

K965155 LATEX EXAM GLOVESMar 5, 1997
72 days to decisionK965155 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k965155/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Dec 23, 1996 |
| Decision date | Mar 5, 1997 |
| Days to decision | 72 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | P.T. Irama Dinamika Latex |
| Location | Medan - Indonesia, ID |
| Contact | ABRAHAM KURIAN |
| 510(k) history | 11 submissions · 11 cleared · 1991-1999 |

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