

**K965141 TRUQUANT BR RIA**Oct 31, 1997  
312 days to decisionK965141 · Product code: **MOI** · Immunology  
Source: <https://www.510kdatabase.net/k965141/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | System, Test, Immunological, Antigen, Tumor (MOI) |
| Date received         | Dec 23, 1996                                      |
| Decision date         | Oct 31, 1997                                      |
| Days to decision      | 312 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Biomira USA, Inc.</b>              |
| Location       | Cranberry, NJ, US                     |
| Contact        | JILLIAN CASTRUCCI                     |
| 510(k) history | 1 submissions · 1 cleared · 1997-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k965141/> 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 29, 2026