510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

A. 510(k) Number:
K033873

B. Analyte:
C-Peptide

C. Type of Test:
Calibrator

D. Applicant:
Roche Diagnostics

E. Proprietary and Established Names:
Elecsys C-Peptide CalSet

F. Regulatory Information:
1. Regulation section:
   CFR 21 662.1150
2. Classification:
   II
3. Product Code:
   JIT
4. Panel:
   Chemistry (75)

G. Intended Use:
1. Intended use(s):
   Refer to Indications for use.

2. Indication(s) for use:
   The Elecsys C-Peptide CalSet is intended for calibrating the quantitative Elecsys C-Peptide assay on the Elecsys immunoassay systems.

   The device is for in vitro diagnostic use.
   The device is for prescription use.

3. Special condition for use statement(s):
   None

4. <u>Special instrument Requirements:</u>
Elecsys immunoassay systems.   There are three instruments in this family, the Elecsys 1010, Elecsys 2010, and the Modular Analystics E170 Immunoassay Analyzers.

H. Device Description:
The product is a lyophilized equine serum based calibrator into which synthetic C-Peptide is added. There are two levels of Calibrator, targeted to 0.5 and 20 ng/mL.

I. Substantial Equivalence Information:
1. <u>Predicate device name(s):</u>
Elecsys LH CalSet II
2. <u>Predicate K number(s):</u>
K031299
3. <u>Comparison with predicate:</u>
Both devices are two level lyophilized calibrator material. The devices are intended to calibrate different assays. The formulations vary between the two devices, i.e., the candidate device is equine serum with synthetic C-Peptide added whereas the predicate is human serum with human LH added.

J. Standard/Guidance Document Referenced (if applicable):
The sponsor did not reference any standards in their submission.

K. Test Principle:
Not applicable.

L. Performance Characteristics (if/when applicable):
1. <u>Analytical performance:</u>
   a. *Precision/Reproducibility:*
      Not applicable.

   b. *Linearity/assay reportable range:*
      Not applicable.

   c. *Traceability (controls, calibrators, or method):*

      The product consists of two levels of calibration material. Representative values of the materials are provided and seem appropriate.

      Calibrators are gravimetrically prepared to the targeted concentrations and their values are assigned by the following procedure:

Roche maintains a set of master calibrators traceable to the WHO Reference Reagent, 1ˢᵗ RR, code 84/510 (NIBSC). Samples are run in duplicate on two independent series of analysis. Samples are run on four different analyzers. The target value is then calculated as the median of the determined values.

Although the sponsor states that the calibrators are traceable, a measure or limit of agreement between the reference calibrator and the prepared calibrator is not identified.

Accelerated stability studies are summarized. The frequency of testing, method for testing the materials, environmental conditions of storage, and acceptance criteria for the study (95-105% recovery) are identified. Accelerated studies are being used by the sponsor to estimate the expiration date. The sponsor also describes in a similar manner, how they have established their stability claims for reconstituted materials. All procedures appear to be standard for the industry.

Real-time stability testing is in progress at the time of this submission. Reagents are stored at 2 - 8°C. Complete testing is carried out at intervals of 0, 19, and 25 months. The procedure includes bottle testing for appearance, bioburden, and turbidity of solution; and function testing for recovery of C-Peptide in control samples, including PreciControl MultiAnalyte and internal control samples.

The acceptance criteria for the real-time stability studies are: recovery of 76% to 124% based on the target value of the control used.

d. *Detection limit:*
Not applicable.

e. *Analytical specificity:*
Not 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):*

4. Clinical cut-off:
   Not applicable.
5. Expected values/Reference range:
   Not applicable.

M. Conclusion:

I recommend that this device be found substantially equivalent to the predicate device.