510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
k061069

B. Purpose for Submission:
These are new devices.

C. Measurand:
Immunoglobulins A, G, and M
Lambda and Kappa light chains

D. Type of Test:
Immunofixation electrophoresis
Qualitative

E. Applicant:
Helena Laboratories

F. Proprietary and Established Names:
SPIFE® IFE-3 Pentavalent Kit
SPIFE® IFE-6 Pentavalent Kit
SPIFE® IFE-9 Pentavalent Kit
SPIFE® IFE-15 Pentavalent Kit

G. Regulatory Information:

1. Regulation section:
   21CFR§ 866.5510 Immunoglobulins A, G, M, D, and E Immunological Test System
   21CFR§ 866.5550 Immunoglobulin (light chain specific) Immunological Test System
2. Classification:
   Class II
3. Product code:
   CFF Immunoelectrophoretic, Immunoglobulins (G, A, M)
   DFH Kappa, Antigen, Antiserum, Control
   DEH Lambda, Antigen, Antiserum, Control
4. Panel:
   Immunology (82)

H. Intended Use:

1. Intended use(s):
   The SPIFE IFE Pentavalent kits are intended for the qualitative *in vitro* diagnostic separation of abnormal immunoglobulins in serum using protein electrophoresis and immunofixation on the SPIFE 2000/3000 system.
   All specimens exhibiting an abnormal immunoglobin must be retested with antibody specific antisera (G, A, M, K, L) for identification.
   The test is used as an aid in screening abnormal proteins in conjunction with clinical and other findings.
2. Indication(s) for use:
   Same as above

3. Special conditions for use statement(s):
   The device is for prescription use only.
4. Special instrument requirements:
   For use in the SPIFE 2000/3000 system (k013466)

I. Device Description:

The SPIFE Pentavalent kits are designed as a screening tool for abnormal serum immunoglobulins. There are four kits available depending on the number of samples is to be screened per gel.

Name	No. of samples screened/gel
SPIFE® IFE-3 Pentavalent Kit	9
SPIFE® IFE-6 Pentavalent Kit	18
SPIFE® IFE-9 Pentavalent Kit	27
SPIFE® IFE-15 Pentavalent Kit	45

Each kit is comprised of the following:

- SPIFE gels containing agarose in tris-barbital/MOPS buffer with a stabilizer. Ready to Use
- Acid Violet Stain to be dissolved in 1 liter of 10% acetic acid.
- Citric Acid Destain, containing 0.3% (w/v) acetic acid after dissolution.
- Tris-buffered Saline, containing a Tris base with Tris HCl and NaCl.
- SPIFE IFE Protein Fixative which contains 4.0% sulfosalicylic acid, 6.7% trichloroacetic acid, and 0.002% gluteraldehyde and 1.7% guanidine HCl.
- Pooled antisera to human immunoglobulins heavy chains, IgG. IgA, IgM, and to human light chains, Kappa and Lambda both free and bound. The antisera have been prepared in goat and contain a stabilizer and a preservative.

The Titan Gel Immunofix controls sold separately are recommended.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   SPIFE IFE-6
2. Predicate 510(k) number(s):
   k973040
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	SPIFE Pentavalent kits	**SPIFE Ife kits**
Intended Use	Screening device for abnormal serum immunoglobulins using electrophoresis and immunofixation	Same
Methodology	Immunofixation through precipitin formation following protein	Same

Similarities		
Item	Device	Predicate
	separation by electrophoresis	
Instrumentation	SPIFE 2000/3000	Same
Storage conditions	Refrigerate at 2-8^{o}C until expired	Same

Differences		
Item	Device	Predicate
Sample type	Serum only	Serum or urine
Antisera	Pentavalent antisera pooled G, A, M, K, L	Monospecific antisera G, A, M, K and L
Protein fixative formulation	4.0% sulfosalicylic acid, 6.7% trichloroacetic acid, and 0.002% gluteraldehyde and 1.7% guanidine HCl.	2.5% sulfosalicylic acid, 1.0% trichloroacetic acid, and 0.25% gluteraldehyde and no guanidine HCl

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

None referenced.

L. Test Principle:

Immunofixation electrophoresis (IFE) is a two stage procedure using agarose gel high resolution electrophoresis in the first stage and immunoprecipitation in the second. In the second stage, the soluble antigen and antibody are allowed to react. The resultant antigen-antibody complex(es) may become insoluble (as long as the antibody is in slight excess or near equivalency) and precipitate. The precipitation rate depends on the proportion of the reactants, temperature, salt concentration and the pH of the solution. After immunofixation, the slide is washed to remove any excess soluble proteins. The separated complexes are then stained to visualize the bands.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
   - *a. Precision/Reproducibility:*
     An abnormal control was run in replicate on each of 4 gel types. The abnormal control contains an IgM Kappa.
     Visual examination indicated the precision is 100% positive with total agreement on each plate size. No false negative or positive were observed.
   - *b. Linearity/assay reportable range:*
     Not applicable
   - *c. Traceability, Stability, Expected values (controls, calibrators, or methods)*
     No information was provided for traceability.
     The antisera is stable until expiration date indicated on the vial when

stored at 2-8°C

d. *Detection limit:*
The smallest amount of monoclonal bands detectable with the Pentavalent system was determined. Three known samples, IgG kappa (3500 mg/dL), IgA kappa (1800 mg/dL), and IgM lambda (6500 mg/dL) were used. Serial dilutions were prepared and samples were easily seen through the twelfth dilution (1:2048) giving detection limit as follows:
IgG and kappa = 1.7 mg/dL
IgM and kappa = 0.9 mg/dL
IgA and lambda = 3.2 mg/dL

e. *Analytical specificity:*
Since the Pentavalent antisera appear to capture only the gamma region, the sponsor was asked to explain how the antisera can routinely detect an IgA and M protein which could migrate in the Beta region. Two properly labeled examples were submitted to show bands in the Beta region. Since the antisera cover the entire pattern area, it will react with appropriate bands in any region of the pattern.

No data was submitted for Interference study. A statement has been added to the Limitations section of the package insert to indicate that testing had not been done for cross-reacting and interference substances.

f. *Assay cut-off:*
Not provided.

2. Comparison studies:
   a. *Method comparison with predicate device:*
   Sixty serum samples, 15 normal and 45 abnormal, were run with the Pentavalent Antisera kit and the predicate device SPIFE kits. The samples are provided to Helena Labs from hospital labs with no patient demographics. The abnormal specimens demonstrated monoclonal and polyclonal patterns with both methods whereas the normal specimens were exclusively polyclonal. All of the specimens screened with the Pentavalent Antisera and determined positive were then identified with the G, A, M, K and L monospecific antisera in the SPIFE kits. The device demonstrated 100% agreement with the predicate device in identifying band patterns.
   Artifacts were observed in the 15 normal patient, samples 4 through 15 in the P9 slide and samples 1, 2, 4, and 7 in P6 slide.
   The sponsor claimed these bands are split beta or an application phenomenon that occurs at the application site.
   It does not interfere with pattern interpretation.
   This information was in the interpretation section of the package insert
   b. *Matrix comparison:*
   Serum is the only recommended matrix.
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:
Normal samples do not contain monoclonal components.

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.