

**K162923 NITRILE POWDER FREE EXAMINATION GLOVE  
TESTED FOR USE WITH CHEMOTHERAPY DRUGS - AQUA  
BLUE**

Feb 6, 2017  
111 days to decision

K162923 · Product code: **LZA** · General Hospital  
Source: <https://www.510kdatabase.net/k162923/>

**SUBMISSION DETAILS**

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| Decision              | Substantially Equivalent (Cleared)                                                                                                                                                                                                                                                    |
| Submission type       | Traditional                                                                                                                                                                                                                                                                           |
| Device classification | Polymer Patient Examination Glove (LZA)                                                                                                                                                                                                                                               |
| Date received         | Oct 18, 2016                                                                                                                                                                                                                                                                          |
| Decision date         | Feb 6, 2017                                                                                                                                                                                                                                                                           |
| Days to decision      | 111 days                                                                                                                                                                                                                                                                              |
| Third-party review    | No                                                                                                                                                                                                                                                                                    |
| Summary / Statement   | Statement                                                                                                                                                                                                                                                                             |
| Other names           | NITRILE POWDER FREE EXAMINATION GLOVE TESTED FOR USE WITH CHEMOTHERAPY DRUGS - VIOLET BLUE; NITRILE POWDER FREE EXAMINATION GLOVE TESTED FOR USE WITH CHEMOTHERAPY DRUGS - DARK BLUE; NITRILE POWDER FREE EXAMINATION GLOVE TESTED FOR USE WITH CHEMOTHERAPY DRUGS - DARK VIOLET BLUE |

**APPLICANT**

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|----------------|-----------------------------------------|
| Company        | <b>Hartalega NGC Sdn. Bhd.</b>          |
| Location       | Bandar Sri Damansara, MY                |
| Contact        | KUAN MUN LEONG                          |
| 510(k) history | 28 submissions · 28 cleared · 2014-2025 |

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