

**K955425 DASH, SULLIVAN, VITAL GARD HYPOALLERGENIC
WITH PROTEIN CONTENT LABELING CLAIM**Dec 30, 1996
398 days to decisionK955425 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k955425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Nov 28, 1995
Decision date	Dec 30, 1996
Days to decision	398 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Dash Medical Gloves Sdn Bhd
Location	Pelabuhan Klang, Selangor, MY
Contact	KHOO SEANG HOE
510(k) history	3 submissions · 3 cleared · 1996-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k955425/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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