

**K964558 VITROS IMMUNODIAGNOSTICS PRODUCTS/TSH  
REAGENT PACK (GEM. 1001)/TSH CALIBRATORS(GEM.C001)**Dec 16, 1996  
33 days to decisionK964558 · Product code: JLW · Chemistry  
Source: <https://www.510kdatabase.net/k964558/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Traditional   |
| Device classification | Radioimmunoassay, Thyroid-stimulating Hormone (JLW) |
| Date received         | Nov 13, 1996  |
| Decision date         | Dec 16, 1996  |
| Days to decision      | 33 days   |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Johnson &amp; Johnson Clinical Diagnostics, Inc.</b> |
| Location       | Rochester, NY, US                                       |
| Contact        | ANN M QUINN   |
| 510(k) history | 33 submissions · 33 cleared · 1995-1998                 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964558/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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