

**K072661 IMMUNOCAP THYRLOBULIN IMMUNOCAP**Nov 20, 2007  
60 days to decisionK072661 · Product code: **JNL** · Immunology  
Source: <https://www.510kdatabase.net/k072661/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Special  |
| Device classification | Immunochemical, Thyroglobulin Autoantibody (JNL) |
| Date received         | Sep 21, 2007                                     |
| Decision date         | Nov 20, 2007                                     |
| Days to decision      | 60 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Phadia US, Inc.</b>                  |
| Location       | Portae, MI, US                          |
| Contact        | MARTIN R MANN                           |
| 510(k) history | 22 submissions · 21 cleared · 2006-2015 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k072661/> 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 May 14, 2026