



DEPARTMENT OF HEALTH & HUMAN SERVICES

MAR 5 2002

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Robin Weiner
Vice President, Clinical and Regulatory Affairs
Quidel Corporation
10165 McKellar Court
San Diego, CA 92121

We have reviewed the information submitted by Quidel Corporation requesting to add the brand name Quidel QuickVue+Strep A to the CLIA test complexity replacing the CARDS Q.S. Strep A brand name.

Test Name: Quidel QuickVue+Strep A

Analyte: Streptococcus Group A

Re: K955108/A003

Complexity: Moderate

This complexity categorization is effective as of the date of this notification. This categorization will be reported on FDA's home page <http://www.fda.gov/cdrh/clia>. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. This categorization will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice. For questions regarding FDA's categorization procedure, contact Clara A. Sliva, Acting CLIA Coordinator, at (301) 827-0496 or email <http://www.CLIA@CDRH.FDA.GOV>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman".

Steven I. Gutman
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health