

**K992803 SIGMA DIAGNOSTICS INFINITY CHOLESTEROL REAGENT, MODELS 401-25, 401-100P, 401-500P, 401-2000P, 402-20, 02-100P**

Sep 13, 1999  
25 days to decision

K992803 · Product code: **CHH** · Chemistry  
Source: <https://www.510kdatabase.net/k992803/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Aug 19, 1999
Decision date	Sep 13, 1999
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k992803/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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