

**K952283 AMERLITE HCG-60 ASSAY**Jul 17, 1995  
62 days to decisionK952283 · Product code: **DHA** · Chemistry  
Source: <https://www.510kdatabase.net/k952283/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	May 16, 1995
Decision date	Jul 17, 1995
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Johnson &amp; Johnson Clinical Diagnostics, Inc.</b>
Location	Rochester, NY, US
Contact	YVONNE E MIDDLEFELL
510(k) history	33 submissions · 33 cleared · 1995-1998

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