

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

A. 510(k) Number:

K030394

B. Analyte:

Blood collection and testing system for cholesterol, triglycerides, glucose, HDL-cholesterol and calculated LDL-cholesterol

C. Type of Test:

Quantitative

D. Applicant:

Biomed Personal Metabolic and Nutritional Testing, Inc.

E. Proprietary and Established Names:

Personal Fluid Sample Retrieval System

F. Regulatory Information:

1. Regulation section:
21 CFR 862.1675; Tubes, vials, systems, serum separators, blood collection
2. Classification:
Class II
3. Product Code:
JKA
4. Panel:
75

G. Intended Use:

1. Indication(s) for use:
The Personal Fluid Sample Retrieval System is for use for over-the-counter distribution and is a device for collection and transportation of serum for in-vitro diagnostic quantitative determination of cholesterol, triglycerides, glucose, HDL cholesterol and calculated LDL cholesterol. The serum sample is transferred in a transport pouch to the testing laboratory and results are returned directly to the consumer.
2. Special condition for use statement(s):
3. Special instrument Requirements:

H. Device Description:

The Personal Fluid Sample Retrieval System is a kit containing four tubes (two collection tubes and two transport tubes), a transport pouch, an order form, a brochure, a cassette tape, and Priority Mail label. A consumer can purchase the kit and then take the kit to a designated clinic to have his or her blood drawn. The kit will be sold in a retail environment, but the blood is drawn by a professional. The professional draws the blood into the two serum separation tubes included in the kit. The serum separation tubes are manufactured by Kendall and were cleared by FDA

under K915213. The sample is separated and the serum is placed in the two transport tubes provided with the kit. The tubes are closed with a snap top cap. The cap is a polypropylene cap molded to fit without leakage. The tubes are closed, bar-code labeled, and shipped in the transport pouch via Priority Mail to Biomed. The serum sample in the transport tube is transferred in the transport pouch to the certified testing laboratory, the Arkansas Medical Laboratory. The testing is performed on the Vitros Chemistry analyzer using FDA cleared reagents. The testing laboratory uses reagents and instruments certified by the CRMLN for lipid testing. Once the various tests have been processed, the results will be transferred to Biomed's office electronically. The results are mailed back to the consumer within 72 hours. Any abnormal result will be reviewed by a physician. In the event of a markedly abnormal laboratory test result, the consumer will be contacted.

I. Substantial Equivalence Information:

1. Predicate device name(s):
Corvac blood collection tube
2. Predicate K number(s):
K915213
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Sample collection	Vacuum collection tube	Vacuum collection tube
Differences		
Item	Device	Predicate
Intended use	Sample collection and testing, results sent to consumer	Sample collection only

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

K. Test Principle:

The testing is performed on the Vitros Chemistry analyzer using FDA cleared reagents.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. Precision/Reproducibility:
Studies were performed to determine the stability of the samples during mailing. Stability was established for 5 days with the testing laboratory instructed to discard samples mailed more than 5 days previously. The studies were performed on 21 individuals for all of the tests listed in the Indications for Use statement. Out of the 21, 17 had samples taken to Arkansas Medical Lab for immediate testing. Four individual's samples were divided into four separate tubes and dispersed to four different couriers and Express Mailed from different cities in distinctly different geographic locations on different dates to simulate receipt of the samples by the testing lab

up to five days after being drawn. Statistical analysis of the results included ANOVA and difference plots comparing the immediate testing result with the day one through day five result for each sample and for each test with the conclusion that samples are stable for mailing up to five days. The difference plots showed no significant differences for the analytes over the five day testing period and documents the stability of the specimens.

- b. *Linearity/assay reportable range:*
Not applicable
 - c. *Traceability (controls, calibrators, or method):*
Not applicable
 - 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:*
No 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:
Not applicable

M. Conclusion:

Based upon review of the information provided in this 510(k), I recommend that this device is substantially equivalent to devices regulated by 21 CFR 862.1675, tubes, vials, systems, serum separators, blood collection; 75 JKA; Class II.