

K963331 MEDTEXXJan 24, 1997
154 days to decisionK963331 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k963331/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Aug 23, 1996
Decision date	Jan 24, 1997
Days to decision	154 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Regalfield Sdn. Bhd.
Location	Taiping, Perak, MY
Contact	LOW BOK TEK
510(k) history	1 submissions · 1 cleared · 1997-1997

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