DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

OCT - 9 2009

Thera-Test Laboratories Inc.
c/o Dr. Marius Teodorescu
President and CEO
1111 N. Main St
Lombard, IL 60148

Re: k092757
Trade/Device Name: TheraTest EL-β2GPI™ (IgM-IgG-IgA) & TheraTest EL-β2GPI™ Scr
Regulation Number: 21 CFR §866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: MSV
Dated: September 8, 2009
Received: September 9, 2009

Dear Dr. Teodorescu:

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 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,

Maria M. Chan, 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 ***K092757***

Device Name: TheraTest EL-β2GPI™ (IgM-IgG-IgA)

Indications for Use. The TheraTest EL-β2GPI™ (IgM-IgG-IgA) is a set of *in vitro* diagnostic tests for the measurement of IgM, IgG and IgA autoantibodies in human serum directed against serum beta 2-glycoprotein I (β2GPI). This measurement aids in the diagnosis of antiphospholipid antibody syndrome (APS) or certain autoimmune thrombotic disorders such as those secondary to systemic lupus erythematosus.

Prescription use__X_____ AND/OR Over-the-counter use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of in vitro Diagnostic devices (OIVD)

Indications for Use

510(k)Number *K092757*

Device Name: TheraTest EL-β2GPI™ Scr

Indications for Use. The TheraTest EL-β2GPI ™ Scr is an *in vitro* diagnostic test for the screening for autoantibodies in human serum directed against the serum glycoprotein beta 2-glycoprotein I (β2GPI). This measurement aids in the diagnosis of antiphospholipid antibody syndrome (APS) or certain autoimmune thrombotic disorders such as those secondary to systemic lupus erythematosus.

Prescription use___X_____ AND/OR Over-the-counter use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of in vitro Diagnostic devices (OIVD)

Reena Philip

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

k092757