

K973551 MEDI-PLUS, HEALTH-PLUS, SANITEX, RELIANCENov 6, 1997
48 days to decisionK973551 · Product code: **LZA** · General HospitalSource: <https://www.510kdatabase.net/k973551/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Sep 19, 1997 |
| Decision date | Nov 6, 1997 |
| Days to decision | 48 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Pwa Industries Sdn. Bhd. |
| Location | Selangor Darul Ehsan, MY |
| Contact | AZMAN ISMAIL |
| 510(k) history | 11 submissions · 11 cleared · 1995-2001 |

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