

**K012856 STERILE LATEX EXAMINATION GLOVES  
(POWDERED) WITH PROTEIN CLAIM LESS THAN 100UG/G**Nov 16, 2001  
84 days to decisionK012856 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k012856/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 24, 2001
Decision date	Nov 16, 2001
Days to decision	84 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Smart Glove Corp. Sdn Bhd</b>
Location	Klang Selangor, MY
Contact	FOO KHON PU
510(k) history	27 submissions · 27 cleared · 1998-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012856/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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