A. 510(k) Number:

K182298

B. Purpose for Submission:

Expansion of target patient population – addition of pediatric claim

C. Measurand:

Hemoglobin

D. Type of Test:

Quantitative determination of hemoglobin

E. Applicant:

Immunostics, Inc.

F. Proprietary and Established Names:

hemochroma PLUS System
hemochroma PLUS Controls

G. Regulatory Information:

1. Regulation section:

21 CFR 864.5620, Automated hemoglobin system
21 CFR 864.8625, Hematology quality control mixture

2. Classification:

Class II

3. Product code:

GKR, System, hemoglobin, automated
GGM, Control, hemoglobin

4. Panel:
Hematology (81)

H. Intended Use:

1. Intended use(s):

The hemochroma PLUS System is for the quantitative determination of hemoglobin concentration in non-anticoagulated capillary (finger-stick) whole blood or venous whole blood (K2-EDTA, K3-EDTA, sodium citrate, lithium heparin, or sodium heparin). The testing system is designed for point-of-care settings, hospitals, and medical lab facilities.

Estimation of hematocrit, as a function, is only for normal hemoglobin values, 12.0 to 18.0 g/dL (120 to 180 g/dL) and in patients ≥ 6 months old.

The hemochroma PLUS Controls are intended for use as quality control material to assure the validity and performance of the hemochroma PLUS system in measuring the human hemoglobin concentration.

The hemochroma PLUS Microcuvettes are only used with hemochroma PLUS Analyzer. The hemochroma PLUS System is for in vitro diagnostic only.

The hemochroma PLUS Analyzer calculates the test result automatically and displays hemoglobin concentration in terms of g/dL.

2. Indication(s) for use:

Same as intended use

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

hemochroma Plus Analyzer

I. Device Description:

The hemochroma PLUS System consists of a hemochroma PLUS Analyzer, single-use hemochroma PLUS Microcuvettes, hemochroma PLUS ID Chip, optical System Check Microcuvette and hemochroma PLUS Controls.

1. hemochroma PLUS Analyzer

The hemochroma PLUS Analyzer is a battery powered, hand-held device used to
measure total hemoglobin concentration in human whole blood. Whole blood may be collected by fingerstick (capillary) or venipuncture and analyzed without pre-processing. The hemochroma PLUS Analyzer uses hemochroma PLUS Microcuvettes with dual ports where the user applies samples either through capillary action or direct volume pipetting. The hemochroma PLUS Analyzer determines hemoglobin concentration in whole blood samples using a dual wavelength photo-absorption method and measures the degree of light absorption with a spectrophotometer. The optical distance between the hemochroma PLUS Microcuvette walls is fixed and permits photometric determination of hemoglobin in undiluted blood samples. The computed end result is displayed on a LCD display and can be printed on an external printer (optional).

2. hemochroma PLUS Microcuvette

The hemochroma PLUS Microcuvettes are specially designed for use with the hemochroma PLUS Analyzer. The microcuvettes function as measuring devices specifically holding 15 μL of blood and are inserted into the hemochroma PLUS Analyzer by placing it into the cuvette holder. The optical distance between the hemochroma PLUS Microcuvette walls is fixed and by measuring the degree of light absorption permits photometric determination of the hemoglobin in undiluted blood samples.

3. hemochroma PLUS ID Chip

The hemochroma PLUS ID chip contains encoded memory with the calibration data/information of the Microcuvette lot. With the ID chip inserted in the designated port, the hemochroma PLUS Analyzer reads and utilizes the calibration data regarding the lot under consideration and applies appropriate correction to the conversion formula while computing the test result.

4. hemochroma PLUS Optical System Check Microcuvette

hemochroma PLUS Optical System Check Microcuvette is designed for use with the hemochroma PLUS Analyzer only. The Optical System Check Microcuvette is a special glass filter used to measure the degree of light absorption with the spectrophotometric method. If the result is between 11.7–12.3 g/dL, the optic system is working properly according to specification.

5. hemochroma PLUS Controls

The hemochroma PLUS Controls: Level 1 (Low), Level 2 (Middle), and Level 3 (High), are external quality controls designed for use with hemochroma PLUS Analyzer only.

