K052301

JAN 4 2006

510(k) Summary

FastPack® TSH Immunoassay on the FastPack® 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.

1.	**Submitter name, address, contact**	Qualigen, Incorporated 2042 Corte del Nogal Carlsbad, CA 92011	
		Telephone: Fax:	(760) 918-9165 (760) 918-9127
		Contact Person:	Dorothy Peterson
		Date Prepared:	August 15, 2005
2.	**Device name**	Proprietary name:	FastPack® TSH Immunoassay on the FastPack® System
		Common name:	Chemiluminescence assay for the determination of TSH
		Classification Name:	Quantitative Determination of TSH in Human Plasma
3.	**Predicate device**	Abbott Laboratories IMx Ultrasensitive hTSH II (K942566)	

4. **Device description**

FastPack® TSH Immunoassay Reagents

The FastPack® TSH Immunoassay is a competitive chemiluminescence assay.

- Primary incubation: Sample, calibrator, or control (100 µL) is added to the antibody solution (100 µL) to start the sequence. The reaction time is 10 minutes at 37° C.
- Secondary incubation: The initial reaction mixture (200 µL) is transferred to the magnetic particles and is incubated an additional 2 minutes at 37° C.
- Removal of unbound materials: The paramagnetic particles are washed three times with wash buffer (0.2 mL/wash cycle) to remove unbound materials.
- Substrate addition and detection: Chemiluminogenic substrate [140 µL] is added to the solid phase bound complex to form a chemiluminescent glow, which is measured by the FastPack® System at 37° C.

5. **Intended use**

The FastPack® TSH Immunoassay is a paramagnetic particle immunoassay intended for the *in vitro* quantitative determination of TSH in human plasma. The measurements of thyroid stimulating hormone (TSH) produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders. The FastPack® TSH Immunoassay is designed for use with the FastPack® System.

6. **Comparison to Predicate Device**

The following tables compare the FastPack® Immunoassay System for TSH with the Abbott Laboratories Ultrasensitive TSH II method.

Feature	FastPack® System	Abbott IMx® System
Intended Use	For the quantitative measurement of Thyroid-Stimulating Hormone (TSH) in human plasma. The measurements of thyroid stimulating hormone (TSH) produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.	For the quantitative measurement of Thyroid-Stimulating Hormone (TSH) in human serum and heparinized plasma.
Assay Methodology:	Sandwich immunoassay	Sanwich immunoassay
Storage Condition:	2-8 °C	2-8 °C
Data Analysis	Internal data reduction via microcomputer	Internal data reduction via microcomputer
Temperature Control	Required	Required
Test Processing	Automated	Automated
Sample Type:	Plasma	Serum, Heparinized Plasma
Detector:	Photomultiplier Tube (PMT)	Photomultiplier Tube (PMT)
Label	Alkaline Phosphatase	Alkaline Phosphatase
Sample Volume	100 µL	150 µL
Assay Range	0 to 100 µIU/mL	0 to 100 µIU/mL
Instrument Required	FastPack® System	Abbott IMx® System
Control Levels	2	3
Antibody	Monoclonal/Monoclonal	Monoclonal/Polyclonal
Solid Phase	Paramagnetic particles	Latex Microparticles
Substrate	ImmuGlow™ (Indoxyl –3-phosphate and lucigenin)	4-Methylumbelliferyl Phosphate
Detection	Chemiluminescence	Fluorescence
Calibration	Factory generated master curve with a single level calibration adjustment every 14 days.	Full calibration curve (six standards) with change in reagents.
Throughput	Single Sample	Batch
Time to Result	16 minutes	45 minutes to first result

Reagents Supplied as	Box of 50 disposable self contained reagent packs	Reagent Pack for 100 test

Performance Characteristics:

Feature	FastPack® TSH		Abbott IMx® hTSH II	
Precision				
		Mean µIU/mL	%CV	
	Between Run		*Run to Run*	
	1	0.53	10.9	1 0.28 4.20
	2	1.54	7.4	2 6.10 3.42
	3	12.39	5.2	
	Between Analyzer			*Between Run*
	1	0.53	2.2	1 0.28 3.44
	2	1.54	0.5	2 6.10 3.25
	3	12.39	1.1	
	Between Reagent Lot			
	1	0.53	1.2	
	2	1.54	0.3	
	3	12.39	4.8	
Analytical Sensitivity	0.01 µIU/mL		0.02 µIU/mL	
Functional Sensitivity	0.13 µIU/mL		0.04 µIU/mL	
Method Comparison	versus Abbott IMx Ultrasensitive hTSH II: n = 93 Range of values (IMx): 0.00 to 75.00 µIU/mL Range of values (FastPack): 0.03 to 64.25 µIU/mL y = 0.91 x + 1.26 r = 0.98			
Interfering Substances				
Bilirubin	No interference up to: 40 mg/dL		No interference up to: 10 mg/dL	
Hemoglobin	1000 mg/dL		1000 mg/dL	
Triglycerides	1000 mg/dL		1200 mg/dL	
Specificity	500 mIU/mL LH	n.d.	1000 mIU/mL LH	n.d.
	500 mIU/mL FSH	n.d.	1000 mIU/mL FSH	n.d.
n.d. = not detected	200,000 mIU/mL hCG	n.d.	200,000 mIU/mL hCG	n.d

Functional Sensitivity	0.13 µIU/mL	0.04 µIU/mL
Method Comparison	versus Abbott IMx Ultrasensitive hTSH II: n = 93 Range of values (IMx): 0.00 to 75.00 µIU/mL Range of values (FastPack): 0.03 to 64.25 µIU/mL y = 0.91 x + 1.26 r = 0.98	
Interfering Substances	No interference up to:	No interference up to:
Bilirubin	40 mg/dL	10 mg/dL
Hemoglobin	1000 mg/dL	1000 mg/dL
Triglycerides	1000 mg/dL	1200 mg/dL
Specificity	500 mIU/mL LH n.d. 500 mIU/mL FSH n.d.	1000 mIU/mL LH n.d. 1000 mIU/mL FSH n.d.
n.d. = not detected	200,000 mIU/mL hCG n.d.	200,000 mIU/mL hCG n.d

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 4 2006

Ms. Dorothy Deinzer Peterson
Vice President
Quality Assurance and Regulatory Affairs
Qualigen Incorporated
2042 Corte del Nogal
Carlsbad, CA 92011

Re: k052301
Trade/Device Name: FastPack® TSH Immunoassay
FastPack® TSH Calibrator
FastPack® TSH Controls
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: Class II
Product Code: JLW, JJX, JIT
Dated: December 6, 2005
Received: December 14, 2005

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number	K052301
Device Name	FastPack® TSH Immunoassay, FastPack® TSH Calibrator, FastPack® Controls
Indications for Use	The FastPack® TSH Immunoassay is a paramagnetic particle, chemiluminescence immunoassay for the *in vitro* quantitative determination of Thyroid-Stimulating Hormone in human plasma. The measurements of thyroid stimulating hormone (TSH) produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders. The FastPack® TSH is designed for use with the FastPack® System. The FastPack® TSH Calibrator is intended to calibrate the FastPack® System when used for the quantitative determination of TSH in human plasma. The FastPack ® Controls are assayed quality control materials for the verification of the accuracy and precision of the FastPack® System when used for the quantitative determination of PSA in human serum and plasma, and TSH in human plasma.

Prescription Use ___X___ (Per 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Ann Chappie

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052301