

K220401 Pink Powder Free Nitrile Examination Glove With Bubblegum Scented, Chemotherapy Drugs And Fentanyl Test Claim

Apr 9, 2022
57 days to decisionK220401 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k220401/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Feb 11, 2022 |
| Decision date | Apr 9, 2022 |
| Days to decision | 57 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Riverstone Resources Sdn Bhd |
| Location | Kepong Baru, Kuala Lumpur, MY |
| Contact | Suresh Kumar |
| 510(k) history | 15 submissions · 15 cleared · 1999-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220401/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026