

**K003178 ELECSYS HCG AND BETA TEST SYSTEM**Dec 14, 2000  
64 days to decisionK003178 · Product code: **DHA** · Chemistry  
Source: <https://www.510kdatabase.net/k003178/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Traditional                                      |
| Device classification | System, Test, Human Chorionic Gonadotropin (DHA) |
| Date received         | Oct 11, 2000                                     |
| Decision date         | Dec 14, 2000                                     |
| Days to decision      | 64 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Roche Diagnostics Corp.</b>            |
| Location       | Indianapolis, IN, US                      |
| Contact        | KAY A TAYLOR                              |
| 510(k) history | 264 submissions · 263 cleared · 1999-2013 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k003178/> 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 9, 2026