



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Qualigen, Inc.  
c/o Michael S. Poirier, Senior Vice President  
2042 Carte Del Nogal, Suite B  
Carlsbad, CA 92011

Food & Drug Administration  
10903 New Hampshire Avenue  
Building 66  
Silver Spring, MD 20993

Re: k101390  
Trade Name: FastPack TSH Immunoassay  
Regulation Number: 21 CFR §862.1690  
Regulation Name: Thyroid stimulating hormone test system  
Regulatory Class: Class II  
Product Codes: JLW  
Dated: July 12, 2010  
Received: July 14, 2010

AUG 13 2010

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 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); 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).

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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 ) 796-5680 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CCH', with a long horizontal line extending to the right.

Courtney C. 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): K101390

### Device Name:

### Indications for Use:

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

Prescription Use **XX**  
(Part 21 CFR 801 Subpart D)  
C)

AND/OR

Over-the-Counter Use  
(Part 21 CFR 801 Subpart

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

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

Carol Benson  
Division Sign-Off

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Office of In Vitro Diagnostic Device  
Evaluation and Safety

510 K101390