

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

A. 510(k) Number:

K072304

B. Purpose for Submission:

Change in value assignment procedure

C. Measurand:

Fibrinogen

D. Type of Test:

Quantitative

E. Applicant:

Dade Behring, Inc.

F. Proprietary and Established Names:

Fibrinogen Calibrator Kit

G. Regulatory Information:

1. Regulation section:

21 CFR 864.7340, Fibrinogen determination system

2. Classification:

Class II

3. Product code:

GFX, Fibrinogen Standard

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

Fibrinogen Calibrators 1 to 6 are used to prepare reference curves for the assay of fibrinogen by the method of Clauss using Dade Behring Multifibren™ U.

2. Indication(s) for use:

Fibrinogen Calibrators 1 to 6 are used to prepare reference curves for the assay of fibrinogen by the method of Clauss using Dade Behring Multifibren™ U.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

Not applicable.

I. Device Description:

The Fibrinogen Calibrators are lyophilized calibrators prepared using pooled human plasma from selected, healthy donors that has been diluted with buffer solution or supplemented with purified fibrinogen and stabilized. This calibrator is supplied in a one pack, containing 6 - 1.0 mL vials.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Fibrinogen Calibrator Kit

2. Predicate K number(s):

K994341

3. Comparison with predicate:

Similarities		
Item	Fibrinogen Calibrator Kit	Fibrinogen Calibrator Kit K994341
Intended Use	Fibrinogen Calibrators 1 to 6 are used to prepare reference curves for the assay of fibrinogen by the method of Clauss using Dade Behring Multifibren™ U.	Same
Matrix	Pooled human plasma from healthy donors diluted with buffer solution or supplemented with purified fibrinogen.	Same
Analyte	Fibrinogen	Same
Target concentrations	1 – 0.6 g/L 2 – 1.1 g/L 3 – 2.5 g/L 4 – 3.7 g/L 5 – 6.0 g/L 6 – 9.0 g/L	Same
Form	Lyophilized	Same

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

Not Applicable.

L. Test Principle:

The Fibrinogen Calibrators consists of pooled human plasma from selected, healthy donors that has been diluted with buffer solution or supplemented with purified fibrinogen and are stabilized with Herpes Buffer (12g/L) and lyophilized. They are supplied in siliconized vials in order to prevent contact activation of the coagulation system. These calibrators are assigned by determining the quality of coagulable fibrinogen by the method of Ratnoff and Menzie as well as by the Kjeldahl method. The exact values are given on the enclosed lot-dependant table of analytical values and on the vial labels.

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):*

The new value assignment procedure was evaluated by testing three (3) lots of the Fibrinogen Calibrator Kit with two (2) lots of Multifibren™ U reagent on a Dade Behring BCS and a Sysmex® CA-1500 analyzer. Patient samples spanning the measuring range and quality control materials recovered fibrinogen values within the expected ranges.

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 exact values are given on an enclosed lot-dependant table of analytical values and on the vial labels. The calibrators are adjusted to the following values:

- 1 – 0.6 g/L
- 2 – 1.1 g/L
- 3 – 2.5 g/L
- 4 – 3.7 g/L
- 5 – 6.0 g/L
- 6 – 9.0 g/L

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.