



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUL 20 2006

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

Re: k061376

Trade/Device Name: TheraTest EL-ANCA™: anti-MPO  
TheraTest EL-ANCA™: anti-PR3  
TheraTest EL-ANCA™: anti-MPO and anti-PR3  
Regulation Number: 21 CFR 866.5660  
Regulation Name: Multiple Antibodies Immunological Test System  
Regulatory Class: Class II  
Product Code: MOB  
Dated: May 10, 2006  
Received: May 17, 2006

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 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); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,



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

# Attachment 2a

## Indications for Use Statement

TheraTest EL-ANCA™: anti-MPO and anti-PR3;

510(k)Number **K061376.**

Device Name TheraTest EL-ANCA™: anti-MPO;  
TheraTest EL-ANCA™: anti-PR3;  
TheraTest EL-ANCA™: anti-MPO and anti-PR3;

**Indications for Use.** TheraTest EL- ANCA™: anti-MPO- and EL- ANCA™: anti-PR3 are intended for use in clinical laboratories as *in vitro* diagnostic tests for the detection and measurement of autoantibodies in human serum directed against human neutrophil myeloperoxidase and proteinase 3, respectively. Measurement of anti-MPO aids in the diagnosis of microscopic polyangiitis. Measurement of anti-PR3 aids in the diagnosis of Wegener's granulomatosis.

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)

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

*Marva Chan*  
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Division Sign-Off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k)   K061376



# Attachment 2c

## Indications for Use Statement

TheraTest EL-ANCA™: anti-PR3;

510(k)Number **K061376.**

Device Name TheraTest EL-ANCA™: anti-PR3

**Indications for Use.** TheraTest EL- ANCA™: anti-PR3 is intended for use in clinical laboratories as *in vitro* diagnostic tests for the detection and measurement of autoantibodies in human serum directed against human neutrophil proteinase 3. Measurement of anti-PR3 aids in the diagnosis of Wegener's granulomatosis.

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)

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

*Maria Chan*

Division Sign-Off

Office of In Vitro Diagnostic  
Device Evaluation and Safety

510(k) K061376