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

A. 510(k) Number:
K033187

B. Analyte:
Immunoglobulins A, G, and M
Lambda and Kappa chains

C. Type of Test:
Immunofixation electrophoresis
Qualitative

D. Applicant:
InterLab Scientific Instruments srl
Via Rina Monti N 26 C.A.P.
Rome, 00155
Italy

E. Proprietary and Established Names:
InterLab Immunofixation Electrophoresis Test System

F. Regulatory Information:

1. Regulation section:
   866.5510   Immunoglobulins A, G, M, D, and E
   Immunological test system
   866.5150   Bence-Jones Proteins Immunological test system

2. Classification:
   Class II

3. Product Code:
   CFF   Immunoelectrophoretic, Immunoglobulins (G, A, M)
   JKM   Immunochemical, Bence-Jones Protein

4. Panel:
   Immunology

G. Intended Use:

1. Indication(s) for use:
   InterLab Immunofixation Test is for the qualitative *in vitro* diagnostic
   separation and identification of abnormal immunoglobulins and kappa and
   lambda chains in human serum and concentrated urine using cellulose acetate
   supported on Mylar® for the Microtech 672 PC and IFX instruments. This
   test is useful as an aid in identifying suspected monoclonal gammopathies.

2. Special condition for use statement(s):
   NA
3. Special instrument Requirements:
   Cellulose Acetate supported on Mylar for the Microtech 672 PC and IFX 600
   instruments. The Microtech 672 PC and IFX 600 employ the use of a robotic
   arm that moves the strip to the different stations. The instruments are offered
   as "open" systems and other manufacturer's electrophoresis strips and
   reagents can be used with the instruments. The Microtech 672 can be used for
   other electrophoretic separations and IFX 600 only does immunofixation.
   These instruments are considered class I Exempt based on CFR 866.4500,
   product code JZS and CFR 862.2485, product code JJN

H. Device Description:

The InterLab Immunofixation Test provides identification of immunoglobulin bands
visualized by staining of the separated fractions. The kit contains materials for 24
runs. The kit contains the following: Slides, Running Buffer, Staining solution,
Destaining A solution, Destaining B solution, Washing solution, Storing solution,
Antisera which contain monospecific mammalian (goat or rabbit) antibodies raised
against human IgG, IgM, IgA, kappa and lambda chains, and Fixative.
All reagents are ready to use except the Destaining solution. A working destaining
solution is prepared by combining equal volume of Destaining solutions A and B.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Paragon Serum Immunofixation test (Beckman Coulter)
   Sebia Hydragel Bence Jones Kit
2. Predicate K number(s):
   K002799
   K972591
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
	Microtech 672 & IFX 600	Paragon IFE & Sebia system
Methodology	Immunofixation through precipitin formation following protein separation by electrophoresis	Same
Sample type	Serum and Urine	Same
Operating system	Electrophoresis using a gel/membrane strip	Same
	System perform processing steps for visualization of the sample, but require a technician to read and interpret results	Same

Differences		
Item	**Device**	**Predicate**
Medium for electrophoresis	Cellulose acetate supported on Mylar	Agarose gel
Instrument component	Use of robotic arm to move the strip to the different station	Totally manual set-up

J. Standard/Guidance Document Referenced (if applicable):
NA

K. Test Principle:
Immunofixation electrophoresis is based on visualization of specific proteins through antigen-antibody precipitin formation following protein separation by electrophoresis. Dilutions of patient's specimen are placed on separate tracks (fingers) of a cellulose acetate six finger shaped slide. The major protein groups are separated by electrophoresis. One of the fingers of the slide is treated with a chemical fixative solution to fix all proteins and create an electrophoresis reference pattern for the specimen. The other fingers of the slide are immunofixed by antisera with different specificities: IgG, IgA, IgM heavy chains; anti-kappa and anti-lambda (free and bound) light chains. The migration rate depends on the temperature, pH, ionic strength of the solutions and proportion of the reactants. After immunofixation, the slide is washed to remove any excess soluble protein. The separated complexes are then stained to visualize the bands.

Normal samples do not contain monoclonal components. By comparing the locations of stained immunofixed bands with a band of the same location in the reference protein electrophoretic pattern, a specific protein is identified.

