

**K012880 STERILE POWDER-FREE LATEX SURGICAL GLOVES  
(50 MICROGRAMS OR LESS)**Nov 16, 2001  
80 days to decisionK012880 · Product code: **KGO** · General Hospital  
Source: <https://www.510kdatabase.net/k012880/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Surgeon&apos;s Gloves (KGO)        |
| Date received         | Aug 28, 2001                       |
| Decision date         | Nov 16, 2001                       |
| Days to decision      | 80 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Ssn Gloves (M) Sdn Bhd</b>         |
| Location       | Petaling Jaya, Selangor, MY           |
| Contact        | CLINTON A TECK LEONG                  |
| 510(k) history | 4 submissions · 4 cleared · 1999-2001 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k012880/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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