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**510 (k) SUMMARY
AS REQUIRED BY SECTION 807.92(C)**

Identification: Quickstick™ One Step HCG Pregnancy Test

Description: Immunoassay for the Qualitative Detection of Human Chorionic Gonadotropin (hCG) in Urine for the Early Pregnancy

Manufacturer: Phamatech
9265 Activity Road #112, San Diego, California 92126, USA

Intended Use: The Quickstick™ One Step HCG Pregnancy Test is intended to detect the presence of Human Chorionic Gonadotropin (hCG) in Urine for the women who suspect they may be pregnant. HCG is a well known and established analyte used to confirm pregnancy because of its early appearance in urine following conception followed by a dramatic increase in concentration.

Technology: The Quickstick™ One Step HCG Pregnancy Test, like many commercially available pregnancy test kits, qualitatively measures the presence of HCG by visual color sandwich one step immunoassay technology. Examples of such predicate devices include the Unipath Clearview HCG (Mountainview, CA 94043), Abbott Laboratories' Fact Plus (Abbott Park, IL 60064) and the Syntron Bioresearch Be Sure Pregnancy Test (Vista, CA 92083). All of the above devices rely on the basic immunochemical sandwich assay principle of recognition and formation of specific antibody / HCG / antibody / complexes.

Performance: The product performance characteristics of the Quickstick™ One Step HCG Pregnancy Test were evaluated in a clinical sample correlation study and a blind labeled spiked HCG study. The results of these studies demonstrate the Phamatech Quickstick™ One Step HCG Pregnancy Test to be substantially equivalent to the reported performance characteristics of other commercially available tests for the qualitative detection of early pregnancy. Correlations studies, using clinical specimens, produced a >99% correlation when compared to the Quidel Rapidvue (San Diego, CA 92121) and the Syntron Bioresearch Be Sure Pregnancy Test (Vista, CA 92083). A blind labeled spiked consumer study was performed, the Phamatech Quickstick™ exhibited excellent sensitivity (79/79), specificity (79/79), and accuracy (158/158) in the hands of lay users.

Conclusion: For the reasons mentioned above, it may be concluded that the Phamatech Quickstick™ One Step HCG Pregnancy Test is substantially equivalent to a variety of pregnancy tests currently in commercial distribution.