510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
   K062746

B. Purpose for Submission:
   New device

C. Measurand:
   Ferritin

D. Type of Test:
   Particle enhanced immunoturbidimetry

E. Applicant:
   Medicon Hellas SA

F. Proprietary and Established Names:
   Medicon Ferritin - LATEX

G. Regulatory Information:
   1. Regulation section:
      21 CFR 866.5340 Ferritin immunological test system
   2. Classification:
      Class II
   3. Product code:
      DBF Ferritin, antigen, antiserum, control
   4. Panel:
      Immunology (82)

H. Intended Use:
   1. Intended use(s):
      The Medicon Ferritin – LATEX is an in vitro diagnostic reagent intended for the
determination of Ferritin in human serum and plasma using Olympus
AU400/600/640 automated clinical chemistry analyzers.
   2. Indication(s) for use:
      Medicon Ferritin – LATEX reagent is for the determination of ferritin in human
serum and plasma using automated clinical chemistry analyzers. The
measurement of ferritin may aid in the diagnosis of diseases affecting iron
metabolism.
   3. Special conditions for use statement(s):
      Prescription use
   4. Special instrument requirements:
      Olympus Clinical Chemistry Analyzers, Models AU400/600/640

I. Device Description:
   The Ferritin – LATEX reagents consist of R1: 120 nM Tris buffer pH=8.2,
accelerator, surfactant, stabilizers and preservatives; and R2: latex particles coated
with rabbit anti-human ferritin in 20 nM Tris buffer pH=8.4, stabilizers and
preservatives.
J. **Substantial Equivalence Information:**

1. **Predicate device name(s):**
   - Olympus Ferritin Reagent
2. **Predicate 510(k) number(s):**
   - k030124
3. **Comparison with predicate:**

<table>
<thead>
<tr>
<th>Item</th>
<th>New Device</th>
<th>Predicate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Medicon Ferritin</strong></td>
<td><strong>Olympus Ferritin k030124</strong></td>
</tr>
<tr>
<td><strong>Indication for use</strong></td>
<td>Medicon Ferritin – LATEX reagent is for the determination of ferritin in human serum and plasma using automated clinical chemistry analyzers. The measurement of ferritin may aid in the diagnosis of diseases affecting iron metabolism.</td>
<td>Reagent for the determination of ferritin concentrations in human serum using the Olympus family of clinical chemistry analyzers. Serum ferritin is an indicator of body iron stores: Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.</td>
</tr>
<tr>
<td><strong>Constituents</strong></td>
<td>Ferritin R1 (Buffer) Ready to Use Ferritin R2 (Latex) Ready to Use</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Storage conditions</strong></td>
<td>Refrigerate at 2 ° - 8 ° C until expired</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Methodology</strong></td>
<td>Particle enhanced immunoturbidimetry</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Instrument family</strong></td>
<td>Olympus Clinical Chemistry Analyzers</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Formulation</strong></td>
<td>Final reactive ingredients: Tris Buffer pH: 8.2 Latex particles coated with rabbit anti-human ferritin Preservative</td>
<td>Same</td>
</tr>
<tr>
<td>Item</td>
<td>New Device</td>
<td>Predicate</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>---------------------------------</td>
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<tr>
<td></td>
<td>Medicon Ferritin</td>
<td>Olympus Ferritin</td>
</tr>
<tr>
<td></td>
<td></td>
<td>k030124</td>
</tr>
<tr>
<td>Calibrator – recommended but not included with kit</td>
<td>Olympus Serum Protein Multi-Calibrator ODR3021</td>
<td>Same</td>
</tr>
<tr>
<td>Controls – recommended but not included with kit</td>
<td>Olympus ITA Control Sera, ODC0014, ODC0015, ODC0016</td>
<td>Same</td>
</tr>
<tr>
<td>Reagent Stability</td>
<td>On board: 30 days</td>
<td>Same</td>
</tr>
<tr>
<td>Calibration Interval</td>
<td>After each lot and 14 days</td>
<td>Same</td>
</tr>
<tr>
<td>Reference Intervals</td>
<td>Serum / Plasma: Infants – 1 month: 6–400 ng/mL 1 month – 6 months: 6–410 ng/mL 6 months – 12 months: 6–80 ng/mL 1 year – 5 years: 6–60 ng/mL 6 years – 19 years: 6–320 ng/mL adult men: 20–250 ng/mL adult women: 20–200 ng/mL</td>
<td>Same (for serum only)</td>
</tr>
<tr>
<td>Traceability/Standardization</td>
<td>Standardized against the WHO 3rd International Standard for ferritin, Recombinant NBSC code: 94/572.</td>
<td>Same</td>
</tr>
</tbody>
</table>
### Differences

<table>
<thead>
<tr>
<th>Item</th>
<th>New Device Medicon Ferritin</th>
<th>Predicate Olympus Ferritin K030124</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measuring Range</td>
<td>4 – 450 ng/ml</td>
<td>8 – 450 ng/ml</td>
</tr>
<tr>
<td>Sample type</td>
<td>Serum and plasma</td>
<td>Serum</td>
</tr>
</tbody>
</table>

### K. Standard/Guidance Document Referenced (if applicable):
None referenced

### L. Test Principle:
When a sample containing ferritin is mixed with the Ferritin - LATEX reagent and the reaction buffer included in the kit, ferritin reacts with the antibodies leading to agglutination of the latex particles. The agglutination is detected as turbidity change (the decrease of transmitted light caused by the aggregates measured at 600 nm) and is directly proportional to the concentration of ferritin in the sample.