J. Substantial Equivalence Information:

1. Predicate device name(s):
HemoCue Hb 301 System

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

   K061047

3. **Comparison with predicate:**

<table>
<thead>
<tr>
<th>Item</th>
<th>Device</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended Use/ Indications for Use</strong></td>
<td>HemoCroma PLUS System K182298</td>
<td>HemoCue Hb 301 System K061047</td>
</tr>
<tr>
<td>The hemochroma PLUS System is for the quantitative determination of hemoglobin concentration in non-anticoagulated capillary (finger-stick) whole blood or venous whole blood (K₂-EDTA, K₃-EDTA, sodium citrate, lithium heparin, or sodium heparin). The testing system is designed for point-of-care settings, hospitals, and medical lab facilities. Estimation of hematocrit, as a function, is only for normal hemoglobin values, 12.0 to 18.0 g/dL (120 to 180 g/dL) and in patients ≥ 6 months old. The hemochroma PLUS Controls are intended for use as quality control material to assure the validity and performance of the hemochroma PLUS system in measuring the human hemoglobin concentration. The hemochroma PLUS Microcuvettes are only used with hemochroma PLUS Analyzer. The hemochroma PLUS System is for <em>in vitro</em> diagnostic only. The hemochroma PLUS...</td>
<td>The HemoCue Hb 301 System is designed for quantitative point-of-care whole blood hemoglobin determination in primary care using a specially designed analyzer, the HemoCue Hb 301 Analyzer, and specially designed microcuvettes, the HemoCue Hb 301 Microcuvettes. The HemoCue Hb 301 system is for <em>in vitro</em> diagnostic use only. The HemoCue Hb 301 Analyzer is only to be used with HemoCue Hb 301 Microcuvettes.</td>
<td></td>
</tr>
</tbody>
</table>
### Similarities

<table>
<thead>
<tr>
<th>Item</th>
<th>Device</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Hemochroma PLUS System K182298</td>
<td>HemoCue Hb 301 System K061047</td>
</tr>
<tr>
<td>Analyzer</td>
<td>calculates the test result automatically and displays hemoglobin concentration in terms of g/dL.</td>
<td></td>
</tr>
</tbody>
</table>

Parameter(s) | Hemoglobin (Hgb) | Same |

### Differences

<table>
<thead>
<tr>
<th>Item</th>
<th>Device</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>hemochroma PLUS System K182298</td>
<td>HemoCue Hb 301 System K061047</td>
</tr>
<tr>
<td>Test Principle</td>
<td>Dual wavelengths for Hgb measurement and reference absorption.</td>
<td>Dual wavelengths for Hgb measurement and turbidity compensation.</td>
</tr>
<tr>
<td>Wavelength</td>
<td>Dual wavelengths 530 and 850 nm</td>
<td>Dual wavelengths 506 and 880 nm</td>
</tr>
<tr>
<td>Measuring Range</td>
<td>5.0–25.6 g/dL</td>
<td>0–25.6 g/dL</td>
</tr>
<tr>
<td>Sample Type</td>
<td>Capillary and venous whole blood</td>
<td>Capillary, venous, and arterial whole blood</td>
</tr>
<tr>
<td>Sample Volume</td>
<td>15μL</td>
<td>10μL</td>
</tr>
<tr>
<td>Test time</td>
<td>3 seconds</td>
<td>10 seconds</td>
</tr>
<tr>
<td>Parameter(s)</td>
<td>Estimation of hematocrit (HCT)</td>
<td>No estimation of HCT</td>
</tr>
</tbody>
</table>

