

**K161823 Powder Free Nitrile Surgical Glove, Sterile, Tested for use with Chemotherapy Drugs**

Jan 23, 2017  
206 days to decision

K161823 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k161823/>

**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Surgeon&apos;s Gloves (KGO)        |
| Date received         | Jul 1, 2016                        |
| Decision date         | Jan 23, 2017                       |
| Days to decision      | 206 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Wrp Asia Pacific Sdn. Bhd.</b>       |
| Location       | Salak Tinggi, Sepang Selangor, MY       |
| Contact        | SARALA DEVI JAYARAMAN                   |
| 510(k) history | 46 submissions · 46 cleared · 1999-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k161823/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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