

**K152061 IMMULITE 2000 TSI Assay, IMMULITE 2000 TSI Calibration Verification Material**

Mar 3, 2016  
223 days to decision

K152061 · Product code: **JZO** · Immunology  
Source: <https://www.510kdatabase.net/k152061/>

**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | System, Test, Thyroid Autoantibody (JZO) |
| Date received         | Jul 24, 2015                             |
| Decision date         | Mar 3, 2016                              |
| Days to decision      | 223 days                                 |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Siemens Healthcare Diagnostics, Inc.</b>   |
| Location       | New York, NY, US  |
| Contact        | SUSAN BROCCHI   |
| Website        | <a href="https://www.siemens-healthineers.com">https://www.siemens-healthineers.com</a> |
| 510(k) history | 152 submissions · 151 cleared · 2008-2026   |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k152061/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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