

**K200181 Black Colored Powder Free Nitrile Examination Gloves
Tested for Use with Chemotherapy Drugs and Fentanyl Citrate**Apr 15, 2020
82 days to decisionK200181 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k200181/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Jan 24, 2020 |
| Decision date | Apr 15, 2020 |
| Days to decision | 82 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Comfort Rubber Gloves Industries Sdn. Bhd. |
| Location | Matang, MY |
| Contact | Ng Kok Howe |
| Website | http://www.comfort-rubber.com.my/ |
| 510(k) history | 15 submissions · 15 cleared · 1994-2025 |

Comfort Rubber Gloves Industries Sdn. Bhd. manufactures examination gloves for healthcare settings. The company operates with a manufacturing facility in Matang, Malaysia. The company has received FDA 510(k) clearances from total submissions since 1994. All submissions focus on General Hospital devices. The latest clearance was granted in 2025, confirming active regulatory engagement. Product specialization centers on powder-free examination gloves in multiple materials and colors. Recent cleared devices include nitrile and natural rubber latex formulations. Many products...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k200181/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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