

K954415 PATIENT EXAMINATION GLOVES WITH PROTEIN LABELING CLAIMMar 12, 1996
173 days to decisionK954415 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k954415/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Sep 21, 1995
Decision date	Mar 12, 1996
Days to decision	173 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hartalega Sdn Bhd
Location	Kuala Lumpur, MY
Contact	KUAN KAM HON
510(k) history	61 submissions · 61 cleared · 1989-2020

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