**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**DEVICE ONLY TEMPLATE**

**A. 510(k) Number:**
K032122

**B. Analyte:**
Quality control material for BNP and NT proBNP

**C. Type of Test:**
N/A Controls only

**D. Applicant:**
Aalto Scientific Ltd.

**E. Proprietary and Established Names:**
Audit™ MicroControl MicroFD™ BNP Control

**F. Regulatory Information:**

1. Regulation section:
   21 CFR 862.1660, Multi-Analyte Controls, All Kinds (assayed and unassayed)
2. Classification:
   Class I
3. Product Code:
   JJY
4. Panel:
   75

**G. Intended Use:**

1. Indication(s) for use:
   Audit™ MicroFD™ BNP Control is an assayed bi-level reference control consisting of human plasma based solutions. It is intended to simulate human patient plasma samples for the purpose of monitoring the precision and to detect systematic analytical deviations of laboratory testing procedures for both BNP-32 and NT-proBNP assays.
2. Special condition for use statement(s):
   NA
3. Special instrument Requirements:
   NA

**H. Device Description:**
Audit™ MicroFD™ BNP Control is an in vitro diagnostic control composed of a buffered bacteriostatic and fungistatic human plasma matrix.

**I. Substantial Equivalence Information:**

1. Predicate device name(s):
   Biosite Triage® BNP Control; Roche Diagnostics PreciControl proBNP
2. Predicate K number(s):
   K000231; K022516

3. Comparison with predicate:

| Similarities | | | |
|---|---|---|---|
| **Item** | **Audit BNP Control** | **Biosite BNP Control** | **PreciControl BNP** |
| No. of Levels | 2 | 2 | 2 |
| Matrix | Human source | Human source | Human source |
| **Differences** | | | |
| **Item** | **Audit BNP Control** | **Biosite BNP Control** | **PreciControl BNP** |
| Preparation | lyophilized | frozen | lyophilized |
| Analytes | BNP, NT ProBNP | BNP | NT ProBNP |

**J. Standard/Guidance Document Referenced (if applicable):** None referenced

**K. Test Principle: NA**

**L. Performance Characteristics (if/when applicable):**

1. Analytical performance:
   *a. Precision/Reproducibility:* NA

   *b. Linearity/assay reportable range:* NA

   *c. Traceability (controls, calibrators, or method*): Evaluators at pre-selected laboratories follow value assignment protocol.

   *d. Detection limit:* NA

   *e. Analytical specificity:* NA

   *f. Assay cut-off:* NA

2. Comparison studies:
   *a. Method comparison with predicate device:* NA

   *b. Matrix comparison:* NA

3. Clinical studies:
   *a. Clinical sensitivity:* NA

   *b. Clinical specificity:* NA

   *c. Other clinical supportive data (when a and b are not applicable):*

4. Clinical cut-off:
   NA

5. Expected values/Reference range: NA

**M. Conclusion:**

Based upon the information provided for the file, I recommend that the Audit™ MicroControl MicroFD™ BNP Controls are substantially equivalent to the predicate devices.