K101388

Qualigen

FEB 18 2011

510(k) SAFETY AND EFFECTIVENESS SUMMARY

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

1. Submitter's Name, Address, Telephone Number, Contact Person and date the summary was prepared.

Submitter's Name:	Qualigen, Inc.
Address:	2042 Corte Del Nogal Carlsbad, CA 92011 (760)-918-9165
Contact Person:	Michael Poirier Senior Vice President, CSO/CTO mpoirier@qualigeninc.com
Date the summary prepared:	February 18, 2011

2. Device Name

Trade/Proprietary Name:	FastPack® Testo Immunoassay
Common/Usual Name:	Total Testosterone Immunoassay
Classification Name:	Total Testosterone Immunoassay, §21 CFR 862.1690
Class:	Class II

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3. Predicate Device:

FastPack® Testo Immunoassay
510(k) number: K021972

4. Device Description

The FastPack® Testo Immunoassay for the quantitative determination of testosterone in human serum, lithium heparin plasma and K2 EDTA plasma is designed for use on the FastPack® Analyzer.

FastPack® Testo Immunoassay Reagents

The FastPack® Testo Immunoassay Reagents are contained in a disposable pack (FastPack®). Each FastPack® contains the following four components:

1. Paramagnetic Particles, 150 µL
   Paramagnetic particles with covalently coupled testosterone in buffer containing 0.1% sodium azide as a preservative.

2. Testosterone Antibody Solution, 100 µL
   Antibody solution containing mouse monoclonal antibody labeled with alkaline phosphatase in a protein matrix containing 0.03% Proclin® 150 as a preservative.

3. Wash Buffer, 2.0 mL
   Tris buffer containing surfactants.

4. Substrate, 140 µL
   ImmuGlow™: Indoxyl-3-phosphate and lucigenin in buffer containing preservatives.

The FastPack® Testo Immunoassay is a competitive chemiluminescence assay.

- Primary incubation: Antibody solution (a buffer solution containing a monoclonal C3-testosterone-specific antibody labeled with alkaline phosphatase)[100 µL] reacts with testosterone from the patients sample, control, or calibrator [100 µL].

- Secondary incubation: The reaction mixture is added to paramagnetic particle with covalently coupled testosterone. During this incubation, the testosterone-coated beads compete with the sample testosterone.

- Removal of unbound materials: The paramagnetic particles are washed with wash buffer [0.2 mL/wash] to remove unbound materials.

- Substrate addition and detection: Chemiluminogenic substrate [140 µL] is added to the solid-phase bound complex and results in "glow" chemiluminescence, which is measured using the FastPack® Analyzer at 37°C.

- The amount of bound labeled-antibody is inversely proportional to the concentration of testosterone in the sample.

5. Intended Use:

The FastPack® Testo Immunoassay is a paramagnetic particle immunoassay for the in vitro quantitative determination of total testosterone in human serum and plasma. It is intended strictly for in-vitro diagnostic use as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen. The FastPack® Testo Immunoassay is designed for use with the FastPack® System.

6. Assessment of Performance:

An evaluation of the FastPack® Testo Immunoassay was conducted in-house. The studies demonstrated the safety and effectiveness of the device when used as intended.

