K123725

MAR 0 8 2013

SECTION 6
510 (K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR § 807.92.

510(k) Number:

Submitter:

Qualigen, Inc.
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Contact Person:

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Date Prepared: March 8, 2013

Device Identification

Trade Name:	FastPack® Control Kit
Common Name:	Multi-Analyte Controls, All Kinds (Assayed)
Classification:	Class I, reserved
Product Code:	JJY
Regulation Number:	21 CFR § 862.1660

Devices to Which Substantial Equivalence is Claimed

Immunology Control (containing FT4, testosterone, and hCG)
Medical Analysis Systems,
Camarillo, California
K960824

FastPack® Controls (containing PSA)
Qualigen, Inc.
Carlsbad, California
K003095

FastPack® TSH Controls
Qualigen, Inc.
Carlsbad, California
K052301

Device Description

FastPack® Control Kit is prepared in a synthetic matrix containing chemicals, preservatives, and stabilizers with added analyte constituents of human and synthesized origin. The control is provided in liquid form for convenience.

Intended Use

The FastPack® Control Kit is an assayed quality control for the verification of the accuracy and precision of the FastPack® and FastPack® IP Systems when used for the quantitative determination of the analytes listed in the package insert. The following analytes are included in the package insert:

- Free Thyroxine (FT4)
- Human Chorionic Gonadotropin (hCG)
- Testosterone
- Total Prostate Specific Antigen (tPSA)
- Thyroid Stimulating Hormone (TSH)

Comparison of new device to predicate devices

Similarities/Differences between FastPack® Multi-Analyte Assayed Control and Predicate Devices

Characteristic	FastPack® Control Kit	Immunology Control, containing FT4, testosterone, and hCG (K960824)	Predicates: FastPack® Controls for PSA (K003095) and FastPack® TSH Controls (K052301)
Intended Use	The FastPack® Control Kit is an assayed quality control for the verification of the accuracy and precision of the FastPack® and FastPack® IP Systems when used for the quantitative determination of the analytes listed in the package insert.	Immunology Control is intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many immunological determinations. Include immunology control with patient serum specimens when assaying for any of the listed constituents. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.	**PSA**: The FastPack® Controls are assayed quality control materials for the verification of the accuracy and precision of the FastPack® Analyzer system when used for the quantitative determination of PSA in human serum and plasma. **TSH**: 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 TSH in human plasma.
Matrix	Synthetic	Human serum	**PSA**: BSA **TSH**: BSA
Form	Liquid	Liquid	Liquid
Levels	2	3	2
Fill Volume	Each Multi-Analyte Control kit contains 1 vial of Level 1 and 1 vial of Level 2, each filled to 5 mL	Each Control Kit contains 2 vials of Level 1 , 2 and 3, each filled to 5 mL	Each Control Kit contains 1 vial of Level 1 and 1 vial of Level 2, each filled to 5 mL

Characteristic	FastPack® Control Kit	Immunology Control, containing FT4, testosterone, and hCG (K960824)	Predicates: FastPack® Controls for PSA (K003095) and FastPack® TSH Controls (K052301)
Open Vial Stability	120 days at 2-8 °C	30 days at 2-8 °C	9 months at 2-8 °C
Storage Unopened (Shelf Life)	18 months at 2-8 °C	3 years at -20 °C	12 months at 2-8 °C
Analytes	**Contains:** - Free Thyroxine (FT4) - Human Chorionic Gonadotropin (hCG) - Testosterone - Total Prostate Specific Antigen (tPSA) - Thyroid Stimulating Hormone (TSH)	Contains FT4, testosterone, and hCG	PSA (K003095), TSH (K052301)

Value Assignment of Analytes

FastPack® Control Kit lots are value-assigned on 6 FastPack® analyzers with three determinations for each of three lots of FastPack® reagents and using two separate calibrations to yield 36 determinations for each analyte at each of two Levels. Mean, standard deviation (SD), and percent coefficient of variation (% CV) for each level for each analyte are calculated and a range reported based on mean ± 3SD for each level for each analyte. However, laboratories should establish their own acceptable ranges and use those provided only as guides. Laboratory established ranges may vary from those listed during the life of the FastPack® Control Kit as a result of laboratory technique, instrumentation, and reagents.

Stability

Stability studies have been performed for the FastPack® Control Kit to determine the open vial and closed vial shelf-life claims. Product claims are as follows:

Open Vial Stability: 120 days at 2-8 °C
Shelf Life Stability: 18 months at 2-8 °C

SUMMARY

The information provided in this pre-market notification indicates that the FastPack® Control Kit is substantially equivalent to the stated predicate devices. The information further indicates that the FastPack® Control Kit is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 8, 2013

Qualigen, Inc.
C/O Michael Poirier
2042 Corte Del Nogal
Carlsbad, CA 92011

Re: k123725
Trade/Device Name: FastPack® Control Kit
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: Class I, reserved
Product Code: JJY
Dated: February 05, 2013
Received: February 11, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k123725

Device Name: FastPack® Control Kit

Indications for Use:

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- Thyroid Stimulating Hormone (TSH)

Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)___k123725_____