FDA 510(k) Premarket Notification

K891967 PATIENT EXAMINATION GLOVES (NATURAL LATEX)

CLEARED

Jul 14, 1989
107 days to decision

K891967 · Product code: **LYY** · General Hospital
Source: https://www.510kdatabase.net/k891967/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Latex Patient Examination Glove (LYY)
Date received	Mar 29, 1989
Decision date	Jul 14, 1989
Days to decision	107 days
Third-party review	No

APPLICANT

Company	**Butex Products (M'Sia) Sdn.Bhd**
Location	Johor Darul Takzim, MY
Contact	BOON KHIM
510(k) history	1 submissions · 1 cleared · 1989-1989

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k891967/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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