

K954416 POLYMER COATED POWDER-FREE LATEX EXAMINATION GLOVES

Oct 11, 1996
386 days to decision

K954416 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k954416/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Sep 21, 1995
Decision date	Oct 11, 1996
Days to decision	386 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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Device record: <https://www.510kdatabase.net/k954416/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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