

SEP 20 1999

AVANTI[®] POLAR LIPIDS, INC.

K992124

1. Safety and Effectiveness Summary

This 510(k) summary of safety and effectiveness data is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and the Medical Device Amendments of 1992.

a. Submitter:

Avanti Polar Lipids, Inc.
700 Industrial Park Drive
Alabaster, AL 35007
Tel: (205) 663-2494
Fax: (205) 663-0756

b. Contact:

Rowena Shaw, Vice President

c. Date Submitted

June 22, 1999

d. Device Name:

Trade Name:

Avanti Polar Lipids VDRL Antigen Slide Test Kit

Common Name:

VDRL Antigen Slide Test Kit

Classification Name:

ANTIGENS, NON-TREPONEMAL, ALL

e. Device Description

The Venereal Disease Research Laboratory slide test is a test for the detection of syphilis. The test employs an antigen containing cardiolipin, phosphatidylcholine (lecithin), and cholesterol dissolved in ethanol. The antigen is suspended in a buffered saline solution, which flocculates when combined with serum containing IgM and IgG anti-cardiolipin antibodies. The IgM and IgG antibodies are produced in response to infection by *Treponema pallidum* the causative agent of syphilis. The flocculation forms a three-dimensional lattice structure that can be seen at low magnification (10x oculars and 10x objective) with a light

microscope.

- f. **Intended Use:**
Avanti's VDRL antigen and Buffered Saline are intended for use in the Venereal Disease Research Laboratory (VDRL) slide test for syphilis. The VDRL slide test is a non-treponemal, micro-flocculation test, that provides both qualitative and semi-quantitative results. The test is for the detection of IgM and IgG anti-cardiolipin antibodies in serum specimens.
- g. **Substantial Equivalence Claim:**
Avanti Polar Lipids, Inc. VDRL Antigen Slide Test Kit is substantially equivalent to the following currently marketed devices:
- i. *VDRL Antigen For Syphilis Serology.* Becton Dickinson Microbiology Systems, Becton Dickinson and Company, Sparks, MD 21152 USA.
 - ii. *Cenogenics ADRL/STS Test.* Cenogenics Corporation, Morganville, NJ. 07751 USA.
 - iii. *VDRL Antigen.* Lee Laboratories, Inc. 1475 Athens Highway, S.W., Grayson, Georgia 30221 USA.
 - iv. *VDRL Antigen.* Centers for Disease Control and Prevention. Atlanta, GA USA
- h. **Technological Characteristics:**

Lipid components present in VDRL Antigen

Component	Concentration Avanti Polar Lipids VDRL Antigen	Concentration Becton Dickinson's VDRL Antigen
Cardiolipin derived from ox heart tissue	0.1 grams / liter	0.3 grams / liter
Cholesterol derived from lanolin	9.0 grams / liter	9.0 grams / liter
Lecithin derived from egg yolk	sufficient for standard reactivity (1 - 1.9 grams per liter)	sufficient for standard reactivity (1.8 - 2.0 grams per liter)

The components listed in the above table are dissolved in ethanol.

Components present in buffered saline solution

Component	Concentration Avanti Polar Lipids Buffered Saline	Concentration Becton Dickinson VDRL Buffered Saline
Formaldehyde, 37% aqueous, (A.C.S.)	0.5 ml per liter	0.5 ml per liter
Sodium Chloride (A.C.S.)	10.0 grams per liter	10.0 grams per liter
Disodium phosphate, anhydrous (A.C.S.)	0.037 grams per liter	0.037 grams per liter
Monopotassium phosphate, anhydrous (A.C.S.)	0.170 grams per liter	0.170 grams per liter

The components listed in the above table are dissolved in deionized water.

i. Performance Data

i. Specificity Data

The specificity of Avanti Polar Lipids, Inc. VDRL Antigen Slide Test Kit was 100% for a sample population of 100 documented cases of syphilis.

ii. Sensitivity Data

The sensitivity of Avanti Polar Lipids, Inc. VDRL Antigen Slide Test Kit was 86.5% for a sample population of 100 documented cases of syphilis.

iii. Reproducibility Data

Specimens from a blind, coded panel were measured at two independent test sites. Reproducibility was demonstrated with inter-day and intra-day testing. Weakly reactive, reactive and non-reactive specimens were included in the panel. A maximum inter-day and intra-day difference of one doubling dilution was observed when specimens were tested by the same clinician. All reactive specimens gave an end point within two doubling dilutions of the true end point when tested by different clinicians.

j. Conclusion

The safety and effectiveness of Avanti Polar Lipids VDRL Antigen Slide Test Kit is substantially equivalent to legally marketed VDRL Antigen Slide Test Kits, as demonstrated in the comparison of the performance of Avanti Polar Lipids VDRL Antigen Slide Test Kit to these VDRL Antigen Slide Test Kits.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 20 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Rowena Shaw
Vice President
Avanti Polar Lipids, Inc.
700 Industrial Park Drive
Alabaster, Alabama 35007

Re: K992124
Trade Name: Avanti Polar Lipids VDRL antigen Slide Test Kit
Regulatory Class: II
Product Code: GMQ
Dated: June 22, 1999
Received: June 23, 1999

Dear Ms. Shaw:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

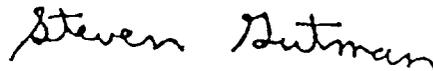
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,



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): K992124

Device Name: Avanti Polar Lipids VDRL Antigen Slide Test Kit

Indications For Use:

Avanti's VDRL antigen and Buffered Saline are intended for use in the Venereal Disease Research Laboratory (VDRL) slide test for syphilis. The VDRL slide test is a non-treponemal, micro-flocculation test, that provides both qualitative and semi-quantitative results. The test detects the presence of IgM and IgG anticardiolipin antibodies in serum. The IgM and IgG antibodies are produced in response to infection by *Treponema pallidum* the causative agent of syphilis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sally J. Selepe for W. Dubois
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K992124

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)