DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

Arlington Scientific, Inc.
Attention: Mr. David Binks
Director of Manufacturing
1840 North Technology Drive
Springville, UT 84663

Re:	BK140192
Trade/Device Name:	ASiManager-AT
Regulatory Class:	I
Product Code:	JQT
Dated:	January 29, 2015
Received:	February 2, 2015

Dear Mr. Binks:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined that 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 (the 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. Please note: CBER does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

If you have any questions concerning the contents of the letter, please contact Vasantha Kumar at (240) 402-8413 or vasantha.kumar@fda.hhs.gov.

Sincerely,

Hira L. Nakhasi, PhD
Director
Division of Emerging and
Transfusion Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation
and Research

Ellen Lazarus, MD
Director
Division of Human Tissues
Office of Cellular, Tissue and Gene Therapies
Center for Biologics Evaluation and Research

Enclosure:
Indications for Use

Indications for Use

510(k) Number: BK140192

Device Name: ASiManager-AT

The ASiManager-AT is intended to be used as an integrated digital particle analyzer to objectively interpret the results of the ASI RPR Card Test for Syphilis. The ASiManager-AT is designed to provide standardized test interpretation and to provide for storage, retrieval, and transmittal of the test results. It is intended to be acquired, possessed and used only by health care professionals. The ASiManager-AT is intended to be used for *in vitro* diagnostics, blood donor and cadaveric (non-heart beating) donor screening.