February 18, 2022

Sekisui Diagnostics P.E.I. INC.
Penny White
Senior Manager, Regulatory Affairs
70 Watts Avenue
Charlottetown, PE C1E 2B9
Canada

Re: K202644
Trade/Device Name: Acetaminophen
Regulation Number: 21 CFR 862.3030
Regulation Name: Acetaminophen Test System
Regulatory Class: Class II
Product Code: LDP
Dated: November 19, 2021
Received: November 22, 2021

Dear Penny White:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality Center for
Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k202644

Device Name
Acetaminophen

Indications for Use *(Describe)*
The Acetaminophen assay is used for the quantitative determination of acetaminophen in human serum or plasma on the ARCHITECT c Systems.

The Acetaminophen assay is to be used as an aid in the diagnosis and treatment of acetaminophen overdose toxicity.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

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: K202644

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

Applicant Name and Address: SEKISUI DIAGNOSTICS P.E.I. INC.
70 Watts Avenue, Charlottetown, PE
Canada, C1E 2B9
Establishment Registration Number: 8020316

Application correspondent: Penny White
Senior Manager, Regulatory Affairs
902-628-0934
Penny.white@sekisuidiagnostics.com

Date Summary prepared: February 8, 2022

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

Proprietary Name	Common Name	Classification Name	Classification	Product Code
Acetaminophen	Acetaminophen	Acetaminophen Test System	Class II 21 CFR 862.3030	LDP

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

Predicate Device	Predicate 510(k) Number
SEKURE Acetaminophen L3K Assay	K081938

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

Trade Name	Device Description
Acetaminophen	List 03R7420 Tests per kit 200 The Acetaminophen assay is an enzymatic, spectrophotometric assay for the measurement of acetaminophen concentration in human serum and plasma. The assay consists two working reagents, an enzyme reagent and a color reagent. The enzyme reagent contains aryl acylamidase, which cleaves the amide bond of acetaminophen, forming *p*-aminophenol which then reacts with the 2,5-dimethylphenol (contained the color reagent) in the presence of manganese. The product of that reaction causes increased absorbance at 660 nm which is directly proportional to the acetaminophen concentration in the sample. Testing is performed on the ARCHITECT c8000 clinical chemistry analyzers in conjunction with a calibrator (510(k) exempt) which is provided separately.

Assay Component	Reactive Ingredient	Concentration
Reagent 1 (2 x 8.6 mL)	Manganese (II) Chloride	0.3 mmol/L
	Aryl acylamidase	0.9 KU/L
Reagent 2 (2 x 22.3 mL)	2,5-dimethylphenol	31 mmol/L

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

The Acetaminophen assay is intended for the *in vitro* quantitative determination of acetaminophen in human serum or plasma on the ARCHITECT c System. The acetaminophen assay is to be used as an aid in the diagnosis and treatment of patients suspected of acetaminophen overdose toxicity.

For prescription use only.

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

The Acetaminophen assay is used for the quantitative determination of acetaminophen in human serum and plasma on the ACHITECT c Systems.

A comparison of the candidate assay (Acetaminophen, List number 03R7420) and the predicate assay (Acetaminophen L3K Assay Part number 506-30) is presented in the table below:

General Device Characteristic Similarities	**Predicate Device (k081938)**	**Candidate Device**
	SEKURE Acetaminophen L3K Assay	**Acetaminophen**
Analyte Measured	Acetaminophen	SAME
Intended Use	For the *in vitro* quantitative measurement of acetaminophen in serum and plasma. Measurement of acetaminophen is used in the diagnosis and treatment of acetaminophen overdose toxicity.	SAME
Methodology	Enzymatic (Aryl acylamidase) and Spectrophotometric (2,5-dimethylphenol chromophore)	SAME
Use of Calibrators	Yes	SAME
Use of Controls	Yes	SAME
General Device Characteristic Differences	**SEKURE Acetaminophen L3K Assay**	**Acetaminophen**
Specimen type	Serum and lithium heparin plasma	Serum, lithium heparin plasma and sodium heparin plasma
Platform	Hitachi 717	ARCHITECT c8000 System
Measuring interval	0.6 to 377.5 µg/mL (4 to 2500 µmol/L)	3 to 377 µg/mL (20 to 2496 µmol/L)

7. Summary of Non-Clinical Performance Data [807.92 (b)(1), 807.92 (b)(3)]

Precision

Testing was conducted according to CLSI EP05-A3 using 2 lots of the Acetaminophen reagent, two lots of the Acetaminophen Calibrator, 1 lot of commercially available controls and 1 ARCHITECT *c*8000 instrument. Three levels of controls and 5 human serum panels were assayed in a minimum of 2 replicates, twice per day on 20 days on 2 reagent lot/calibrator lot combinations, where a unique reagent lot and unique calibrator lot is paired. The performance from a representative combination is summarized in the following table.

