

**K941085 LIPASE-PS ASSAY PROCEDURE NO. 805**May 17, 1994  
70 days to decisionK941085 · Product code: **CHI** · Chemistry  
Source: <https://www.510kdatabase.net/k941085/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipase-esterase, Enzymatic, Photometric, Lipase (CHI)
Date received	Mar 8, 1994
Decision date	May 17, 1994
Days to decision	70 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	WILLIAM GILBERT, PH.D
510(k) history	164 submissions · 164 cleared · 1984-2002

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