

K981348 SMARTTEX PREPOWDERED LATEX EXAMINATION GLOVESMay 18, 1998
38 days to decisionK981348 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k981348/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Apr 10, 1998
Decision date	May 18, 1998
Days to decision	38 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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