

**K000351 HANWELLA LATEX PATIENT EXAM. GLOVES
POWDER-FREE**

Jun 23, 2000
140 days to decision

K000351 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k000351/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Feb 4, 2000
Decision date	Jun 23, 2000
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Hanwella Rubber Products , Ltd.
Location	Colombo 2, LK
Contact	B. DAMITHA P DHARMASENA
510(k) history	1 submissions · 1 cleared · 2000-2000

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k000351/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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