7. Comparison to Predicate Device.

Similarities / Differences between FastPack® Testo Serum & Plasma Assays

CHARACTERISTIC	Qualigen FastPack® Testo Immunoassay Serum or Plasma	Qualigen FastPack® Testo Serum Only K021972
Intended Use	for the *in-vitro* quantitative determination of total testosterone in human serum or lithium-heparin or K2 EDTA plasma. The FastPack® Testo Immunoassay is designed for use with the FastPack® System.	for the *in-vitro* quantitative determination of total testosterone in human serum. The FastPack® Testo Immunoassay is designed for use with the FastPack® System.
Indications for Use	Quantitative determination of total testosterone.	Quantitative determination of total testosterone.
Sample	Serum or plasma (heparin or K2 EDTA)	Serum
Sample Preparation	Standard processing for serum or plasma	Standard processing for serum
Calibration	An active calibration is required every 14 days and with each new lot; system includes calibration solutions and instructions.	An active calibration is required every 14 days and with each new lot; system includes calibration solutions and instructions.
Methodology	The FastPack® Testo Immunoassay is a paramagnetic particle, chemiluminescent immunoassay.	The FastPack® TestoImmunoassay is a paramagnetic particle, chemiluminescent immunoassay.
Testing Environment	Professional use	Professional use
Measuring Range	23 ng/dL to 1600 ng/dL	23 ng/dL to 1600 ng/dL
Precision	Total imprecision is 10.9% CV at 712 ng/dL (high sample) and 0.07 SD at 14 ng/dL (low sample)	Total imprecision is 10.9% CV at 712 ng/dL (high sample) and 0.07 SD at 14 ng/dL (low sample)
Linearity	Assay linear throughout dynamic range	Assay linear throughout dynamic range

Interfering Substances	No interference from Bilirubin up to concentrations of 10mg/dL. No interference fromm Hemoglobin up to concentrations of 250mg/dL. Triglyceride demonstrated interference for all concentrations of interferent tested at < 100 ng/dL of testosterone. Based on these studies, no visibly hemolyzed or cloudy (lipemic) samples should be used with this assay.	No interference from Bilirubin up to concentrations of 10mg/dL. No interference fromm Hemoglobin up to concentrations of 250mg/dL. Triglyceride demonstrated interference for all concentrations of interferent tested at < 100 ng/dL of testosterone. Based on these studies, no visibly hemolyzed or cloudy (lipemic) samples should be used with this assay.
Cross-reactivity	No significant cross-reactivity from high levels of 5-α-DHT. Androsetenediol and 19-Norethisterone Acetate generated the highest cross-reactivity in this study though although the magnitude was limited to <4%.	No significant cross-reactivity from high levels of 5-α-DHT. Androsetenediol and 19-Norethisterone Acetate generated the highest cross-reactivity in this study though although the magnitude was limited to <4%.
Comparative Testing vs Established Methods **(Deming Regressions)**	<u>Serum</u> N = 135 Range of observations: 24.0 – 1587.2 ng/dL Slope: 1.054 y-intercept: 6.5 r^2 = 0.914 <u>Lithium Heparin Plasma vs Serum</u> N = 60 Range of observations: 24.0 – 1440.0 ng/dL Slope: 0.992 y-intercept: -8.0 r^2 = 0.987 <u>K2 EDTA Plasma vs Serum</u> N = 67 Range of observations: 27.5 – 1425.0 ng/dL Slope: 0.998 y-intercept: -10.9 r^2 = 0.996	<u>Serum</u> N = 135 Range of observations: 24.0 – 1587.2 ng/dL Slope: 1.054 y-intercept: 6.5 r^2 = 0.914 <u>Lithium Heparin Plasma vs Serum</u> N = 60 Range of observations: 24.0 – 1440.0 ng/dL Slope: 0.992 y-intercept: -8.0 r^2 = 0.987 <u>K2 EDTA Plasma vs Serum</u> N = 67 Range of observations: 27.5 – 1425.0 ng/dL Slope: 0.998 y-intercept: -10.9 r^2 = 0.996

8. Conclusions

The results of the evaluation studies of the FastPack® Testo Immunoassay demonstrate that the device is equivalent in performance to the predicate device and suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
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Qualigen, Inc.
c/o Mr. Michael S. Poirier
Senior Vice President
2042 Corte Del Nogal, Suite B
Carlsbad, CA 92011-1438

FEB 18 2011

Re: k101388
Trade/Device Name: Fastpack® Testo Immunoassay
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone test system
Regulatory Class: I, reserved
Product Code: CDZ
Dated: February 3, 2011
Received: February 4, 2011

Dear Mr. Poirier:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, 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

510(K) Number (if known): K101388

Device Name:

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Prescription Use **XX** Use (Part 21 CFR 801 Subpart D) Subpart C)	AND/OR	Over –the-Counter (Part 21 CFR 801

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE AS NEEDED)

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

Carol Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K101388