

**K003419 RCRP FLEX REAGENT CARTRIDGE**Feb 14, 2001  
104 days to decisionK003419 · Product code: **DCN** · Immunology  
Source: <https://www.510kdatabase.net/k003419/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | System, Test, C-reactive Protein (DCN) |
| Date received         | Nov 2, 2000                            |
| Decision date         | Feb 14, 2001                           |
| Days to decision      | 104 days                               |
| Third-party review    | No                                     |
| Combination product   | No                                     |
| PCCP authorized       | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---|
| Company        | <b>Dade Behring, Inc.</b>                 |
| Location       | Newark,, DE, US                           |
| Contact        | LORRAINE H PIETRAK                        |
| 510(k) history | 343 submissions · 343 cleared · 1978-2010 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003419/> 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 June 19, 2026