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


### L. Test Principle:

The hemochroma PLUS Analyzer utilizes a dual wavelength LED light source by which the hemoglobin absorbance is detected and converted into an electrical signal. The signal is directly proportional to the amount of hemoglobin present in the sample. The concentration of hemoglobin is calculated based on a pre-programmed calibration. The hemochroma PLUS Microcuvette is specifically designed for the hemochroma PLUS Analyzer. Approximately 15 μL of capillary or venous blood is taken up by capillary action using the tip of the hemochroma PLUS Microcuvette or by direct volume pipetting of the sample. The blood filled Microcuvette is inserted onto the microcuvette holder, and the hemochroma PLUS Analyzer measures the degree of light absorption with a spectrophotometer. The absorbance of the light from the hemochroma PLUS Microcuvette is converted into an electrical signal. The optical distance between the hemochroma PLUS Microcuvette walls is fixed and permits
photometric determination of the hemoglobin in undiluted blood samples.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   In premarket notification K163465 the following studies were performed for the hemochroma PLUS System: method comparison to the HemoCue Hb 301 System, precision/reproducibility, linearity, detection limit, stability, and interference studies. The established performance and technological characteristics cleared in K163465 remain unchanged; therefore, additional performance studies were not required to support substantial equivalence in this premarket notification.

   a. Precision/Reproducibility:

      Refer to K163465

   b. Linearity/assay reportable range:

      Refer to K163465

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

      Refer to K163465

   d. Detection limit:

      Refer to K163465

   e. Analytical specificity:

      Refer to K163465

   f. Assay cut-off:

      Not applicable

2. Comparison studies:

   a. Method comparison with predicate device:

      Refer to K163465

   b. Matrix comparison:
Refer to K163465

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:
      
      Adult references ranges were based on existing medically accepted published reference ranges¹.
      
      | Group       | Cited Reference Range |
      |-------------|-----------------------|
      | Adult Male  | 14.0 – 18.0 g/dL       |
      | Adult Female| 12.0 – 16.0 g/dL       |

      Pediatric reference ranges were based on existing medically accepted published references ranges².
      
      | Group               | Cited Reference Range |
      |---------------------|-----------------------|
      | 2–6 months          | 9.5 – 13.5 g/dL       |
      | 7 months – 2 years  | 10.5 – 14.0 g/dL      |
      | 3–6 years           | 11.5 – 14.5 g/dL      |
      | 7–12 years          | 11.5 – 15.5 g/dL      |
      | 13–18 years male    | 13.0 – 16.0 g/dL      |
      | 13–18 years female  | 12.0 – 16.0 g/dL      |

N. Instrument Name:

hemochroma PLUS Analyzer

O. System Descriptions:

1. Modes of Operation:

   Does the applicant’s device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ________ or No ___X____

   Does the applicant’s device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ________ or No ___X____

2. Software:

   FDA has reviewed applicant’s Hazard Analysis and software development processes for this line of product types:

   Yes __X__ or No ________

3. Specimen Identification:

   There is no sample identification function for the hemochroma PLUS Analyzer. Samples are applied directly to the microcuvettes as they are collected. The end user must develop a manual system to identify patients that are tested with the hemochroma PLUS Analyzer.

4. Specimen Sampling and Handling:

   Capillary or venous whole blood is directly applied from the finger or blood tube (using a disposable pipette) to the Microcuvette. Wipe off excess blood from the surface of the microcuvette using a piece of soft gauze. The blood-filled Microcuvette is then inserted into the hemochroma PLUS Analyzer.

5. Calibration:

   The hemochroma PLUS ID chip contains encoded memory with the calibration data/information of the Microcuvette lot. With the ID chip inserted in the designated port, the hemochroma PLUS Analyzer reads and utilizes the calibration data regarding the lot under consideration and applies appropriate correction to the conversion formula while computing the test result.
6. **Quality Control:**

The hemochroma PLUS Controls (low, middle, and high hemoglobin) are intended for use as quality control material to assure the validity and performance of the hemochroma PLUS System in measuring the human hemoglobin concentration. The hemochroma PLUS Controls should be assayed according to the manufacturer’s instructions and following the local and state guidelines. If controls do not perform as expected, the test results should not be used.

The hemochroma PLUS Optical System Check is used to assure the performance of the Optic System of the hemochroma PLUS. The Optical System Check Microcuvette is a special glass filter used to measure the degree of light absorption with the spectrophotometric method. If the result is between 11.7–12.3 g/dL, the optic system is working properly according to specification.

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:**

Not applicable

**Q. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

**R. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.