DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 27 2002

Silvia S. Pierangeli, Ph.D.
Technical Director
Louisville APL Diagnostics, Inc.
3988 Flowers Road – Suite 620
Doraville, GA 30360

Re: k021398
Trade/Device Name: APL® IgA ELISA Kit
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: Class II
Product Code: MID
Dated: July 25, 2002
Received: July 29, 2002

Dear Dr. Pierangeli:

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.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number if Known: K021398
Device Name: *APL® IgA ELISA Kit*

## Indications for Use:

The Antiphospholipid Syndrome is a clinical diagnosis supported by finding a positive antiphospholipid ELISA and/or lupus anticoagulant test. Indications for the test include: patients with unexplained venous thrombosis, particularly if recurrent or at unusual sites as the inferior vena cava or renal veins; unexplained venous thrombosis, particularly if recurrent or at unusual sites as the inferior vena cava or renal veins; unexplained occlusion of the arterial circulation resulting in stroke, myocardial infarction, or peripheral gangrene. In patients with unexplained venous thrombosis, other disorder should be excluded, such as protein C, S, or antithrombin III deficiency, as well as malignancy or the nephrotic syndrome. The test is also indicated in women with one or more unexplained second or third trimester pregnancy losses or two or more first trimester losses. Finally, patients with unexplained thrombocytopenia as well as other abnormalities said to be associated with the Antiphospholipid Syndrome should be tested.

## Intended Use

*The APL® IgA ELISA Kit* is a semiquantitative enzyme linked immunosorben assay (ELISA) for use as an aid in diagnosing the Antiphospholipid Syndrome (APS) in patients presenting with thrombosis, pregnancy losses and/or thrombocytopenia. It enables measurement of IgA anticardiolpin antibody levels in human serum.

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

Concurrence of CDRH, Office of ~~Device~~ Evaluation (ODE)

Donna S. Alter

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K021398

Prescription Use ✓ OR Over the counter USE__
(Per 21 CFR 801.109) (Optional Format 1-2-96)