

K183562 Powder-Free Nitrile Examination Glove (White Colored, Blue Colored, and Black Colored) Tested for Use with Chemotherapy DrugsOct 23, 2019
307 days to decisionK183562 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k183562/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Medical Glove, Specialty (LZC) |
| Date received | Dec 20, 2018 |
| Decision date | Oct 23, 2019 |
| Days to decision | 307 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Encompass Industries Sdn. Bhd. |
| Location | Kemaman, MY |
| Contact | Eunice Yee |
| 510(k) history | 3 submissions · 3 cleared · 2019-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183562/> 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