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

A. 510(k) Number:

K051472

B. Purpose for Submission:

This a bundled submission for the clearance of 5 devices

C. Measurand:

Low Molecular Weight Heparin (LMWH)

Unfractionated Heparin (UF**)**

D. Type of Test:

Quality Control Material

E. Applicant:

Hyphen BioMed

F. Proprietary and Established Names:

Biophen Low Molecular Weight Heparin (LMWH) Control Plasma

Biophen Low Molecular Weight Heparin (LMWH) Control Plasma Low

Biophen Unfractionated Heparin (UFH) Control Plasma

Biophen Heparin Calibrator,

Biophen Unfractionated (UFH) Calibrator

G. Regulatory Information:

1. Regulation section:

21 CFR 864.5425
21 CFR 864.7525

2. Classification:

Class II

3. Product code:

GGN, GGC, KFF

4. Panel:

81 Hematology

H. Intended Use:

1. Intended use(s):

The Biophen LMWH Control Kit is a set of control plasmas for the quality control of Low Molecular Weight Heparin (LMWH) measurements, using anti-Xa colorimetric assays.

The Biophen LMWH Control Low Kit is a set of control plasmas for the quality control of Low Molecular Weight Heparin (LMWH) measurements, using anti-Xa colorimetric assays.

The Biophen UFH Control Kit is a set of control plasmas for the quality control of Low Molecular Weight Heparin (LMWH) measurements, using anti-Xa colorimetric assays.

The Biophen UFH Calibrator is a set of calibration plasmas for Unfractionated Heparin (UFH) measurements, using anti-Xa colorimetric assays.

The Biophen Heparin Calibrator is a set of calibration plasmas for Heparin (UFH and LMWH) measurements, using anti-Xa colorimetric assays.

2. Indication(s) for use:

   Same as Intended Use

3. Special conditions for use statement(s):

   Not applicable

4. Special instrument requirements:

   Not applicable

I. Device Description:

Biophen UFH Control Plasma -12-1 mL vials of human plasma supplemented at 2 different concentrations of unfractionated heparin (6 vials at each concentration)

Biophen LMWH Control Plasma -12-1 mL vials of human plasma supplemented at 2 different concentrations of low molecular weight heparin (6 vials at each concentration)

Biophen LMWH Control Plasma Low -12-1 mL vials of human plasma supplemented at 2 different concentrations of low molecular weight heparin (6 vials at each concentration)

Biophen UFH Calibrator - 20 vials (4 sets of 5 vials) -1 mL vials of human plasma supplemented with different concentrations of unfractionated heparin (4 vials at each concentration)

Biophen Heparin Calibrator- 20 vials (4 sets of 5 vials) -1 mL vials of human plasma supplemented with different concentrations of unfractionated heparin (4 vials at each concentration)

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Instrumentation Laboratories Control Plasma LMW Heparin

   American Bioproducts Heparin Control

   Instrumentation Laboratories Calibration Plasma LMW Heparin

   Dade Behring Heparin Calibrators and Controls.

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

   K030965, K943520, K030964, K042941

3. Comparison with predicate:

Similarities		
Item	Device	Predicate

Differences		
Item	Device	Predicate

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

Not applicable

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

	Intra-assay %CV
Biophen LMWH Control Level 3	1.9
Biophen LMWH Control Level 4	1.5
Biophen LMWH Control Low Level1	1.9
Biophen LMWH Control Low Level 2	0.9
Biophen UFH Control Level 1	1.1
Biophen UFH Control Level 2	0.7

	Intra-assay %CV
Biophen UFH Calibrator Cal 1	na
Biophen UFH Calibrator Cal 2	1.4
Biophen UFH Calibrator Cal 3	1.0
Biophen UFH Calibrator Cal 4	0.5
Biophen UFH Calibrator Cal 5	0.5

	Intra-assay %CV
Biophen Heparin Calibrator Cal 1	na
Biophen Heparin Calibrator Cal 2	2.3
Biophen Heparin Calibrator Cal 3	0.5
Biophen Heparin Calibrator Cal 4	1.0
Biophen Heparin Calibrator Cal 5	0.5

b. *Linearity/assay reportable range:*

Not applicable

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

International Standard for protein for LMWH (NIBSC) (Code 85/600)

5th International Standard for UFH (NIBSC) (Code 97/578)

d. *Detection limit*

e. Analytical specificity:

f. Assay cut-off:

2. Comparison studies: Not applicable

a. Method comparison with predicate device:

b. Matrix comparison:

3. Clinical studies: Not applicable

a. Clinical Sensitivity:

b. Clinical specificity:

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, based on a Tier 1 review.