DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 2 2004

Mr. Stanley Ammons
US Correspondent
Aesku. Inc
8880 Northwest 18th Terrace
Miami, FL 33172

Re: k040463
Trade/Device Name: AESKULISA® Cardiolipin AGM
AESKULISA® Cardiolipin A
AESKULISA® Cardiolipin GM
AESKULISA® Cardiolipin Check
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autobodies immunological test system
Regulatory Class: Class II
Product Code: MID
Dated: May 3, 2004
Received: May 7, 2004

Dear Mr. Ammons:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Joseph L. Hackett

Joseph L. Hackett, Ph.D.
Acting Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

3 Indications for use

510(k) Number (if known): K040463

Device Name: AESKULISA Cardiolipin-AGM

Indications For Use:

AESKULISA Cardiolipin-AGM is a solid phase enzyme immunoassay employing highly purified cardiolipin plus native ***human*** ß2-glycoprotein I for the semiquantitative and qualitative detection of IgA, IgG and /or IgM antibodies against cardiolipin in human serum. Anti-cardiolipin antibodies mainly recognize specific epitopes on a complex composed of cardiolipin and ß2-glycoprotein I which are only expressed when ß2-glycoprotein I interacts with cardiolipin.

The assay is an aid in the diagnosis of systemic lupus erythematosus (SLE), primary and secondary anti-phospholipid syndrome (APS) and should be used in conjuction with other serological tests and clinical findings.

Prescription Use ✓ 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)

Marie Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040463

510(k) Number (if known): K040463

Device Name: AESKULISA Cardiolipin-A

Indications For Use:

AESKULISA Cardiolipin-A is a solid phase enzyme immunoassay employing highly purified cardiolipin plus native ***human*** ß2-glycoprotein I for the semiquantitative and qualitative detection of IgA antibodies against cardiolipin in human serum. Anti-cardiolipin antibodies mainly recognize specific epitopes on a complex composed of cardiolipin and ß2-glycoprotein I which are only expressed when ß2-glycoprotein I interacts with cardiolipin.

The assay is an aid in the diagnosis of systemic lupus erythematosus (SLE), primary and secondary anti-phospholipid syndrome (APS) and should be used in conjuction with other serological tests and clinical findings.

Prescription Use ✓ 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)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040463

510(k) Number (if known): K040463

Device Name: AESKULISA Cardiolipin-GM

Indications For Use:

AESKULISA Cardiolipin-GM is a solid phase enzyme immunoassay employing highly purified cardiolipin plus native ***human*** ß2-glycoprotein I for the semiquantitative and qualitative detection of IgG and /or IgM antibodies against cardiolipin in human serum. Anti-cardiolipin antibodies mainly recognize specific epitopes on a complex composed of cardiolipin and ß2-glycoprotein I which are only expressed when ß2-glycoprotein I interacts with cardiolipin.

The assay is an aid in the diagnosis of systemic lupus erythematosus (SLE), primary and secondary anti-phospholipid syndrome (APS) and should be used in conjuction with other serological tests and clinical findings.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

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

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K040463

510(k) Number (if known): K040463

Device Name: AESKULISA Cardiolipin-Check

Indications For Use:

AESKULISA Cardiolipin-Check is a solid phase enzyme immunoassay employing highly purified cardiolipin plus native ***human*** ß2-glycoprotein I for the combined semiquantitative and qualitative detection of IgA, IgG and IgM antibodies against cardiolipin in human serum. Anti-cardiolipin antibodies mainly recognize specific epitopes on a complex composed of cardiolipin and ß2-glycoprotein I which are only expressed when ß2-glycoprotein I interacts with cardiolipin.

The assay is an aid in the diagnosis of systemic lupus erythematosus (SLE), primary and secondary anti-phospholipid syndrome (APS) and should be used in conjuction with other serological tests and clinical findings.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

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

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