510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k100716

B. Purpose for Submission:
Clearance of a new device

C. Measurand:
D-dimer

D. Type of Test:
Quantitative

E. Applicant:
Aalto Scientific, Ltd.

F. Proprietary and Established Names:
Audit™ MicroCV™ D-Dimer Linearity Set

G. Regulatory Information:

1. Regulation section:
   21 CFR 864.5425
2. Classification:
   Class II
3. Product code:
   GGN-Plasma, Coagulation Control
4. Panel:
   81 (Hematology)

H. Intended Use:

1. Intended use(s):
   The Audit™ MicroCV™ D-Dimer Linearity Set is a quantitative, assayed quality control material consisting of five levels of D-dimer analyte. The five D-dimer levels demonstrate a linear relationship to each other for D-dimer analyte. The Audit™ MicroCV™ D-Dimer Linearity Set is intended to use with the Biomerieux miniVIDAS® analyzer and VIDAS® D-dimer assay to verify the calibration of the measuring range. Audit™ MicroCV™ D-Dimer Linearity Set is "For *In Vitro* Diagnostic Use Only."
2. Indication(s) for use:
   Same as intended use(s)
3. Special conditions for use statement(s):
   For prescription use only
4. Special instrument requirements:
   Biomerieux miniVIDAS® analyzer and VIDAS® D-dimer assay

I. Device Description:
The Audit™ MicroCV™ D-Dimer Linearity Set is a human based, lyophilized, five level set of QC material, A, B, C, D, and E. Each level contains D-dimer complex. It is used to confirm the proper calibration of the measuring range of D-dimer on the miniVIDAS® analyzer. Level A D-dimer is near the lower limit level and level E D-dimer is near the upper limit of the measuring range. Levels B, C, and D are related by linear dilution of level A and level E. The target ranges for five levels are:

Levels	A	B	C	D	E
Target Range	<150 ng/mL	1105-1495 ng/mL	2010-2760 ng/mL	2145-4255 ng/mL	3700-6000 ng/mL

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Triage® D-dimer Calibration Verification Controls
2. Predicate K number(s):
   k050799
3. Comparison with predicate:

Similarities		
Item	Device: Audit™ MicroCV™ D-Dimer Linearity Set	Predicate: Triage® D-dimer Calibration Verification Controls
Intended Use	The Audit™ MicroCV™ D-Dimer Linearity Set is a quantitative, assayed quality control material consisting of five levels of D-dimer analyte. The five D-dimer levels demonstrate a linear relationship to each other for D-dimer analyte. The Audit™ MicroCV™ D-Dimer Linearity Set is intended to use with the Biomerieux miniVIDAS® analyzer and VIDAS® D-dimer assay to verify the calibration of the measuring range.	The Triage® D-dimer Calibration Verification Controls are to be used with the Triage® D-dimer Test and Triage® MeterPlus to verify the calibration of the Triage® D-dimer test throughout the measurable range. The Triage® D-dimer Calibration Verification Controls are assayed materials to be used with the Triage® D-dimer Test and Triage® MeterPlus to assist the laboratory in monitoring test performance.
Number of levels per set	5	Same
Matrix	Human based plasma	Same

Differences		
Item		
Matrix	Lyophilized	Liquid
Closed vial stability	2-8°C for 24 months	-20°C for 9 months
Open vial stability	2 days when stored at 2-8°C	1 day when stored at 2-8°C

K. Standard/Guidance Document Referenced (if applicable):

CLSI EP06-A: Evaluation of Linearity of Quantitative Measurement Procedures: A Statistical Approach.

L. Test Principle:

The Audit™ MicroCV™ D-Dimer Linearity Set is used to verify the calibration of the D-dimer measuring range of the miniVIDAS® analyzer.

M. Performance Characteristics:

1. Analytical performance:
   a. Precision/Reproducibility:

For each level of D-Dimer Linearity Set, 15 replicates were tested on the miniVIDAS® on three lots. All levels resulted <10% CV.

b. *Linearity/assay reportable range:*
Linearity was determined using three lots of the D-Dimer Linearity Set. The mean D-dimer concentration of each of the 5 levels was plotted vs. five assigned levels of concentration. A linear regression value was obtained for each lot, and all results were within the limit of acceptance $r^2 > 0.95$.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*
- Traceability: All reagent components are obtained from commercial vendors.
- Open vial stability: A 2-day open vial stability claim was verified using three lots of the Audit™ MicroCV™ D-Dimer Linearity Set. All 5 levels were tested on day zero and day 2. The percent recovery is determined in comparison to day zero values. The percent recovery is within ±10% limit of acceptance.
- Closed vial stability: An accelerated stability is used to predict shelf life. The vials are stressed at 25°C for 64 days to predict two-year stability when stored at 2-8°C. The percent recovery of all levels is determined in comparison to day zero values and the product is considered stable when the recovered values are within ±10%. Real time studies are ongoing to support the shelf life of the product.
- Value assignment: For each level of D-Dimer Linearity Set, 15 separate vials were tested on one miniVIDAS® analyzer yielding 15 measurements. The mean of each level was used to calculate the target concentration. The target range of each level was calculated as ±1SD of the target concentration.

d. *Detection limit:*
Not applicable

e. *Analytical specificity:*
Not applicable

f. *Assay cut-off:*
Not applicable

2. Comparison studies:
   a. *Method comparison with predicate device:*
   Not applicable
   b. *Matrix comparison:*
   Not applicable
3. Clinical studies:
   a. *Clinical Sensitivity:*
   Not applicable
   b. *Clinical specificity:*
   Not applicable
   c. Other clinical supportive data (when a. and b. are not applicable):
   Not applicable
4. Clinical cut-off:
   Not applicable

5. Expected values/Reference range:

The mean and expected assay range for each level are provided in the labeling.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.