

**K091661 POWDER-FREE VINYL PATIENT EXAMINATION  
GLOVES**Jul 27, 2009  
48 days to decisionK091661 · Product code: LYZ · General Hospital  
Source: <https://www.510kdatabase.net/k091661/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Traditional                           |
| Device classification | Vinyl Patient Examination Glove (LYZ) |
| Date received         | Jun 9, 2009                           |
| Decision date         | Jul 27, 2009                          |
| Days to decision      | 48 days                               |
| Third-party review    | No                                    |
| Summary / Statement   | Summary                               |

**APPLICANT**

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|----------------|--|
| Company        | <b>Zhang Jia Gang Huayuan Plastic Co. , Ltd.</b> |
| Location       | Zhang Jia Gang, Jiangsu, CN                      |
| Contact        | CHU XIAOAN                                       |
| 510(k) history | 2 submissions · 2 cleared · 2007-2009            |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091661/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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