K062957

APR - 2 2007

510(k) Summary

FastPack® Total PSA Method Verification Kit

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:	Melissa Saam
		Date Prepared:	September 28, 2006
2.	**Device name**	Proprietary name:	FastPack® Total PSA Method Verification Kit
		Common name:	Total PSA Quality Controls
		Classification Name:	Single (specified) Analyte Controls (assayed and unassayed)
3.	**Predicate device**	FastPack® Controls	
4.	**Device description**	***FastPack® PSA Method Verification Kit*** The FastPack® Total PSA Method Verification kit components are in liquid form, in vials, from which the user can directly remove sample. They are formulated at three (3) levels packaged together as a kit.	
5.	**Intended use**	The FastPack® Total PSA Method Verification Kit consists of assayed quality control materials for verification of the calibration and reportable range of the FastPack® Total PSA Immunoassay to meet CLIA requirements.	

6. **Comparison to Predicate Device**

The following table compares the FastPack® PSA Method Verification Kit with the FastPack® Calibrators.

Feature	**Predicate Device**	**New Device**
	FastPack® Controls	**FastPack® Total PSA Method Verification Kit**
Intended Use	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 or plasma.	. Assayed quality control materials for the verification of the calibration and reportable range of the FastPack® Total PSA Immunoassay to meet CLIA requirements.
Analytes	Total PSA	Total PSA
Matrix	Bovine Serum Albumin	Bovine Serum Albumin
Form	Liquid	Liquid
Volume	5.0 mL	5.0 mL
Levels	2	3
PSA Concentrations	2 ng/mL 10 ng/mL	0 ng/mL 25 ng/mL 50 ng/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Qualigen, Inc.
c/o Ms. Melissa Saam
Manager, QA/RA
2042 Corte Del Nogal
Carlsbad, CA 92011

Re: k062957
Trade/Device Name: Qualigen™ FastPack® Total PSA Method Verification Kit
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: March 13, 2007
Received: March 19, 2007

Dear Ms. Saam:

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 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); 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) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan
for Dr Robert Becker

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062957

Device Name: FastPack® Total PSA Method Verification Kit

Indications for Use:

The FastPack® Total PSA Method Verification Kit consists of assayed quality control materials for verification of the calibration and reportable range of the FastPack® Total PSA Immunoassay to meet CLIA requirements.

Prescription Use) ___X___ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062957