

**K892043 PATIENT EXAMINATION GLOVE (LATEX)**Aug 23, 1989  
145 days to decision

K892043 · Product code: LYY · General Hospital

Source: <https://www.510kdatabase.net/k892043/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received         | Mar 31, 1989                          |
| Decision date         | Aug 23, 1989                          |
| Days to decision      | 145 days                              |
| Third-party review    | No                                    |

**APPLICANT**

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|----------------|--|
| Company        | <b>Mwe Asia America Industries Sdn</b> |
| Location       | Selangor, MY                           |
| Contact        | SEONG LYE                              |
| 510(k) history | 1 submissions · 1 cleared · 1989-1989  |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k892043/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 8, 2026