

JUN 28 2000

510(k) Summary**FastPack™ PSA Immunoassay on the FastPack™ Analyzer System**

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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| 1. Submitter name, address, contact | <p>Qualigen, Incorporated
2042 Corte del Nogal
Carlsbad, CA 92009</p> <p>Telephone: (760) 918-9165
Fax: (760) 918-9127</p> <p>Contact Person: Vijay K. Mahant, Ph.D.</p> <p>Date Prepared: June 22, 2000</p> |
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| 2. Device name | <p>Proprietary name: FastPack™ PSA Immunoassay on the FastPack™ Analyzer System</p> <p>Common name: Chemiluminescence assay for the determination of Prostate-Specific Antigen (PSA).

Photometer for clinical use.</p> <p>Classification Name: Prostate-Specific Antigen (PSA) for Management of Prostate Cancer</p> |
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| 3. Predicate device | Abbott IMx® PSA (P910007) using Abbott IMx® Analyzer (K864319) |
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| 4. Device description | <p><i>FastPack™ PSA Immunoassay Reagents</i></p> <p>The FastPack™ PSA Immunoassay is a two-site chemiluminescence assay.</p> <ul style="list-style-type: none"> • 1st incubation: 5 minutes at 37° C. Sample, control or calibrator [100 µL] and PSA antibody solution [100 µL] react to form a sandwich complex. |
|------------------------------|---|

- 2nd incubation: 5 minutes at 37° C. Streptavidin-coated paramagnetic particle solution is added to the reaction mixture. After the 5-minute incubation, the sandwich complex is bound to the solid phase via the interaction of biotin and streptavidin.
- Removal of unbound materials: The paramagnetic particles are washed six times with wash buffer [0.2 mL/wash] to remove unbound materials.
- Substrate addition and detection: Chemiluminogenic substrate [175 µL] is added to the solid phase bound complex to form a chemiluminescent glow, which is measured by the FastPack™ Analyzer System.

FastPack™ Analyzer System

The FastPack™ Analyzer System is a compact chemiluminescent immunoassay system. The system consists of four components:

- FastPack™ (Reagent Pack)
- FastPack™ Sample Filler
- FastPack™ Analyzer
- Pressure/Power Supply

The FastPack™ is a small essentially two-dimensional plastic package that contains all the pre-measured reagents, in sealed chambers, necessary to perform the desired test. The pack label contains a barcode with all necessary information required by the analyzer to run the test.

The FastPack™ Sample Filler delivers an accurate quantified sample (100 µL) of sample, calibrator or control for testing.

The FastPack™ Analyzer is designed to receive the FastPack™ and to perform the necessary assay by automatically mixing and moving the sample and reagents within the pack. The sample and reagents are moved from one chamber to another by applying uniform pressure to the compartments by means of pressure pads extended from the analyzer. The analyzer uses a small magnet to hold the paramagnetic particles during the wash phase. During the entire run of the FastPack™, temperature control is achieved by heating metal plates that adjoin the FastPack™.

5. Intended use

The FastPack™ PSA Immunoassay is a paramagnetic particle, chemiluminescence immunoassay intended for the *in vitro* quantitative determination of prostate-specific antigen (PSA) in human serum. The FastPack™ PSA Immunoassay is indicated as an aid in the management of patients with prostate cancer. The FastPack™ PSA Immunoassay is designed for use with the FastPack™ Analyzer System.

6. Comparison to predicate device

The FastPack™ PSA Immunoassay on the FastPack™ Analyzer System is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Abbott IMx® PSA on the Abbott IMx® Analyzer.

The following tables compare the FastPack™ Immunoassay System for PSA with the Abbott IMx® System for PSA:

Similarities:

• Assay Methodology:	Sandwich immunoassay
• Sample Type:	Serum
• Storage Condition:	2-8 °C
• Label	Alkaline Phosphatase
• Detector:	Photomultiplier Tube (PMT)
• Data Analysis	Internal data reduction via microcomputer
• Temperature Control	Required
• Test Processing	Automated

Comparison to predicate device (continued)

Differences:

