Aalto Scientific, Ltd.

K101226

510(k) Summary

A. Submitter

AUG 3 1 2010

Aalto Scientific, Ltd.
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Carlsbad, CA 92008
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B. Contact Person

Dessi Lyakov
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C. Date of Summary Preparation

April 30, 2010

D. Device Identification

Product Trade Name:	Audit™ MicroCV™ RF/CRP Linearity Set
Common Name:	Calibration Verification
Classification Name:	Multi analyte controls (Assayed and Unassayed)
Device Classification:	Class I
Regulation Number:	21 CFR 862.1660
Panel:	75
Product Code:	JJY

E. Device to Which Substantial Equivalence is claimed

Product Trade Name:

LiniCAL Calibration Verifier RF/CRP
CLINIQA, Fallbrook, CA 92028
K023661

Liquichek Lipids Control
Bio-Rad Laboratories, Irvine, California
K012513

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

Aalto Scientific, Ltd.

F. Description of the Device

The Audit™ MicroCV™ RF/CRP Linearity Set is a 5 level quality control solution set containing C-reactive protein and Rheumatoid Factor as the messurand. It is used to confirm the proper calibration, linear operating range, and reportable range of RF and CRP. 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 Audit™ MicroCV™ RF/CRP Linearity Set is an assayed quality control material consisting of five levels human based serum. Each level contains Rheumatoid Factor (RF) and C-Reactive Protein (CRP) analytes. The five levels demonstrate a linear relationship to each other for Rheumatoid Factor (RF) and C-Reactive Protein (CRP) analytes. This product may also be used as unassayed quality control material for Rheumatoid Factor (RF) and C-Reactive Protein (CRP) analytes. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The product is intended for use with quantitative assays on manual, automatic, and semi-automatic analyzers. The Audit™ MicroCV™ RF/CRP Linearity Set is "For In Vitro Diagnostic Use Only".

I. Summary of Performance Data

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

Open Vial Stability: Once a vial has been reconstituted, all analytes will be stable for 5 days when stored tightly capped at 2-8 C.

Shelf Life: 19 months at 2 - 8° C.

Note: Real time studies are ongoing to support the shelf life of this product.

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H. Technical Characteristics Compared to Predicate Device

Characteristics	Audit™ MicroCV™RF/CRP Linearity Set K101226)	Bio-Rad Liquichek Lipids Control (K012513)	Audit™ MicroCV™ General Chemistry Linearity Set (K042318)	LiniCAL Calibration Verifier RF/CRP (K023661)
Intended Use	The Audit™ MicroCV™ RF/CRP Linearity Set is an assayed quality control material consisting of five levels human based serum. Each level contains Rheumatoid Factor (RF) and C-Reactive Protein (CRP) analytes. The five levels demonstrate a linear relationship to each other for Rheumatoid Factor (RF) and C-Reactive Protein (CRP) analytes. This product may also be used as unassayed quality control material for Rheumatoid Factor (RF) and C-Reactive Protein (CRP) analytes. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. The product is intended for use with quantitative assays on manual, automatic, and semi-automatic analyzers. The Audit™ MicroCV™ RF/CRP Linearity Set is "For In Vitro Diagnostic Use Only".	Liquichek Lipids Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the listed analytes.	Audit® Micro*CV*™ General Chemistry Linearity Set consists of five levels of human based serum. Each level contains the following analytes: Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO_2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, Lactate, LDH, LDL Cholesterol, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid. These five levels demonstrate a linear relationship to each other for their respective analytes, reagents and instruments[1]. This product may also be used as unassayed quality control material for these analytes. When used for quality control purposes, it is recommended that each laboratory establish its own means and acceptable ranges and use the values provided only as guides. In addition, it may be used for proficiency testing in interlaboratory surveys and to perform CLIA directed calibration verification[2] for these same analytes in accordance with current CLIA-88 guidelines and regulations[3].	LiniCAL Calibration Verifier RF/CRP is intended for use in the clinical laboratory to objectively verify calibration and assess linearity regarding RF and CRP. Five targeted assayed materials are provided to allow monitoring the manufacturer's reportable range.

Number of Analytes per vial	2	8	31	2
Number of levels per set	5	2	5	5
Contents	5 x 1mL	2 x 3mL	5 x 1mL	5 x 1mL
Matrix	Human Serum	Human Serum	Human Serum	Human Serum
Type of Analytes	C-Reactive Protein Rheumatoid Factor	C-Reactive Protein Apolipoprotein A-I Apolipoprotein B Cholesterol HDL Cholesterol LDL Cholesterol Lipoprotein (a) Triglycerides	Albumin, Alkaline Phosphatase, ALT, Amylase, AST, Bilirubin (Total and Direct), BUN, Calcium, Chloride, Cholesterol, CO_2, Creatine Kinase, Creatinine, Gamma-GT, Glucose, HDL Cholesterol, Iron, Lactate, LDH, LDL Cholesterol, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Protein, Triglycerides and Uric Acid.	Rheumatoid Factor (RF) C-Reactive Protein (CRP)
Form	Liquid	Liquid	Lyophilized	Liquid
Storage	2 to 8° C for 19 months	-20°C to -70°C for 36 months	2 to 8° C for 48 months	2 to 8° C for 48 months
Open Bottle Stability	5 days at 2 to 8° C	14 days at 2 to 8°C	7 days at 2 to 8° C	14 days at 2 to 8°C

J. SIMILARITIES AND DIFFERENCES between the Audit™ MicroCV™RF/CRP Linearity Set (K101226) and the Predicate Devices

Similarities between the Audit™ MicroCV™RF/CRP Linearity Set (K101226) and all Predicate Devices:

- All products are human serum based quality control materials intended to monitor the precision of laboratory testing procedures for the listed analytes.
- All products were made using the same method of spiking various constituents to human based matrix.
- All products content multiple levels.
- Audit™ MicroCV™RF/CRP Linearity Set (K101226) and LiniCAL Calibration Verifier RF/CRP (K023661) have the same analytes.

Diferences between the Audit™ MicroCV™RF/CRP Linearity Set (K101226) and all Predicate Devices:

- Audit™ MicroCV™RF/CRP Linearity Set (K101226), Bio-Rad Liquichek Lipids Control (K012513), and LiniCAL Calibration Verifier RF/CRP (K023661) are liquid products Audit™ MicroCV™ General Chemistry Linearity Set (K042318) is lyophilized product.
- Audit™ MicroCV™RF/CRP Linearity Set (K101226), Bio-Rad Liquichek Lipids Control (K012513), and LiniCAL Calibration Verifier RF/CRP (K023661) have different analytes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

AUG 31 2010

Aalto Scientific, Ltd.
c/o Ms. Dessi Lyakov
Manager, Regulatory Affairs
1959 Kellogg Ave.
Carlsbad, CA 92008

Re: k101226
Trade/Device Name: Audit™ MicroCV™ RF/CRP Linearity Set
Regulation Number: 21 CFR§862.1660
Regulation Name: Quality Control Material (assayed and unassayed)
Regulatory Class: Class I (Reserved)
Product Code: JJY
Dated: August 18, 2010
Received: August 18, 2010

Dear Ms. Lyakov:

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety 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,

Maria M Chan

Maria M. Chan, 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

Aalto Scientific, Ltd.

Indications for Use

510(k) Number: K101226

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Device Name: Audit™ MicroCV™ RF/CRP Linearity Set

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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)

Reena Philip

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K k101226