin Retailing (Hk) Limited</b>
Location	Hong Kong, CN
Contact	Alvin Ho
510(k) history	4 submissions · 4 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Dawa Medical, LLC</b>
Contact	Stephan Toupan

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/k222715/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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