

**K180646 Halyard Lavender Nitrile Powder-Free Exam Glove
Tested for Use with Chemotherapy Drugs**Jun 27, 2018
107 days to decisionK180646 · Product code: **LZC** · General Hospital
Source: <https://www.510kdatabase.net/k180646/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Medical Glove, Specialty (LZC) |
| Date received | Mar 12, 2018 |
| Decision date | Jun 27, 2018 |
| Days to decision | 107 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Halyard Health |
| Location | Minneapolis, MN, US |
| Contact | Christine L. Macauley |
| 510(k) history | 7 submissions · 7 cleared · 2014-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180646/> 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 June 23, 2026