

K970773 POWDER-FREE EXAM GLOVESDec 4, 1997
275 days to decisionK970773 · Product code: LYY · General Hospital
Source: <https://www.510kdatabase.net/k970773/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Mar 4, 1997 |
| Decision date | Dec 4, 1997 |
| Days to decision | 275 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Pt. Sarana Indoprotex |
| Location | Lampung 35001-Iodonesia, IO |
| Contact | MD YUSOF BIN IBRAHIM |
| 510(k) history | 4 submissions · 4 cleared · 1992-1998 |

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