

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

**A. 510(k) Number:** k033937

**B. Analyte:** Multi-analyte Controls assayed and unassayed (C peptide and Insulin)

**C. Type of Test:** n/a

**D. Applicant:** Roche Diagnostics Corporation

**E. Proprietary and Established Names:** Proprietary name – Elecsys PreciControl MultiAnalyte Established name - PreciControl MultiAnalyte

**F. Regulatory Information:**

1. Regulation section: 21 CFR 862.1660
2. Classification: I
3. Product Code: JJY
4. Panel: 75

**G. Intended Use:**

1. Intended use(s): The Elecsys PreciControl MultiAnalyte is used for quality control of the Elecsys C-Peptide and Elecsys Insulin Immunoassay systems.
2. Indication(s) for use: n/a
3. Special condition for use statement(s):
4. Special instrument Requirements: This control is for use on the Elecsys immunoassay systems

**H. Device Description:** The Elecsys PreciControl MultiAnalyte is a lyophilized product consisting of synthetic human C-Peptide and recombinant human insulin in a buffered equine serum matrix. During manufacture, the analytes are spiked into the matrix at the desired concentration levels.

**I. Substantial Equivalence Information:**

1. Predicate device name(s): Elecsys PreciControl Cardiac
2. Predicate K number(s): k032089

3. Comparison with predicate:

<b>Device comparisons</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate</b>
Intended use	The Elecsys PreciControl MultiAnalyte is used for quality control of the Elecsys C-Peptide and Elecsys Insulin Immunoassay systems.	PreciControl Cardiac is used for quality control of the Elecsys CK-MB, Digoxin, Myoglobin, and NT-proBNP immunoassay on the Elecsys immunoassay systems.
Levels	Two	Same
Format	Lyophilized	Same
Handling	Reconstitute with exactly 2.0mL distilled water and allow to stand closed for 15 minutes	Same
Matrix	Equine serum with added C-Peptide and insulin	Human Serum with added CK-MB, digoxin, myoglobin, and NT-proBNP
Stability	<u>Unopened</u>  Store at 2- 8 <sup>0</sup> C until the expiration date  <u>Reconstituted</u>  At -20 <sup>0</sup> C : 1 month On the analyzer 3 hours	<u>Unopened</u>  Store at 2- 8 <sup>0</sup> C until the expiration date  Reconstituted  At 2- 8 <sup>0</sup> C 3 days At -20 <sup>0</sup> C 3 months On the analyzers 3 hours

**J. Standard/Guidance Document Referenced (if applicable):** None referenced

**K. Test Principle:** N/A

**L. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:* N/A

*b. Linearity/assay reportable range: N/A*

*c. Traceability (controls, calibrators, or method):* The Elecsys PreciControl MultiAnalyte is a lyophilized product consisting of synthetic human C-Peptide and recombinant human insulin in a buffered equine serum matrix. During manufacture, the analytes are spiked into the matrix at the desired concentration levels.

*d. Detection limit: N/A*

*e. Analytical specificity N/A:*

*f. Assay cut-off: N/A*

2. Comparison studies:

*a. Method comparison with predicate device: N/A*

*b. Matrix comparison: N/A*

3. Clinical studies:

*a. Clinical sensitivity: N/A*

*b. Clinical specificity: N/A*

*c. Other clinical supportive data (when a and b are not applicable):  
N/A*

4. Clinical cut-off: N/A

5. Expected values/Reference range: N/A

**M. Conclusion:** Based upon the information provided, I recommend that the Roche Elecsys PreciControl MultiAnalyte be found substantially equivalent with similar defined products based upon 21 CFR 862.1660.