### M. Performance Characteristics (if/when applicable):

1. **Analytical performance:**
   a. **Precision/Reproducibility:**
      A precision study was performed on an OLYMPUS AU640 Clinical Chemistry Analyzer using OLYMPUS ITA Control Levels (Low, Medium, and High). The within run, between run, and total %CV were calculated according to CLSI (NCCLS) EP5-A protocol.

<table>
<thead>
<tr>
<th></th>
<th>Within Run</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Level 1</td>
<td>Level 2</td>
</tr>
<tr>
<td>Mean (ng/mL)</td>
<td>38.0</td>
<td>108.1</td>
</tr>
<tr>
<td>SD</td>
<td>1.22</td>
<td>1.42</td>
</tr>
<tr>
<td>% CV</td>
<td>3.20</td>
<td>1.31</td>
</tr>
</tbody>
</table>

   b. **Linearity/assay reportable range:**
      Linearity was performed on an OLYMPUS AU640 Clinical Chemistry Analyzer according to CLSI (NCCLS) EP6-P Guideline. A serum sample with high Ferritin level was serially diluted and each of the 14 dilutions was assayed in quadruplicate on the Olympus AU 640. The acceptance criterion is ± 10% deviation from regression line. The percent deviation from the regression line for the 14 points ranged from -10.2 to 3.1%. The assay is linear over the reportable range of 4-450 ng/ml.
**Prozone Effect:** High pool of Ferritin (SCIPAC) was diluted with saline. No hook effect was observed for the tested specimen at 10,000 ng/ml compared to the upper limit of the measuring range of 450 ng/mL.

c. **Traceability, Stability, Expected values (controls, calibrators, or methods):**
The recommended calibrator is standardized against the WHO 3rd International Standard for ferritin, Recombinant NBSC code: 94/572.

d. **Detection Limit:**
The **Lowest Detectable Level** was defined as the Mean (20 replicates) + 3SD = 0.8 + 3(0.9) = 3.4 ng/mL. Detection Limit is stated at 4.0ng/mL. **Functional Lower Limit** is estimated to be 4.0ng/mL. A serum with initial concentration value of 58.7ng/mL was serially diluted 1:1 with saline (0.9g NaCl /100ml).

e. **Analytical specificity:**
**Interference:** Interference testing was performed by spiking levels of each interferant into pooled serum. Acceptance criterion was set at \( \leq \pm 10\% \) (Final/Original results x 100%).
- Ascorbic Acid: Less than 5% up to 3 mg/dL ascorbic acid
- Hemolysis: Less than 5% up to 500 mg/dL hemoglobin.
- Lipemia: Less than 10% up to 400 mg/dL Intralipid®.
- Icterus: Less than 5% up to 20 mg/dL bilirubin.
- Rheumatoid Factor: Less than 5% up to 900 IU/ml RF.

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

2. **Comparison studies:**
   a. **Method comparison with predicate device:**
   One hundred seventy-six (176) patient serum samples ranging from 7.50 - 491.40 ng/mL were analyzed using Ferritin-LATEX and Olympus Ferritin Reagent (predicate device) on an OLYMPUS AU 640 Clinical Chemistry Analyzer. No artificially prepared samples were used in this study. The following results were obtained using Linear Regression Analysis:
   \[ y = 1.0016x + 4.3849 \text{ ng/mL} \] with a correlation coefficient of \( R = 0.9958 \).

   b. **Matrix comparison:**
   40 patient plasma (EDTA) ferritin samples ranging from 8.90 - 482.85 ng/mL were compared to serum ferritin values obtained using Medicon Ferritin-LATEX on an OLYMPUS AU 640 Clinical Chemistry Analyzer. The following results were obtained using Linear Regression Analysis:
   \[ y = 0.9847x - 1.1275 \text{ ng/mL} \], with a correlation coefficient of \( R = 0.9978 \).

   138 patient plasma (LiH) ferritin samples ranging from 5.6 - 477.50 ng/mL were compared to serum ferritin values obtained using Medicon Ferritin-
3. Clinical studies:
   a. Clinical Sensitivity:
      Not determined
   b. Clinical specificity:
      Not determined
   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:
   Reference ranges were taken from Tietz:

   Serum / Plasma:
   Infants – 1 month: 6-400 ng/mL
   1 month – 6 months: 6-410 ng/mL
   6 months – 12 months: 6–80 ng/mL
   1 year – 5 years: 6–60 ng/mL
   6 years – 19 years: 6–320 ng/mL
   Adult men: 20-250 ng/mL
   Adult women: 20-200 ng/mL
   As stated in the product insert, each laboratory should determine its own expected values as dictated by GLP.

N. Proposed Labeling:
   The labeling is sufficient and 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.