



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Robin Weiner  
Vice President, Regulatory Affairs  
Quidel Corporation  
10165 McKellar Court  
San Diego, California 92121

OCT 4 2000

RE: K991633

Quidel QuickVue® Influenza Test Waiver

Dear Ms. Weiner:

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

Test System: Quidel QuickVue® Influenza Test

Analyte: Influenza A/B

Waived status is applicable to test systems and their instructions approved by the FDA. We recommend that the test system instructions include a statement that the test 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/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 re-categorize 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 [cas@cdrh.fda.gov](mailto:cas@cdrh.fda.gov).

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory  
Devices  
Office of Device Evaluation  
Center for Devices Radiological  
Health

Cc: Nancy Cahill