

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

A. 510(k) Number:

k060364

B. Purpose for Submission:

New device

C. Measurand:

Not applicable (devices may be used to collect blood samples for many different assays)

D. Type of Test:

Not applicable

E. Applicant:

Teco Diagnostics

F. Proprietary and Established Names:

Teco Diagnostics Vacu Lab Plain Tube

Teco Diagnostics Vacu Lab Gel and Clot Activator Tube

G. Regulatory Information:

1. Regulation section:

21 CFR 862.1675

2. Classification:

Class II

3. Product code:

JKA

4. Panel:

75 (Clinical Chemistry)

H. Intended Use:

1. Intended use(s):

The Vacu Lab Plain Tube is a sterile, plastic, evacuated blood collection tube with a silica clot activator that provides a means of collecting, transporting, separating, and processing blood in a closed tube. The specimens are used for clinical laboratory assays involving the use of patient serum.

The Vacu Lab Gel & Clot Activator Tube is a sterile, plastic, evacuated blood collection tube with a silica clot activator and a barrier gel that provides a means of collecting, transporting, separating, and processing blood in a closed tube. The specimens are used for clinical laboratory assays involving the use of patient serum.

2. Indication(s) for use:

Refer to intended use above

3. Special conditions for use statement(s):

Prescription Use only.

These blood collection tubes are not intended to be used to collect blood specimens for therapeutic drug monitoring.

4. Special instrument requirements:

Not applicable

I. Device Description:

The Teco Diagnostics Vacu Lab Plain Tube is a sterile, plastic, evacuated blood collection tube. It consists of a closure assembly, a silica clot activator, and a silicone surfactant coated on the inside of the plastic tube. The Teco Diagnostics Vacu Lab Gel and Clot Activator Tube is identical to the Plain Tube except for the addition of a barrier gel that separates the serum from the cells when centrifuged.

J. Substantial Equivalence Information:

1. Predicate device name(s):

BD Vacutainer Plus SST Serum Separator Tube

2. Predicate 510(k) number(s):

k023075

3. Comparison with predicate:

Similarities			
Item	Plain Tube	Gel Separator Tube	Predicate
Components	Same, except no gel barrier	Same	closure assembly, inert polyester gel barrier, silica clot activator, silicone surfactant coated plastic tube
Matrix	Same	Same	Serum
Analytes	Same	Same	General Clinical Chemistry Analytes

Differences			
Item	Plain Tube	Gel Separator Tube	Predicate
Therapeutic Drug Monitoring (TDM)	Not intended for use with TDM samples	Not intended for use with TDM samples	May be used for TDM samples

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

CLSI (formerly NCCLS) H18-A: Procedures for the Handling and Processing of Blood Specimens; Approved Guideline

CLSI (formerly NCCLS) H1-A5: Evacuated Tubes and Additives for Blood Specimen Collection, Approved Standard – Fifth Edition

CLSI (formerly NCCLS) H3-A5: Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture, Approved Standard – Fifth Edition

ANSI/AAMI/ISO 11137: Sterilization of Health Care Products - Requirements for Validation and Routine Control - Radiation Sterilization

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable.

b. Linearity/assay reportable range:

Not applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

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:

To demonstrate comparable performance with the predicate device, the sponsor collected blood samples into the Plain Tube, the Gel and Clot Activator Tube, and the predicate tube. The specimens were allowed to clot, and the serum was removed for testing immediately after centrifugation. Serum from the three tubes was then tested on two different analyzers for total protein, albumin, total bilirubin, direct bilirubin, AST, ALT, ALP, r-GT, cholesterol, potassium, glucose, creatinine, calcium, chloride, creatine kinase, hCG, magnesium, phosphorous, triglyceride, uric acid, BUN, sodium, CK-MB, TSH, free T4, ferritin, and prolactin. The sponsor's acceptance criterion was that the r^2 value from linear regression be ≥ 0.95 . Linear regression was performed using the predicate (independent variable) vs. the Plain Tube (dependent variable) and the predicate (independent variable) vs. the Gel and Clot Activator Tube (dependent variable). All of the comparisons met the acceptance criteria.

b. Matrix comparison:

Not applicable. These blood collection tubes are for serum only.

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):

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

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.