

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

A. 510(k) Number:

K042941

B. Purpose for Submission:

New Device

C. Measurand:

Calibrator and Quality control material for heparin

D. Type of Test:

Quantitative

E. Applicant:

Dade Behring Inc.

F. Proprietary and Established Names:

Dade Behring Heparin Calibrator and Controls

G. Regulatory Information:

1. Regulation section:

21 CFR 864.5425, Multipurpose system for in vitro coagulation studies

2. Classification:

Class II

3. Product code:

GIZ, Plasma, Control, Normal

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

Dade Behring Heparin Calibrator is an *in vitro* diagnostic product used to calibrate the Berichrom® Heparin assay for the measurement of unfractionated heparin. Dade Behring Heparin Controls are *in vitro* diagnostic products intended to be used as assayed, unfractionated heparin quality control materials for the Berichrom® Heparin assay.

2. Indication(s) for use:

Dade Behring Heparin Calibrator is an *in vitro* diagnostic product used to calibrate the Berichrom® Heparin assay for the measurement of unfractionated heparin. Dade Behring Heparin Controls are *in vitro* diagnostic products intended to be used as assayed, unfractionated heparin quality control materials for the Berichrom® Heparin assay.

3. Special conditions for use statement(s):

Not applicable.

4. Special instrument requirements:

Not applicable.

I. Device Description:

Dade Behring Heparin Calibrator and Controls are lyophilized products prepared from citrated human plasma and contains unfractionated heparin from a porcine source. The kit consists of one calibrator and two levels of assayed controls intended to monitor the performance of Berichrom® Heparin reagent when testing for unfractionated heparin using coagulation analyzers.

J. Substantial Equivalence Information:

1. Predicate device name(s):

aca® Heparin Calibrator

Ci-Trol® Heparin Controls, Low and High

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

K843202, K812424

3. Comparison with predicate:

CALIBRATOR

Similarities		
Item	Device	Predicate
	<i>Heparin Calibrator</i>	<i>aca® Heparin Calibrator</i>
Intended Use	Used to calibrate the Berichrom® Heparin assay for the measurement of unfractionated heparin.	Used to calibrate the aca® discrete clinical analyzer for the Heparin method. This product was designed to meet the needs of users to assure accurate results over the assay range of this method.
Composition	Citrated human plasma and heparin from porcine intestine.	Same
Analytes	Unfractionated heparin	Same
Form	Lyophilized	Same

Differences

Item	Device	Predicate
Instrumentation	Photo-optical coagulation analyzers	aca® discrete clinical analyzer

CONTROLS

Similarities		
Item	Device	Predicate
	<i>Heparin Controls, Level 1 and Level 2</i>	<i>Ci-Trol® Heparin Controls, Low and High</i>
Intended Use	Used as assayed, unfractionated heparin quality control materials for Berichrom® Heparin assay.	Used as a control for heparin assay procedures.
Composition	Citrated human plasma and heparin from porcine intestine.	Citrated human plasma with sodium heparin, buffer and stabilizers.
Analytes	Unfractionated heparin	Same
Form	Lyophilized	Same

Differences		
Item	Device	Predicate
Instrumentation	Photo-optical coagulation analyzers	Photo-optical and mechanical coagulation analyzers.

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

USP Heparin Sodium Reference Standard

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):*

Using at least duplicate determinations, reconstitution stability data met the acceptance criteria of recovering within the assigned values when stored for eight (8) hours at 2 to 8°C.

Different dilutions of USP Heparin Sodium Reference Standard were spiked into citrated plasma samples and the heparin recovery evaluated using a calibration curve established using the USP Heparin Sodium Reference Standard. The same samples were then measured using a calibration curve established with the new Heparin calibrator. Results were compared using regression analysis and the following statistics were obtained:

Dade Behring BCS® Analyzer: $Y = 1.07x - 0.01$, $r = 0.9985$

Sysmex® CA-1500 Analyzer: $Y = 0.97x + 0.01$, $r = 0.9996$

d. *Detection limit:*

Not Applicable.

O. Conclusion:

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