This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR §807.92. This is a Traditional 510(k).

The assigned 510(k) number: K182702

**Applicant Information and Date [807.92 (a)(1)]**

Applicant Name and Address: SEKISUI DIAGNOSTICS P.E.I. INC.
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Date Summary prepared: April 10, 2019

**Device Name and Classification [807.92 (a)(2)]**

| Trade Name | Common Name | Classification Name | Classification | Product Code |
|---|---|---|---|---|
| SEKURE Creatine Kinase Assay | Creatine Kinase Assay or CK Assay | Creatine phosphokinase/ creatine kinase or isoenzymes test system | Class II<br>21 CFR 862.1215 | CGS |

**Identification of Legally Marketed Predicate Devices [807.92 (a)(3)]**

| Predicate Device | Predicate 510(k) Number |
|---|---|
| Creatine Kinase-SL Assay | K973999 |

**Device Description [807.92 (a)(4)]**

| Trade Name | Device Description |
|---|---|
| SEKURE Creatine Kinase Assay | The SEKURE Creatine Kinase Assay (CK Assay) is a spectrophotometric, coupled enzyme assay for the quantitative measurement of creatine kinase (CK) activity.<br>The assay consists of two working reagents, a buffer solution (R1) and a substrate reagent (R2). The SEKURE CK Assay employs the reverse reaction of CK, to produce adenosine triphosphate (ATP). The reaction is coupled to hexokinase and G6PDH which consumes ATP to generate NADPH. The rate of NADPH formation is monitored at 340 nm and is directly proportional to CK activity.<br>Testing is performed on the SK500 in conjunction with calibrator and controls which are provided separately. |
| SK500 Clinical Chemistry Analyzer | The SK500 Analyzer is manufactured as Clinical Chemistry Analyzer Tokyo Boeki Medisys Inc. Biolis 50i Superior. “SK500” is the Sekisui Diagnostics labelled name for the Tokyo Boeki Medisys Inc. Biolis 50i Superior instrument. |

**Intended Use [807.92 (a)(5)]**

For the *in vitro* quantitative measurement of creatine kinase activity in serum and plasma on the SK500 Clinical Chemistry System. Measurements of creatine kinase are used in the diagnosis and treatment of myocardial infarction and muscle diseases such as progressive, Duchenne-type muscular dystrophy.

**Technological Similarities and Differences to the Predicate [807.92 (a)(6)]**

| Characteristic | Predicate Device | New Device |
|---|---|---|
| | Creatine Kinase-SL Assay | SEKURE Creatine Kinase Assay |
| Intended Use | For the *in vitro* quantitative measurement of creatine kinase activity in serum. | Similar<br>For the *in vitro* quantitative measurement of creatine kinase activity in serum and plasma on the SK500 Clinical Chemistry System. |
| Platform | Hitachi 717 Analyzer (K953239) | SK500 Clinical Chemistry Analyzer |
| Methodology | Colorimetric (NADPH), Enzymatic (coupled hexokinase-G6PD) | SAME |
| Specimen type | Serum | Similar<br>Serum and lithium heparin plasma |
| Measuring interval | 2-1500 U/L | Similar<br>11-1500 U/L |

**Summary of Non-Clinical Performance Data [807.92 (b)(1)]**

Precision

Testing was conducted as per CLSI EP05-A3 using two lots of SEKURE CK reagents on one SK500 instrument. Two levels of sera controls, one level of pooled serum, and three levels of pooled plasma were assayed in duplicate in two runs per day for twenty (20) days. The CK activity data (U/L) are summarized in the following table.

| Lot | Sample | N | Mean CK (U/L) | Repeatability | | Within Laboratory | |
|---|---|---|---|---|---|---|---|
| | | | | SD | %CV | SD | %CV |
| Lot 1 | Serum Control 1 | 80 | 145.3 | 1.6 | 1.1 | 2.5 | 1.7 |
| | Serum Control 2 | 80 | 438.1 | 3.2 | 0.7 | 6.0 | 1.4 |
| | Serum High Pool | 80 | 772.2 | 5.3 | 0.7 | 13.4 | 1.7 |
| | Plasma Low Pool | 80 | 155.9 | 1.9 | 1.2 | 3.4 | 2.2 |
| | Plasma Med Pool | 80 | 372.3 | 3.1 | 0.8 | 7.7 | 2.1 |
| | Plasma High Pool | 80 | 576.5 | 3.4 | 0.6 | 20.0 | 3.5 |
| Lot 2 | Serum Control 1 | 80 | 143.3 | 1.7 | 1.2 | 2.4 | 1.7 |
| | Serum Control 2 | 80 | 436.9 | 3.3 | 0.8 | 5.3 | 1.2 |
| | Serum High Pool | 80 | 773.9 | 4.8 | 0.6 | 13.8 | 1.8 |
| | Plasma Low Pool | 80 | 153.5 | 2.0 | 1.3 | 3.3 | 2.1 |
| | Plasma Med Pool | 80 | 370.6 | 2.6 | 0.7 | 7.2 | 1.9 |
| | Plasma High Pool | 80 | 574.2 | 3.8 | 0.7 | 20.4 | 3.6 |

Analytical Sensitivity

*Limit of Blank (LoB) and Limit of Detection (LoD)*

Limit of Blank and Limit of Detection testing was based on guidance from the CLSI guidance document EP17-A2. Testing was completed by analyzing low level samples (saline blanks and dilutions of pooled serum or plasma in saline) in quadruplicate for three days producing a total of 60 measurements of each level. All samples were assayed on two lots of CK reagents and one SK500 analyzer. The LoB and LoD were determined individually for each reagent lot, dilution level, and matrix type; the maximal values are claimed for the SEKURE CK Assay.

| Parameter | CK Activity |
|---|---|
| LoB | 3 U/L |
| LoD | 5 U/L |

*Limit of Quantitation (LoQ)*

Limit of Quantitation testing was based on guidance from the CLSI guidance document EP17-A2. Eight linear serum samples and eight linear plasma samples were assayed in five runs over three days to give 40 replicates. All samples were assayed on two lots of CK reagents and one SK500 analyzer. The LoQ was determined as the lowest CK value at which the %CV was ≤20%. The LoQ was determined individually for each reagent lot and each matrix type; the maximal value is claimed as the LoQ for the SEKURE CK Assay. The LoQ claimed is 11 U/L.

