

**K013996 LATEX POWDERFREE STERILE EXAMINATION GLOVES, MODELS-EXTRA SMALL, SMALL, MEDIUM, LARGE, EXTRA LARGE**

Feb 26, 2002  
85 days to decision

K013996 · Product code: LYY · General Hospital  
Source: <https://www.510kdatabase.net/k013996/>

**SUBMISSION DETAILS**

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|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Latex Patient Examination Glove (LYY) |
| Date received         | Dec 3, 2001                           |
| Decision date         | Feb 26, 2002                          |
| Days to decision      | 85 days                               |
| Third-party review    | No                                    |
| Summary / Statement   | Summary                               |

**APPLICANT**

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|----------------|---|
| Company        | <b>Pt. Maja Agung Latexindo</b>         |
| Location       | Indonesia, ID                           |
| Contact        | EMMY T JOENG                            |
| 510(k) history | 11 submissions · 11 cleared · 1990-2022 |

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

Device record: <https://www.510kdatabase.net/k013996/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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