

**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.

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):

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

The product insert contains mean values derived from multiple analyzers and reagent lots, and are specific for the lot of product. It is recommended that each laboratory establish its own means and acceptable ranges and use those provided only as guides.

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.