



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

JUL 27 2001

Re: K011097/A003
Device Trade Name: QuickVue® Dipstick Strep A
Dated: May 10, 2001
Received: May 10, 2001

Dear Ms. Weiner:

This replaces the waiver categorization notification dated July 26, 2001.

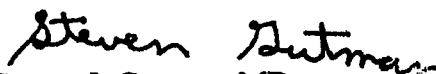
The Center for the Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your application for waived status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. We are pleased to inform you that the QuickVue® Dipstick Strep A test is waived.

Test System Name: QuickVue® Dipstick Strep A Analyte Name: Group A Streptococcus

Waived status is applicable to the test systems and their instructions approved by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for evaluation of waiver.

This categorization is effective as of the date of the notification. This categorization will be reported on FDA's home page <http://www.fda.gov/cdrh/cli>. 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, CLIA Coordinator (Acting) at ((301) 827-0496 or email CLIA@CDRH.FDA.GOV.

Sincerely yours,



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