Feature	FastPack™ PSA	Abbott IMx® PSA
Intended Use	For the <i>in vitro</i> quantitative determination of PSA in human serum. It is indicated as an aid in the management of patients with prostate cancer.	As an aid in the management of prostate cancer patients.
Sample Volume	100 µL	150 µL
Assay Range	0 to 50 ng/mL	0 to 100 ng/mL
Instrument Required	FastPack™ Analyzer System	Abbott IMx® Analyzer
Control Levels	2	3
Calibration Levels	5	6
Capture Antibody	Monoclonal	Polyclonal
Solid-phase	Streptavidin-coated paramagnetic particles	Monoclonal Anti-PSA coated microparticles
Substrate	ImmuGlow™ (Indoxyl -3-phosphate and lucigenin)	4-Methylumbelliferyl Phosphate

Detection	Chemiluminescence	Fluorescence
Calibration	Factory generated master curve with daily two-level calibration adjustment	Full calibration curve every 4 weeks
Throughput	Single Sample	24 Samples
Time to Result	30 minutes	40 minutes
Sample Cartridge	All reagent included	Reagent pack and wash separate

Performance Characteristics:

Feature	FastPack™ PSA	Abbott IMx® PSA	
<i>Precision</i>	ng/mL PSA		
	<i>Between Run</i>		
	Low (0.75)	13.1%	<i>Intra-assay</i>
	Med (2.94)	11.2%	
	High (23.41)	9.4%	
	<i>Between Analyzer</i>		<i>Inter-assay</i>
	Low (0.75)	6.2%	
	Med (2.94)	3.7%	
	<i>Between Reagent Lot</i>		
	Low (0.75)	1.7%	
Med (2.94)	5.0%		
High (23.41)	1.4%		
<i>Analytical Sensitivity</i>	0.04 ng PSA/mL	0.1 ng PSA/mL	
<i>Spike Recovery</i>	96 to 107%	91 to 103%	
<i>Dilution Recovery</i>	94 to 120%	Not reported	
<i>Method Comparison</i>	versus Abbott IMx® PSA: n = 110 Range of values (Abbott): 0 to 51.6 ng PSA/mL Range of values (FastPack): 0 to 57.0 ng PSA/mL $y = 0.971x - 0.2367$ (Deming) $r^2 = 0.984$ (Spearman) $S^2_{\text{slope}} = 0.000403$ $S^2_{\text{intercept}} = 0.111306$		

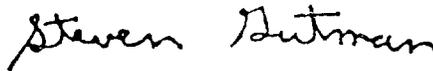
<i>Interfering Substances</i>	No interference up to:	No interference up to:
Bilirubin	49 mg/dL	25 mg/dL
Hemoglobin	600 mg/dL	600 mg/dL
IgG	1900 mg/dL	250-2900 mg/dL
PAP	1000 ng/mL	1000 ng/mL
HSA	<i>Interference found at 3 g/dL</i>	3-13 g/dL
Triglycerides	3000 mg/dL	3000 mg/dL
Cyclophosphamide	700 µg/mL	700 µg/mL
DES	1 µg/mL	2 µg/mL
Doxorubicin HCl	16 µg/mL	16 µg/mL
Methotrexate	8 µg/mL	30 µg/mL
Megestrol Acetate	90 µg/mL	90 µg/mL
Flutamide	10 µg/mL	10 µg/mL
Lupron	100 µg/mL	100µg/mL
<i>High Dose Hook Effect</i>	No high dose hook effect up to 500 ng/mL	Not reported

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 1

Indications for Use Statement

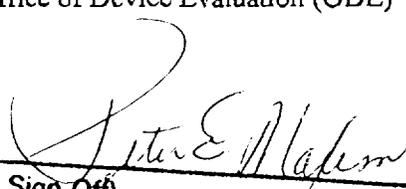
510(k) Number K994419

Device Name FastPack™ PSA Immunoassay and the FastPack™ Analyzer System

Indications for Use The FastPack™ PSA Immunoassay is a paramagnetic particle, chemiluminescence immunoassay for the *in vitro* quantitative determination of prostate-specific antigen (PSA) in human serum. The FastPack™ PSA Immunoassay is indicated as an aid in the management of patients with prostate cancer. The FastPack™ PSA Immunoassay is designed for use with the FastPack™ Analyzer System.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994419

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____