

**K040108 OPUE-E DISPOSABLE POWDER FREE VINYL  
SYNTHETIC EXAM GLOVES WITH VITAMIN COMPLEX, NOPAL  
AND LANOLIN**Aug 17, 2004  
210 days to decisionK040108 · Product code: **LYZ** · General Hospital  
Source: <https://www.510kdatabase.net/k040108/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Vinyl Patient Examination Glove (LYZ)
Date received	Jan 20, 2004
Decision date	Aug 17, 2004
Days to decision	210 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Est International Corporation</b>
Location	Rancho Cucamonga, CA, US
Contact	ELIZABETH DENG
510(k) history	4 submissions · 4 cleared · 2003-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040108/>; 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 July 2, 2026