

**K101000 WELLMIEN SURGICAL MASK**Aug 9, 2010  
119 days to decisionK101000 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k101000/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Abbreviated                        |
| Device classification | Mask, Surgical (FXX)               |
| Date received         | Apr 12, 2010                       |
| Decision date         | Aug 9, 2010                        |
| Days to decision      | 119 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|--|
| Company        | <b>Wellmien (Suzhou) Import &amp; Export Trading Co., Ltd.</b> |
| Location       | Pennington, NJ, US   |
| Contact        | CHENGYU SHEN   |
| 510(k) history | 1 submissions · 1 cleared · 2010-2010                          |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101000/> 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 June 20, 2026