

**K983568 OSTAR D'PRO LATEX POWDERED
EXAMINATION GLOVES, PROTEIN CLAIM OF 100 MCGM
OR/LESS OF TOTAL WATER EXTRACTABLE PROTEIN PER**Dec 21, 1998
69 days to decisionK983568 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k983568/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Oct 13, 1998
Decision date	Dec 21, 1998
Days to decision	69 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Contract Latex Dippers Sdn Bhd
Location	Malaysia, ML
Contact	VINAYAGAN RAMALINGAM
510(k) history	5 submissions · 5 cleared · 1994-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983568/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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