

**K040030 BIOCHECK CARDIAC-1 CRP RAPID TEST, MODEL BC-804114**Jun 16, 2004  
161 days to decisionK040030 · Product code: **DCN** · Immunology  
Source: <https://www.510kdatabase.net/k040030/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | System, Test, C-reactive Protein (DCN) |
| Date received         | Jan 7, 2004                            |
| Decision date         | Jun 16, 2004                           |
| Days to decision      | 161 days                               |
| Third-party review    | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biocheck, Inc.</b>                   |
| Location       | Northridge, CA, US                      |
| Contact        | ROBIN J HELLEN                          |
| 510(k) history | 14 submissions · 14 cleared · 1999-2004 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040030/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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