

**K041668 OLYMPUS CRP LATEX IMMUNOTURBIDIMETRIC REAGENT**Aug 19, 2004  
62 days to decisionK041668 · Product code: **NQD** · Chemistry  
Source: <https://www.510kdatabase.net/k041668/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                |
| Submission type       | Traditional   |
| Device classification | Cardiac C-reactive Protein, Antigen, Antiserum, And Control (NQD) |
| Date received         | Jun 18, 2004  |
| Decision date         | Aug 19, 2004  |
| Days to decision      | 62 days   |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Olympus America, Inc.</b>              |
| Location       | Lake Success, NY, US                      |
| Contact        | BEV HARDING                               |
| 510(k) history | 149 submissions · 149 cleared · 1994-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k041668/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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