

**K190860 Disposable Powder Free Nitrile Examination Glove,
Tested For Use With Chemotherapy Drugs, White color,
Disposable Powder Free Nitrile Examination Glove, Tested For
Use With Chemotherapy Drugs, Orange color**Dec 23, 2019
265 days to decisionK190860 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k190860/>**SUBMISSION DETAILS**

| | |
|-----------------------|-----------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Apr 2, 2019 |
| Decision date | Dec 23, 2019 |
| Days to decision | 265 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|-----------------------------------------|
| Company | Ever Growth (Vietnam) Co. , Ltd. |
| Location | Long Khanh Township, VN |
| Contact | Ming Lee |
| 510(k) history | 4 submissions · 4 cleared · 2017-2020 |

REGULATORY CONSULTANT

| | |
|-----------------|-----------------------|
| Consulting firm | Elizabeth Deng |
| Contact | Elizabeth Deng |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190860/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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