DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AESKU, Inc.
c/o Mr. David Bell
US Correspondent
8880 Northwest 18th Terrace
Miami, FL 33172

DEC 13 2006

Re: k062217
Trade/Device Name: AESKULISA® β2-Glyco-A Protocol 30-30-30, AESKULISA® β2-Glyco-A Protocol 30-15-15, AESKULISA® β2-Glyco-GM Protocol 30-30-30, AESKULISA® β2-Glyco-GM Protocol 30-15-15, AESKULISA® β2-Glyco-Check Protocol 30-30-30, AESKULISA® β2-Glyco-Check Protocol 30-15-15
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple Autoantibodies Immunological Test System
Regulatory Class: Class II
Product Code: MSV
Dated: July 31, 2006
Received: August 3, 2006

Dear Mr. Bell:

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 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

3 Indications for use

510(k) Number (if known): K062217

Device Name: AESKULISA β2-Glyco-A

Indications For Use:

AESKULISA ***β2 Glyco-A*** is a solid phase enzyme immunoassay employing native β2 glycoprotein I highly purified from human plasma for the semiquantitative and qualitative detection of IgA antibodies against β2 glycoprotein I in human serum.

The presence of anti-β2 glycoprotein I antibodies in conjunction with clinical findings and other laboratory results can be used as an aid in the diagnosis of thrombotic disorders related to primary and secondary antiphospholipid syndrome.

Maria M Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062217

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

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

510(k) Number (if known): K062217

Device Name: *AESKULISA* β2-Glyco-GM

Indications For Use:

AESKULISA* β2 *Glyco-GM is a solid phase enzyme immunoassay employing native β2 glycoprotein I highly purified from human plasma for the separate semiquantitative and qualitative detection of IgG and/or IgM antibodies against β2 glycoprotein I in human serum.

The presence of anti-β2 glycoprotein I antibodies in conjunction with clinical findings and other laboratory results can be used as an aid in the diagnosis of thrombotic disorders related to primary and secondary antiphospholipid syndrome.

Maria M Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

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

510(k) Number (if known): K062217

Device Name: *AESKULISA* β2-Glyco-Check

Indications For Use:

AESKULISA* β2 *Glyco-Check is a solid phase enzyme immunoassay employing native β2 glycoprotein I highly purified from human plasma for the combined semiquantitative and qualitative detection of IgA, IgG and IgM antibodies against β2 glycoprotein I in human serum.

The presence of anti-β2 glycoprotein I antibodies in conjunction with clinical findings and other laboratory results can be used as an aid in the diagnosis of thrombotic disorders related to primary and secondary antiphospholipid syndrome.

Maria M Chan
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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