DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 16 2003

AESKU, Inc.
c/o Mr. Stanley Ammons
8880 Northwest 18th Terrace
Miami, FL 33172

Re: k032469
Trade/Device Name: AESKULISA® ANA 8Pro Test Kit
AESKULISA® ENA 6Pro Test Kit
AESKULISA® U1-70 Test Kit
AESKULISA® snRNP-C Test Kit
AESKULISA® Sm Test Kit
AESKULISA® SS-A Test Kit
AESKULISA® SS-B Test Kit
AESKULISA® Cenp-B Test Kit
AESKULISA® Scl-70 Test Kit
AESKULISA® Jo-1 Test Kit
Regulation Number: 21 CFR 866.5100
Regulation Name: Antinuclear antibody immunological test system
Regulatory Class: Class II
Product Code: LLL, LJM
Dated: November 18, 2003
Received: November 19, 2003

Dear Mr. Ammons:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined these devices are 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 these devices, 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 devices are 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 devices can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your devices 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 devices comply 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).

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 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). 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032469

Device Name: AESKULISA ANA 8Pro

Indications For Use:

AESKULISA ANA-8Pro is a solid phase enzyme immunoassay for the separate qualitative detection of IgG antibodies against eight cellular and nuclear antigens in human serum. The wells are separately coated with recombinant 70 kDa U1 snRNP, SS-B, SS-A 52 kDa, Scl 70, centromere protein B (CenpB), Jo-1 and highly purified native human snRNP/Sm, Sm and SS-A 60 kDa. The assay is an aid in the differential diagnosis of systemic rheumatic diseases and should be used in conjunction 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)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K032469

Indications for Use

510(k) Number (if known): K032469

Device Name: AESKULISA ENA 6Pro

Indications For Use:

AESKULISA ENA-6Pro is a solid phase enzyme immunoassay for the separate semi-quantitative detection of IgG antibodies against six cellular and nuclear antigens in human serum. The wells are coated with recombinant SS-B, SS-A 52 kDa, Scl 70, Jo-1 and highly purified native human snRNP/Sm, Sm and SS-A 60 kDa. The assay is an aid in the differential diagnosis of systemic rheumatic diseases and should be used in conjunction with other serological tests and clinical findings.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
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510(k) K032469

Indications for Use

510(k) Number (if known): K032469

Device Name: AESKULISA U1-70

Indications For Use:

AESKULISA U1-70 is a solid phase enzyme immunoassay employing recombinant human 70 kDa protein of the U1-snRNP complex for the semi-quantitative and qualitative detection of antibodies against the 70 kDa U1-RNP in human serum. The assay is an aid in the diagnosis of mixed connective tissue diseases (MCTD) and systemic lupus erythematosus (SLE) and should be used in conjunction 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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510(k) K032469

Indications for Use

510(k) Number (if known): K032469

Device Name: AESKULISA snRNP-C

Indications For Use:

AESKULISA snRNP-C is a solid phase enzyme immunoassay for the qualitative and semi-quantitative detection of antibodies against the snRNP complex in human serum. The assay employs native human U1-snRNP complex purified from the cell-line HeLa. The U1-snRNP complex comprises of the Smith antigen (Sm) and RNPs, the 70kDa U1-specific protein plus protein A and C. The assay is an aid for the diagnosis of mixed connective tissue diseases (MCTD) and systemic lupus erythematosus (SLE) and should be used in conjunction 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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510(k) K032469

Indications for Use

510(k) Number (if known): K032469

Device Name: AESKULISA Sm

Indications For Use:

AESKULISA Sm is a solid phase enzyme immunoassay with purified native Smith antigen (Sm) from human eukaryotic cells (HeLa) for the qualitative and semiquantitative detection of antibodies against Sm in human serum. Anti-Sm antibodies recognize specific conformational epitopes only accessible on native human Sm. The assay is an aid in the differential diagnosis of systemic lupus erythematosus (SLE) and should be used in conjunction with other serological tests and clinical findings.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
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510(k) K032469

Indications for Use

510(k) Number (if known): K032469

Device Name: AESKULISA SS-A

Indications For Use:

AESKULISA SS-A is a solid phase enzyme immunoassay for the semi-quantitative and qualitative detection of antibodies against Ro/ SS-A in human serum. The assay employs human Ro/SS-A antigen composed of purified native 60kDa and recombinant human 52 kDa Ro/SS-A protein. Anti-SS-A antibodies preferentially react with the native 60kDa molecule where as most antibodies to the 52 kDa protein prefer the denatured molecule. The assay is an aid in the diagnosis of Sjögren's syndrome (SS) and systemic lupus erythematosus (SLE) and should be used in conjunction 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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510(k) K032469

Indications for Use

510(k) Number (if known): K032469

Device Name: AESKULISA SS-B

Indications For Use:

AESKULISA SS-B is a solid phase enzyme immunoassay employing human recombinant La-antigen/ SS-B for the qualitative and semi-quantitative detection of antibodies against La-antigen / SS-B in human serum. The assay is an aid in the diagnosis of Sjögren`s syndrome (SS) and systemic lupus erythematosus (SLE) and should be used in conjunction 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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510(k) K032469

Indications for Use

510(k) Number (if known): K032469

Device Name: AESKULISA Scl-70

Indications For Use:

AESKULISA Scl-70 is a solid phase enzyme immunoassay with human recombinant 70 kDa fragment of DNA topoisomerase I for the qualitative and semi-quantitative detection of antibodies against Scl-70 (70 kDa scleroderma antigen) in human serum. The assay is an aid in the differential diagnosis of systemic sclerosis and should be used in conjunction with other serological tests and clinical findings.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
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510(k) K032469

Indications for Use

510(k) Number (if known): K032469

Device Name: AESKULISA Cenp-B

Indications For Use:

AESKULISA CENP-B is a solid phase enzyme immunoassay employing purified recombinant human 80 kDa centromere protein B (Cenp-B) for the qualitative and semi-quantitative detection of IgG antibodies against Cenp-B in human serum. The assay serves as an aid in the diagnosis of systemic sclerosis and CREST syndrome and should be used in conjunction with other serological tests and clinical findings.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
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510(k) K032469

Indications for Use

510(k) Number (if known): K032469

Device Name: AESKULISA Jo-1

Indications For Use:

AESKULISA Jo-1 is a solid phase enzyme immunoassay with recombinant human histidyl-tRNA-synthetase (HRS) for the semi-quantitative and qualitative detection of antibodies against Jo-1 in human serum. The assay is an aid in the diagnosis of polymyositis and dermatomyositis and should be used in conjunction 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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