JUL 0 3 2003

510(k) Summary K030329

FastPack® Free T_4 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.

1.	**Submitter name, address, contact**	Qualigen, Incorporated 2042 Corte del Nogal Carlsbad, CA 92009	
		Telephone: Fax:	(760) 918-9165 (760) 918-9127
		Contact Person:	Dorothy Deinzer
		Date Prepared:	January 28, 2003
2.	**Device name**	Proprietary name:	FastPack® Free T_4 Immunoassay on the FastPack® Analyzer System
		Common name:	Chemiluminescense assay for the determination of Free T_4
		Classification Name:	Quantitative Determination of Free T_4 in Human Serum
3.	**Predicate device**	Abbott Laboratories IMx Free T_4 (K902834)	
4.	**Device description**	***FastPack® Free T4 Immunoassay Reagents***	

The FastPack® Free T_4 Immunoassay is a competitive chemiluminescense 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 seconds at 37° C.

- Secondary incubation: The initial reaction mixture (200 µL) is transferred to the magnetic particles with bound testosterone and competition between the sample testosterone and the beads continues for an additional 2.5 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® Analyzer System at 37° C.

5. Intended use

The FastPack® Free T_4 Immunoassay is a paramagnetic particle immunoassay intended for the *in vitro* quantitative determination of Free T4 in human serum. The FastPack® Free T_4 Immunoassay is designed for use with the FastPack® Analyzer System. It is intended strictly for *in vitro* diagnostic use as an aid in the diagnosis and management of thyroid dysfunction.

---

6. Comparison to Predicate Device

The following tables compare the FastPack® Immunoassay System for Free T_4 with the Abbott Laboratories Free T_4 method.

Feature	FastPack® System	Abbott IMx® System
Intended Use	For the quantitative measurement of free thyroxine in human serum.	For the quantitative measurement of free thyroxine (FT_4) in human serum and heparinized plasma.
Assay Methodology:	Competitive immunoassay	Competitive 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:	Serum	Serum, Heparinized Plasma
Detector:	Photomultiplier Tube (PMT)	Photomultiplier Tube (PMT)
Label	Alkaline Phosphatase	Alkaline Phosphatase

Sample Volume	100 µL	150 µL
Assay Range	0.4 to 6 ng/dL	0.4 to 6 ng/dL
Instrument Required	FastPack® Analyzer System	Abbott IMx® System
Control Levels	2(not supplied)	3
Antibody	Monoclonal	Polyclonal
Competing component	T_3 covalently coupled to paramagnetic particles	T_3-Alkaline Phosphatase Conjugate
Solid Phase	Paramagnetic particles	Latex Microparticles
Substrate	ImmuGlow™ (Indoxyl –3-phosphate and lucigenin)	4-Methylumbelliferyl Phosphate
Detection	Chemiluminescense	Fluorescence
Calibration	Factory generated master curve with single-level calibration adjustment every 14 days.	Full calibration curve (six standards) with change in reagents.
Throughput	Single Sample	Batch
Time to Result	7 minutes	45 minutes to first result
Reagents Supplied as	Box of 50 disposable self contained reagent packs	Free T_4 Reagent Pack for 100 test, 6 vials of calibrator

Performance Characteristics:

Feature	**FastPack® Free T_4**			**Abbott IMx® Free T_4**		
Precision		Mean ng/dL	%CV		Mean ng/dL	%CV
	Between Run			*Run to Run*		
	1	1.43	7.4	1	1.18	4.47
	2	3.51	6.2	2	3.23	5.59
	Between Analyzer			*Between Run*		
	1	1.43	2.8	1	1.18	3.80
	2	3.51	1.8	2	3.23	4.79
	Between Reagent Lot					
	1	1.43	11.1			
	2	3.51	4.8			
Analytical Sensitivity	0.4 ng T_4/dL			0.4 ng T_4/dL		
Method Comparison	versus Abbott IMx Free T_4: n = 131 Range of values (IMx): 0.61 to 5.52 ng T_4/dL Range of values (FastPack): 0.52 to 5.93 ng T_4/dL y = 1.07x – 0.17 r = 0.95					

Interfering Substances	No interference up to:	No interference up to:
Bilirubin	40 mg/dL	20 mg/dL
Hemoglobin	1000 mg/dL	1000 mg/dL
Triglycerides	1000 mg/dL	1200 mg/dL
Specificity	$L\text{-}T_3$ ≤ 0.9%	$L\text{-}T_3$ ≤ 0.5%
	$D\text{-}T_4$ 100%	$D\text{-}T_4$ 100%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 0 3 2003

Ms. Dorothy Deinzer
Vice President
Quality and Regulatory Affairs
Qualigen, Inc.
2042 Corte Del Nogal
Carlsbad, CA 92009

Re: k030329
Trade/Device Name: FastPack® Free T_4 Immunoassay
FastPack® Testo/Free T_4 Calibrator
Regulation Number: 21 CFR 862.1695
Regulation Name: Free thyroxine test system
Regulatory Class: Class II
Product Code: CEC; JIX
Dated: May 23, 2003
Received: May 28, 2003

Dear Ms. Deinzer:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Attachment 4

Indications for Use Statement

510(k) Number	K030329
Device Name	FastPack® Free T_4 Immunoassay
Indications for Use	The FastPack® Free T_4 Immunoassay is a paramagnetic particle, chemiluminescence immunoassay for the *in vitro* quantitative determination of free thyroxine (FT_4) in human serum. The FastPack® Free T_4 Immunoassay is designed for use with the FastPack® Analyzer System. It is intended strictly for *in vitro* diagnostic use as an aid in the diagnosis and management of thyroid dysfunction.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K030329

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Indications for Use Statement

510(k) Number K030329

Device Name FastPack® Testo/Free T_4 Calibrator

Indications for Use The FastPack® Testo/Free T_4 Calibrator is intended to calibrate the FastPack® Analyzer system when used for the quantitative determination of Total Testosterone or Free T_4 in human serum

Jean Cooper

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K030329

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)