

K882896 ONE-STEP HCGOct 31, 1988
112 days to decisionK882896 · Product code: **DHA** · Chemistry
Source: <https://www.510kdatabase.net/k882896/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Jul 11, 1988
Decision date	Oct 31, 1988
Days to decision	112 days
Third-party review	No

APPLICANT

Company	Wampole Laboratories
Location	Mchenry, IL, US
Contact	ANN MACLEARIE
510(k) history	12 submissions · 12 cleared · 1976-1997

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