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

A. 510(k) Number:

k131479

B. Purpose for Submission:

New devices

C. Measurand:

Multi-analyte control materials: Albumin, alpha-1 globulins, alpha-2 globulins, beta globulins, gamma globulins

D. Type of Test:

Control material for Capillary Zone Electrophoresis

E. Applicant:

Helena Laboratories Corporation

F. Proprietary and Established Names:

V8 SP Normal Control and V8 SP Abnormal Control

G. Regulatory Information:

1. Regulation section:

   21 CFR §862.1660 – Quality Control Material (Assayed and Unassayed)

2. Classification:

   Class I

3. Product code:

   JJY – Multi-Analyte Controls, All Kinds (Assayed)

4. Panel:

   Chemistry (75)

H. Intended Use:

1. Intended use(s):

   V8 SPE Normal Control is to be used as a qualitative and/or quantitative control for serum protein by Helena V8 Capillary Electrophoresis (CE) System.

   V8 SPE Abnormal Control is to be used as a qualitative and/or quantitative control for serum protein by Helena V8 Capillary Electrophoresis (CE) System.

2. Indication(s) for use:

   Same as Intended Use

3. Special conditions for use statement(s):

   For prescription only

4. Special instrument requirements:

   Helena V8 Capillary Electrophoresis System (k111369)

I. Device Description:

Lyophilized vials of Normal and Abnormal Controls, 10x2mL stable for 12 mos; dilute w/ 2 mL deionized water stable for 5 days

J. Substantial Equivalence Information:

1. Predicate device name(s) and 510(k) number(s):

   Sebia Normal Control Serum & Sebia Hypergamma Control Serum, k040925

2. Comparison with predicate:

Similarities		
Item	Device	Predicate
	V8 SP Normal Control and V8 SP Abnormal Control	Sebia Normal Control Serum & Sebia Hypergamma Control Serum
Intended Use	Control sera for electrophoretic based test and quantification of the resulting migration patterns by densitometry	Same
Sample matrix	Human serum based	Same
Form	Lyophilized	Same

Differences		
Item	Device	Predicate
Storage of Lyophilized Control	2-8°C for 12 months	-20°C or colder
Storage of Reconstituted Control	2-8°C	Not available

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

CLSI EP-5A2: Evaluation of Precision of Clinical Chemistry Devices Quantitative Measurement (2004)

CLSI C28-A3: Defining, Establishing and Verifying Reference Intervals in the Clinical Laboratory (2008)

ISO 14971: Application of Risk Management to Medical Devices (2007_

ASTM D4169: Standard Practices for Performance Testing and Shipping Containers & Systems (2009)

CLSI M29-A3: Protection of Laboratory Workers from Occupational Acquired Infections (2005)

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Within run precision, between run precision and lot to lot reproducibility studies of three lots of V8 SP Normal and three lots of abnormal assayed control were performed. Testings were done on V8 Capillary Electrophoresis System for a total of 24 replicates divided into three eight channel runs per control type. Each lot of control has an assay range assigned. All protein fraction (albumin, alpha 1 globulin, alpha 2 globulin, beta globulin and gamma globulin) results for both normal and abnormal controls were within the assay range assigned.

   b. Linearity/assay reportable range:

   Not applicable

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

   Traceability/ value assignment: The mean values were derived from repetitive measurements of reference control. Serum protein fractions separated and scanned on the V8 Capillary Electrophoresis instrument are measured directly by their absorbance at 214 nm.

   Stability: The sponsor provided protocol, acceptance criteria and line data of two lots to support the claim of lyophilized control: 12 months at 2-8°C and 5 days for reconstituted controls at 2-8°C. Accelerated studies were performed at 0, 1, 3, 6, 9, 12 and 13 weeks intervals. Real time stability is on-going on a third lot.

   d. Detection limit:

   Not applicable

   e. Analytical specificity:

   Bot 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:

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.