

**K950554 NORTH BLOODBORNE PATHOGEN RESPONSE KIT**Jun 28, 1995  
145 days to decisionK950554 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k950554/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Mask, Surgical (FXX)               |
| Date received         | Feb 3, 1995                        |
| Decision date         | Jun 28, 1995                       |
| Days to decision      | 145 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>North Safety Products</b>          |
| Location       | Rockford, IL, US                      |
| Contact        | JAMES WRIGHT                          |
| 510(k) history | 1 submissions · 1 cleared · 1995-1995 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950554/> 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 30, 2026