Aalto Scientific, Ltd.

K082717

510(k) Summary

OCT 30 2008

A. Submitter

Aalto Scientific, Ltd.
1959 Kellogg Ave.
Carlsbad, CA 92008
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B. Contact Person

Brandon J Percz
Telephone: (760) 431-7922 Ext. 120
E-mail: bperez@aaltoscientific.com

C. Date of Summary Preparation

September 15, 2008

D. Device Identification

Product Trade Name:	Audit™ MicroCV™ Tumor Markers Linearity Set
Common Name:	Tumor Markers Linearity
Classification Name:	Assay QC Material
Device Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	75
Product Code:	JJY

E. Device to Which Substantial Equivalence is Claimed

Audit™ MicroCV™ General Chemistry Linearity Set
Aalto Scientific, Ltd., Carlsbad, CA
K042318

F. Description of the Device

The Audit™ MicroCV™ Tumor Markers Linearity Set is a human based, lyophilized, five level set of QC material, with each level containing 6 analytes. It is used to confirm the proper calibration, linear operating range, and reportable range of Tumor Marker methods for the analytes listed. Level A is near the lower limit level and Level E has concentrations near the upper limit of instruments. Levels B – D are related by linear dilution of Level A and Level E.

G. Statement of Intended Use

The Tumor Markers Linearity Set is intended to simulate human patient serum samples for the purpose of verifying and validating the Analytical Measurement Range for non-waived tumor marker testing methods as identified in the package insert.

I. Summary of Performance Data

Stability studies have been performed to determine the reconstituted stability and shelf life for the Audit™ MicroCV™ Tumor Markers Linearity Set. All supporting data is retained on file at Aalto Scientific, Ltd. Product claims are as follows:

Reconstituted Stability: Once a vial has been reconstituted, all analytes will be stable for 7 days when stored tightly capped at 2 - 8° C.

Shelf Life: Two years, when stored unopened at 2 - 8° C.
Note: Real time studies are ongoing to support the shelf life of this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Aalto Scientific Ltd.
C/O Brandon J. Perez
1959 Kellogg Avenue
Carlsbad, CA 92008

OCT 3 0 2008

Re: K082717
Trade/Device Name: Audit™ MicroCV™ Tumor Markers Linearity Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: I
Product Code: JJY
Dated: September 16, 2008
Received: September 18, 2008

Dear Mr. Perez

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-***[See Below For Phone Numbers]***. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

for Maria M. Chan, 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

Indications for Use

510(k) Number (if known): K082717

Device Name: Audit™ MicroCV™ Tumor Markers Linearity Set

Indications For Use:

The Audit™ MicroCV™ Tumor Markers Linearity Set consists of five levels in Human based serum. Each level contains the following analytes: Alpha fetoprotein (AFP), Carcinoembryonic antigen (CEA), CA 125, CA 15-3, Prostate specific antigen-free (free PSA), total PSA. The five levels demonstrate a linear relationship to each other for their respective analytes, reagents, and instruments. This product may be used for proficiency testing in interlaboratory surveys.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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