

K903857 NON-STERILE LATEX DENTAL PROCEDURE GLOVESOct 29, 1990
70 days to decision

K903857 · Product code: LYY · General Hospital

Source: <https://www.510kdatabase.net/k903857/>**SUBMISSION DETAILS**

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|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received | Aug 20, 1990 |
| Decision date | Oct 29, 1990 |
| Days to decision | 70 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Formtex Medical Sdn. Bhd. |
| Location | Klang Pelabohan Klang, MY |
| Contact | C. S LOW |
| 510(k) history | 3 submissions · 3 cleared · 1990-1993 |

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