

K950823 ANDALMay 10, 1995
76 days to decisionK950823 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k950823/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Feb 23, 1995
Decision date	May 10, 1995
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pt. Sarana Indoprotex
Location	Lampung 35001-Indonesia, IO
510(k) history	4 submissions · 4 cleared · 1992-1998

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