K962906

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SECTION VI.

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

VI. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitter Identification

1. Name and Address

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4. Date of Submission

July 22, 1996

B. Names of Device

1. Proprietary Name

SCRIPPS LABORATORIES hCG One-Step

2. Common Name

A Rapid, One-Step Immunoassay for the Qualitative Detection of Human Chorionic Gonadotropin (hCG) in Urine for the Early Detection of Pregnancy.

3. Classification Name

Human Chorionic Gonadotropin (hCG) Test System.

C. Legally Marketed Devices to Which Substantial Equivalence is Claimed

1. Quidel® QuickVue® One-Step hCG Urine Test (ref. K925435)

2. Wyntek Diagnostics OSOM™ hCG-Urine Test (ref. K953383)

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D. Description

HCG is a hormone produced and secreted by the placenta following implantation. Its early presence and rapid increase in maternal urine make it an excellent marker for use in the diagnosis of pregnancy.

Scripps Laboratories hCG One-Step uses monoclonal and polyclonal antibody technology to specifically detect hCG in urine.

The product is configured in a dipstick format. When the product is partially submerged in urine, the sample travels through the Test Strip. If hCG is present at levels of 25 mIU/ml (W.H.O. 3rd I.S. 75/537) or greater, a positive result, two distinct red bands will appear. If no hCG is present, a negative result, one red band, will appear.

E. Intended Use Statement

Scripps Laboratories hCG One-Step is a rapid, one step immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine for the early detection of pregnancy. For Laboratory and Professional Use.

F. Summary of Similarities to Legally Marketed Devices

Scripps Laboratories hCG One-Step is substantially equivalent in methodology, intended use, technology and performance characteristics to Quidel® QuickVue® One-Step hCG Urine Test and to Wyntek Diagnostics OSOM™ hCG-Urine Test. The similarities between the three tests are shown in the following table.

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Summary of Similarities Between Scripps Laboratories hCG One-Step, Quidel® QuickVue® One-Step hCG Urine Test and Wyntek Diagnostics OSOM™ hCG-Urine Test.

Characteristic	Scripps Laboratories hCG One-Step	Quidel® QuickVue® One-Step hCG Urine Test	Wyntek Diagnostics OSOM™ hCG-Urine Test
Intended Use			
Diagnostic Use	Early Detection of Pregnancy	Early Detection of Pregnancy	Early Detection of Pregnancy
Use Setting	Laboratory and Professional	Laboratory and Professional	Laboratory and Professional
Methodology			
Sample	Urine	Urine	Urine
Timing	5 minutes	3 minutes	1 minute
Format	One-Step	One-Step	One-Step
Results Interpretation	Visual, Qualitative	Visual, Qualitative	Visual, Qualitative
Detection Limit	25 mIU/ml	25 mIU/ml	25 mIU/ml
Standardization	WHO 3rd IS 75/537	WHO 3rd IS 75/537	WHO 3rd IS 75/537
Technology			
Assay Type	Chromatographic Immunoassay	Chromatographic Immunoassay	Chromatographic Immunoassay
Antibodies	Murine Monoclonal and Caprine Polyclonal Anti-hCG	Murine Monoclonal and Caprine Polyclonal Anti-hCG	Murine Monoclonal and Rabbit Polyclonal Anti-hCG
Solid Phase	Membrane	Membrane	Membrane
Performance			
Sensitivity	100%	99.5%	99.6%
Specificity	99.6%	99.6%	99.6%
Accuracy	99.8%	99.5%	99.6%

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G. Performance Data

1. Clinical Accuracy

Scripps Laboratories hCG One-Step was evaluated and compared to a commercially available visual hCG test in a multicenter field study. Five hundred seven urine specimens presented for pregnancy testing were run on Scripps Laboratories hCG One-Step and designated as qualitatively positive or negative for hCG based on the results of Quidel® QuickVue® One-Step hCG Urine Test. All testing was performed in the intended use setting by individuals with different educational backgrounds and training.

The clinical accuracy of Scripps Laboratories hCG One-Step in the intended use setting was 99.8% when compared to a commercially available visual hCG test. The sensitivity was 100% and the specificity was 99.6%.

Clinical Accuracy of Scripps Laboratories hCG One-Step

		Comparative Test +	Comparative Test -
Scripps Laboratories hCG One-Step	+	238	1*
	-	0	268

* Sample contained 17.9 mIU/ml hCG

2. Sensitivity

Urine samples with hCG concentrations of 25 mIU/ml (W.H.O. 3rd I.S. 75/537) or greater yielded positive results on Scripps Laboratories hCG One-Step.

3. Interference

The following substances were added to urine containing either 0 mIU/ml or 25 mIU/ml hCG and did not interfere with the performance of Scripps Laboratories hCG One-Step at the concentration indicated:

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G. Performance Data (continued)

3. Interference (continued)

Drug/Chemical	Concentration
Acetaminophen	20 mg/dl
Acetylsalicylic Acid	20 mg/dl
Ampicillin	4 mg/dl
Atropine	20 mg/dl
Caffeine	20 mg/dl
Ephedrine	20 mg/dl
Ethylenediaminetetraacetic Acid	80 mg/dl
Gentisic Acid	20 mg/dl
Ibuprofen	20 mg/dl
Ethanol	10%
Phenylpropanolamine HCl	4000 mg/dl
Tetracycline	20 mg/dl

Urine Analyte	Concentration
Albumin, human	2000 mg/dl
Ascorbic Acid	20 mg/dl
Bilirubin	1 mg/dl
Creatinine	200 mg/dl
Estradiol	25 ng/ml
Estriol	25 ng/ml
Glucose	2000 mg/dl
Hemoglobin	500 mg/dl
ß-Hyroxybutyric Acid	100 mg/dl
Pregnanediol	1000 ng/ml
Progesterone	40 ng/ml
Riboflavin	3750 µg/dl
Uric Acid	10 mg/dl

4. Cross Reactivity

The addition of 500 mIU/ml LH, 1000 mIU/ml FSH, and 1000 µIU/ml TSH to samples containing either 0 mIU/ml or 25 mIU/ml hCG did not exhibit cross reactivity in Scripps Laboratories hCG One-Step.

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G. Performance Data (continued)

5. Urine pH

Urine samples containing either 0 mIU/ml or 25 mIU/ml hCG adjusted to different pH levels from 4 to 9 did not affect the performance of Scripps Laboratories hCG One-Step.