

08-SEP-2003

Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

QUIDEL CORP.
10165 MCKELLAR CT.
SAN DIEGO CA 92121

Re: K973858/A002

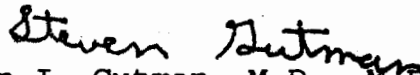
Categorization Notification

Regulations codified at 42 CFR 493.17 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test systems or assay for the analyte is categorized below:

Test Systems/Analyte(s): (SEE ATTACHMENT)

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 at CLIA@CDRH.FDA.GOV

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

ATTACHMENT

510K or PMA Number : K973858/A002

Test System: QUIDEL QUICKVUE+ ONE-STEP HCG COMBO
Analyte : HCG, SERUM, QUALITATIVE
Complexity : Moderate
Rationale : CHEM-006

Test System: QUIDEL QUICKVUE+ ONE-STEP HCG COMBO
Analyte : URINE HCG BY VISUAL COLOR COMPARISON TESTS
Complexity : Waived
Rationale :