

**K992800 SIGMA DIAGNOSTICS INFINITY BUN REAGENT,  
MODELS 63-25, 63-100P, 63-500P, 63-2000P, 64-20, 64-100P**

Sep 28, 1999  
40 days to decision

K992800 · Product code: **CDQ** · Chemistry  
Source: <https://www.510kdatabase.net/k992800/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ)
Date received	Aug 19, 1999
Decision date	Sep 28, 1999
Days to decision	40 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/k992800/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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