L. Performance Characteristics (if/when applicable):
1. Analytical performance:
    a. *Precision/Reproducibility:*
       An abnormal control, a pooled serum sample and a pooled urine sample were run in duplicate runs and duplicate lots to demonstrate reproducibility of the test. The abnormal control contained IgM, lambda monoclonal band of approximately 10g/L.
       Pooled serum were prepared by mixing three different types of sera each containing monoclonal IgG, IgM, IgA, with kappa and lambda light chains. The final nominal concentration of each monoclonal immunoglobulin type was 5 g/L. Each pool was diluted before use.
       Pooled urine were prepared by mixing two different types of urine, each containing a monoclonal light chain (Bence-Jones protein), either kappa or lambda.
       The multiple patterns were visually inspected and found to be qualitatively identical. The bands are correctly identified. No false negative or positives were observed.

    b. *Linearity/assay reportable range:*
       NA

    c. *Traceability (controls, calibrators, or method):*
      NA
    d. *Detection limit:*
      NA
    e. *Analytical specificity:*
      Interference:
      A statement was included in the package insert regarding the use of hemolyzed or lipemic samples in the test. Because interference may vary from sample to sample, it was recommended that: "Fresh serum samples without hemolysis or lipemia are the optimal choice for testing." This is based on accepted practice and published literature. The sponsor also provided examples of lipemic and hemolyzed sample showing bands are detectable.
      Example 1 – Lipemic sample with monoclonal band - A lipemic serum was spiked with sera containing IgM kappa and lambda respectively. The effect of higher titer of lipids is shown by the increased background spanning the alpha 1, alpha 2 and beta bands. Mark of application point is evident in the antisera tracks and prozone effect is displayed in some immunofixed bands, due to excess antigen. The monoclonal band is still detectable.
      Example 2 – Serum sample with marked hemolysis - A grossly hemolyzed sample with a monoclonal band was used. The hemoglobin-haptoglobin complex appears as a large band, close to the beta band. The monoclonal band(s) is still detectable.

    f. *Assay cut-off:*
      NA

2. <u>Comparison studies:</u>
    a. *Method comparison with predicate device:*
      Studies were performed using 40 serum samples and 20 urine samples from both normal and suspected pathological patients. The samples contained a mixture of IgG, IgM, IgA, kappa and lambda fractions. From the 40 sera, 10 were from normal patients. The serum samples were evaluated with the InterLab IFE electrophoresis test system and the Paragon IFE gel method. Of the 20 urine samples, 2 were from normal patients. The urine samples were tested using the InterLab IFE test system and the SEBIA Hydragel IF gel. A normal and abnormal control was used in each run to assess that the correct migration pattern was obtained.
      The device demonstrated 100% agreement to the predicate device in identifying equivalent band patterns. Neither method detected bands in the normal patients.
      InterLab used two different labs to obtain the number of samples. The lab that did the serum used the Paragon system but did not have

enough urine samples. Hence another lab using the Sebia instrument was used to gather the urine data

Clinical disease states of the patients were not included in the correlation study.

	Predicate device		
	Positive	Negative	Total
Positive	50	0	50
Negative	0	10	10
Total	50	10	60

Relative Sensitivity   100% (serum and urine)
Relative specificity   100% (serum and urine)
Relative Agreement   100% (serum and urine)

b. *Matrix comparison:*
Throughout the method comparison study, a 100 % correlation was obtained for the serum and urine to the predicate devices. A photograph of the electrophoretic pattern of a matched patient sample {serum and urine with kappa light chain (Bence-Jones)} run on the InterLab was provided.

3. Clinical studies:
   a. *Clinical sensitivity:*
   NA
   b. *Clinical specificity:*
   NA
   c. *Other clinical supportive data (when a and b are not applicable):*
   NA
4. Clinical cut-off:
   NA
5. Expected values/Reference range:
   Normal samples do not contain monoclonal components. In monoclonal gammopathies, IFE yields a distinct, sharply defined precipitin band.

M. Conclusion:
Based on the review of the information provided in this 510(k), the InterLab Immunofixation Test appears to be **Substantially Equivalent** to devices regulated under 21CFR866.5510 Immunoglobulins A, G, M, D, and E immunological test system, product code CFF, and 21 CFR 866.5150 Bence-Jones Proteins immunological test system, product Code JKM.