

K000913 POWDER FREE LATEX PATIENT EXAMINATION GLOVES WITH PROTEIN LABELING CLAIM (50 MICROGRAMS OR LESS)

Aug 10, 2000
141 days to decision

K000913 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k000913/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Mar 22, 2000
Decision date	Aug 10, 2000
Days to decision	141 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Handsafe Products Sdn. Bhd.
Location	Muar, Johor, MY
Contact	NG KOK HWA
510(k) history	2 submissions · 2 cleared · 1996-2000

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k000913/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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