

K000838 DIGITCARE POWDER FREE COATED EXAMINATION GLOVES WITH PROTEIN CONTENT LABELING CLAIM (50 MICROGRAMS OR LESS)Oct 23, 2000
223 days to decisionK000838 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k000838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Mar 14, 2000
Decision date	Oct 23, 2000
Days to decision	223 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	P.T. Healthcare Glovindo
Location	Jakarta, ID
Contact	ELLEN HUTAPEA
510(k) history	7 submissions · 7 cleared · 1993-2002

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