

K230564 Green Non Sterile Powder Free Nitrile Examination Gloves

May 23, 2023
83 days to decisionK230564 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k230564/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Mar 1, 2023 |
| Decision date | May 23, 2023 |
| Days to decision | 83 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Central Medicare Sdn Bhd |
| Location | Diamond Bar, CA, US |
| Contact | Ang Shiao Ping |
| 510(k) history | 15 submissions · 15 cleared · 2010-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230564/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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