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Bayer Corporation, Business Group Diagnostics
CLINITEK® hCG Test Strips

510(k) Safety and Effectiveness Summary
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510(k) SAFETY AND EFFECTIVENESS SUMMARY

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Device: Trade/Proprietary Name: CLINITEK® hCG Test Strips for
Detection of hCG in Urine
Common/Usual Name: Urine Pregnancy Test
Document Control Number: K97 _____

Classification Name: Human Chorionic Gonadotropin (hCG) Test System

Predicate Devices: QuickVue® One-Step HCG Combo
Manufactured by QUIDEL Corporation
Test Pack +Plus hCG Combo
Manufactured by Abbott Laboratories

Device Description: CLINITEK® hCG Test Strips are unitized reagent strips used with the CLINITEK® 50 and CLINITEK® 100 Urine Chemistry Analyzers. Each bottle contains 25 test strips.

Intended Use: CLINITEK® hCG Test Strips are for the qualitative measurement of Human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy. CLINITEK hCG Test Strips are for professional use in clinical laboratories, physician offices and other point-of-care healthcare locations.

Technological Characteristics:

The CLINITEK® hCG Test Strip uses immunochromatographic assay methods for detecting human chorionic gonadotropin (hCG) in urine. It is intended to be read instrumentally on the CLINITEK 50 and CLINITEK 100 Urine Chemistry Analyzers. The first zone of the test strip contains antibody to hCG (monoclonal anti-beta hCG) coupled with red dye. The urine rehydrates this zone and mobilizes the antibody-dye. Any hCG present will bind with the antibody-dye conjugate. Another zone of hCG specific antibodies (polyclonal anti-alpha hCG) is bound to the strip. As the hCG-antibody-dye moves along the strip it will bind to this zone producing a red line (positive result). A similar migration pattern occurs with the built-in procedural control feature. A blue line appears which indicates that a sufficient amount of urine has saturated the test strip. If there is no hCG present in the urine only the blue line will appear (negative result). The CLINITEK 50 and CLINITEK 100 Urine Chemistry Analyzers are reflectance photometers that analyze the color and intensity of the light reflected from the test strip. The algorithm in the instruments converts the measured reflectance and displays the results as either "positive" or "negative" on the instrument display panel. No calculations are required by the user.

Assessment of Performance:

The performance of CLINITEK® hCG Test Strips was assessed according to the FDA Reviewer's Guidance *Review Criteria for Assessment of Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVD's)*¹ and the National Committee for Clinical Laboratory Standards (NCCLS) guideline *Chorionadotropin Testing: Nomenclature, Reference Preparations, Assay Performance, and Clinical Application*². Studies were performed in-house and in external field evaluations utilizing clinical urine specimens.

Conclusion:

The results of the internal and external studies demonstrate that CLINITEK® hCG Test Strips are equivalent in performance to predicate devices currently in interstate commerce and suitable for use in point-of-care locations.

¹ *Review Criteria for Assessment of Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices (IVD's)*. Department of Health and Human Services, Food and Drug Administration. CDRH, 2098 Gaither Road, Rockville, MD 20850, 1995.

² *Choriogonadotropin Testing: Nomenclature, Reference Preparations, Assay Performance, and Clinical Application; Proposed Guideline*. National Committee for Clinical Laboratory Standards (NCCLS) Document I/LA10-P (ISBN 1-56238-275-6). NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087, 1995.