

**K954051 SIME POWDERFREE PLUS**Nov 15, 1995  
78 days to decision

K954051 · Product code: LYY · General Hospital

Source: <https://www.510kdatabase.net/k954051/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 29, 1995
Decision date	Nov 15, 1995
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sime Health, Ltd.</b>
Location	Seattle, WA, US
Contact	SUSAN GOLDSTEIN-FALK
510(k) history	11 submissions · 11 cleared · 1991-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k954051/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 29, 2026