

**K001403 SIGMA DIAGNOSTICS INFINITY GLUCOSE REAGENT,  
MODELS 17-25, 17-100P, 17-500P, 17-2000P, 18-20, 18-100P**

Aug 10, 2000  
99 days to decision

K001403 · Product code: CFR · Chemistry  
Source: <https://www.510kdatabase.net/k001403/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hexokinase, Glucose (CFR)
Date received	May 3, 2000
Decision date	Aug 10, 2000
Days to decision	99 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/k001403/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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