

K980667 INFINITY CHOLESTEROL REAGENT (PROCEDURE NO. 401)Apr 21, 1998
60 days to decisionK980667 · Product code: **CHH** · Chemistry
Source: <https://www.510kdatabase.net/k980667/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Feb 20, 1998
Decision date	Apr 21, 1998
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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