

**K033478 VACUETTE QUICKSHIELD SAFETY TUBE HOLDER**Dec 29, 2003  
56 days to decisionK033478 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k033478/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received         | Nov 3, 2003                            |
| Decision date         | Dec 29, 2003                           |
| Days to decision      | 56 days                                |
| Third-party review    | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---|
| Company        | <b>Greiner Bio-One Vacuette North America</b> |
| Location       | Baldwin, MD, US                               |
| Contact        | Judi Smith                                    |
| 510(k) history | 5 submissions · 5 cleared · 2001-2008         |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033478/> 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 25, 2026