

**K102175 RAPIDVUE HCG TEST**Aug 25, 2010  
23 days to decisionK102175 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k102175/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Special                                       |
| Device classification | Visual, Pregnancy Hcg, Prescription Use (JHI) |
| Date received         | Aug 2, 2010                                   |
| Decision date         | Aug 25, 2010                                  |
| Days to decision      | 23 days                                       |
| Third-party review    | No  |
| Summary / Statement   | Summary                                       |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>Quidel Corporation</b>               |
| Location       | San Diego, CA, US                       |
| Contact        | Michelle Bodien                         |
| 510(k) history | 37 submissions · 35 cleared · 2010-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102175/> 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