

**K002148 ELECSYS HCG TEST SYSTEM**Aug 22, 2000  
36 days to decisionK002148 · Product code: **DHA** · Chemistry  
Source: <https://www.510kdatabase.net/k002148/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Jul 17, 2000
Decision date	Aug 22, 2000
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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