



Wyntek
diagnostics

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8. **510 (k) Summary** FEB - 4 1997

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Contact Person: Shu-Ching Cheng

Product Name:

Proprietary Name: OSOM™ Classic hCG-Urine Test
Common Name: hCG Urine Pregnancy Test Kit
Classification Name: Human chorionic gonadotropin (hCG)
test
Classification Number: 75JHI

Intended Use: The OSOM™ Classic hCG-Urine Test is intended for the qualitative determination of human chorionic gonadotropin (hCG) in urine for early detection of pregnancy.

Description: OSOM Classic hCG-Urine Test uses color immunochromatographic technology with antibodies coated on the membrane. If hCG is present in urine, a blue test line will appear to indicate a positive result.

Substantial Equivalence:

OSOM Classic hCG-Urine Test is substantially equivalent to Quidel RapidVue hCG Test and Abbott TestPack Plus hCG Urine Test. All three tests utilize immunochromatographic technology and anti-hCG antibodies to detect hCG in urine. All three tests interpret the results through the development of the color lines.

Applicant Signed: Shu-Ching Cheng Date: 1/14/97
Shu-Ching Cheng