



AESKU Diagnostics, Inc.  
c/o Dr. Helene Paxton  
Bioguidance, LLC  
87 Pedrick - Woodstown Road  
Pedrickstown, NJ 08067

OCT 15 2012

Re: k120889

Trade/Device Name: AESKUSLIDES ANA-HEp-2  
Regulation Number: 21 CFR §866.5100  
Regulation Name: Antinuclear Antibody Immunological Test System  
Regulatory Class: Class II  
Product Code: DHN  
Dated: September 24, 2012  
Received: September 25, 2012

Dear Dr. Paxton:

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 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); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

For 

Maria Chan, Ph.D.

Director

Division of Immunology and Hematology Devices

Office of *In Vitro* Diagnostics and

Radiological Health

Center for Devices and Radiological Health

Enclosure

## Indications for Use Form

510(k) Number (if known):           K120889          

Device Name:           AESKUSLIDES ANA-HEp-2 Test System          

### Indications for Use:

AESKUSLIDES ANA-HEp-2 is an indirect fluorescent antibody assay utilizing HEp-2 tissue culture cells as a substrate for the qualitative and/or semi-quantitative determination of antinuclear antibodies (ANA) in human serum. AESKUSLIDES ANA-HEp-2 Test System is intended for use as an aid in the diagnosis of systemic rheumatic diseases in conjunction with other clinical and laboratory findings.

Prescription Use             
(Part 21 CFR 801 Subpart D)

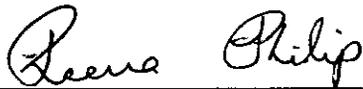
AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

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

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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)           k120889