*Linearity/Assay Reportable Range*

A linearity study was performed based on guidance from the CLSI guidance document EP06-A. Linearity testing for serum was conducted using eight dilutions of pooled serum to generate a CK activity range from 0 - 1650 U/L. Linearity testing for plasma was conducted using ten dilutions and admixtures of pooled plasma to generate a CK activity range from 3 - 2700 U/L. All samples were run in quadruplicate on two lots of SEKURE CK reagents and one SK500. The sample observed mean values were within ± 10% or ± 3 U/L of the sample theoretical values across all sample concentrations. The serum and plasma linearity data support the measuring range claim up to 1500 U/L for the SEKURE CK Assay.

Traceability, Stability, Expected Values (controls calibrators or methods)

*Value Assignment*

Calibration and control material are provided separately. Sekisui DC-Cal Multi-Analyte Calibrator (Cat. SE-035, Product Code JIX, 510(k) Exempt) and DC-Trol Multi-Analyte Controls (Parts SM-052 and SM-056, Product Code JJY, 510(k) Exempt) are recommended for use with the SEKURE Creatine Kinase Assay. The CK activity value assignment for DC-Cal is traceable to an IFCC reference method.

*Stability*

Product stability has been previously established as 18 months at 2-8°C. The product stability is verified by annual long-term stability testing conducted at half-expiry (9 months) and one-month past expiry (19 months).

Onboard Stability of SEKURE CK on the SK500 analyzer was demonstrated to be 30 days. Calibration stability for CK using the DC-Cal Multi-Analyte calibrator on the SK500 was determined to be 30 days.

Analytical Specificity

An interference study was performed based on the CLSI EP07-A2 guideline to assess common or known substances that could interfere with the CK Assay. Interference testing was conducted using two lots of SEKURE CK reagents. All interferents were tested according to the paired difference method with CK activity levels of 180 and 415 U/L and a minimum of seven interferent concentrations in replicates of five on each reagent lot. Testing was performed using serum only, plasma data is expected to be similar. Significant interference was identified as a percent difference greater than 10% from control.

The interference study results are summarized in the following table:

| Potential Interferent | Highest Tested Concentration at which no significant interference was observed | |
|---|---|---|
| | Conventional Units | SI Units |
| Conjugated Bilirubin | 40 mg/dL | 475 µmol/L |
| Unconjugated Bilirubin | 40 mg/dL | 684 µmol/L |
| Hemoglobin | 200 mg/dL | 31 µmol/L |
| Intralipid | 1000 mg/dL | 11.3 mmol/L |
| Ascorbic Acid | 3 mg/dL | 170 µmol/L |

**Summary of Method Comparison**

Method Comparison with Predicate Device

Method comparison testing was conducted based on CLSI EP09-A3 on using two lots of SEKURE CK reagents on one SK500 instruments and two lots of SEKURE CK reagent on the Hitachi 717 (predicate). A set of 112 serum specimens were tested in duplicate over five or more operating days. The CK activity of the samples ranged from 23 to 1413 U/L. The regression was generated using first replicate data from the candidate method and mean sample values from the predicate method and is summarized in the following table.

| Deming Regression | Lot 1 | Lot 2 |
|---|---|---|
| y Intercept (U/L) | 2.4 | 2.3 |
| Correlation Coefficient | 0.9998 | 0.9997 |
| Bias | -2.7% | -2.2% |
| Slope | 0.964 | 0.970 |

Matrix Comparison

Matrix comparison testing was conducted to evaluate the suitability of lithium heparin plasma with the SEKURE CK Assay on the SK500. A set of 75 matched serum and lithium heparin plasma specimens were assayed in duplicate using two lots of CK reagents on the SK500. The CK activity ranged from approximately 35 to 1500 U/L. The regression was generated using first replicate data from plasma and mean sample values from serum and is summarized in the following table.

| Deming Regression | Lot 1 | Lot 2 |
|---|---|---|
| Slope | 1.013 | 1.015 |
| y Intercept (U/L) | -1.8 | -3.4 |
| Correlation Coefficient | 0.9991 | 0.9991 |
| Mean Bias (%) | 0.9 | 0.7 |

Clinical studies

*(clinical sensitivity, clinical specificity, other clinical supportive data)*

Not Applicable

Expected values/Reference Range

The IFU for the SEKURE CK Assay includes the following statement on reference intervals:

Males: 46-171 U/L (37°C)

Females: 34-145 U/L (37°C)

(Rifai, N.; Horvath, A.R.; Wittwer, C., (Eds). Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, Sixth Edition. Elsevier, St. Louis, Missouri (2018), p. 409-11)

These values are suggested guidelines. It is recommended that each laboratory establish the normal range for the area in which it is located.

**Proposed Labeling**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

**Conclusion**

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