[a]Includes within run, between run, and between-day variability.

			Within-Run		**Within-Laboratory[a]**		
Sample	**N**	**Mean (µg/mL)**	**SD**	**%CV**	**SD**	**SD 95% CI**	**%CV**
Control Level 1	120	15	0.1	0.9	0.2	(0.2, 0.2)	1.3
Control Level 2	119	73	0.5	0.6	0.6	(0.5, 0.7)	0.8
Control Level 3	120	227	0.8	0.3	1.3	(1.1, 1.6)	0.6
Panel A	120	5	0.3	5.6	0.5	(0.4, 0.6)	9.1
Panel B	120	51	0.3	0.6	0.4	(0.3, 0.5)	0.7
Panel C	120	84	0.4	0.4	0.6	(0.5, 0.7)	0.7
Panel D	120	278	1.0	0.4	2.0	(1.6, 2.5)	0.7
Panel E	120	362	1.6	0.4	2.6	(2.2, 3.2)	0.7

Reproducibility

Testing was conducted according to CLSI EP05-A3 using 1 lot of Acetaminophen reagent, a minimum of 1 lot of Acetaminophen Calibrator, 1 lot of commercially available controls, and 3 ARCHITECT instruments. Three levels of controls and 1 human serum panel were assayed in a minimum of 3 replicates at 2 separate times per day on 5 different days.

		Mean µg/mL	**Repeatability**		**Within-Laboratory[a]**		**Reproducibility[b]**	
Sample	**N**		**SD**	**%CV**	**SD**	**%CV**	**SD**	**%CV**
Control 1	146	14	0.3	1.8	0.4	3.1	0.5	3.2
Control 2	149	68	0.3	0.5	0.5	0.8	0.6	0.9
Control 3	150	208	0.8	0.4	1.3	0.6	1.6	0.8
Panel	147	163	0.6	0.4	1.0	0.6	1.2	0.7

[a] Within-Laboratory variability contains repeatability (within-run), between-run, and between-day variability.

[b] Reproducibility contains repeatability (within-run), between-run, between-day, and between-instrument variability.

Analytical Sensitivity

Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation

A study was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP17-A2.

The zero analyte samples were tested in replicates of 10. The low analyte samples were tested in replicates of 10. Testing was conducted using 2 lots of the Acetaminophen reagent on 1 instrument over a minimum of 3 days.

The LoB was 0 µg/mL (0 µmol/L), the LoD was 0.2 µg/mL (1.3 µmol/L), and the LoQ was 1.9 µg/mL (12.6 µmol/L). For results reporting purposes, the sponsor chose to use 1 ug/mL (7 µmol/L) for the LoD and 3 ug/mL (20 µmol/L) for the LoQ.

Linearity/Assay Reportable Range

Linearity was evaluated based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP06-A.

One unique sample set was prepared by combining a low and high acetaminophen sample (human serum). The 13 sample levels were tested using the Acetaminophen assay in a minimum of 2 replicates using two lots of the Acetaminophen Calibrator, 1 lot of commercially available controls and 1 instrument.

The Acetaminophen assay was demonstrated to be linear across the range of 0 to 386 µg/mL, which spans the analytical measuring interval of 3 to 377 µg/mL.

Traceability, Stability (controls, calibrators or methods)

Value Assignment

The Acetaminophen Calibrator is prepared gravimetrically from USP grade reference acetaminophen material to a concentration of 151 µg/mL (1000 µmol/L). The calibrator preparation is verified against the master calibrator (an internal reference standard). Two lots of Acetaminophen Calibrator were verified and met acceptance criteria.

Analytical Specificity (Endogenous and Exogenous Interference)

Potential interference was evaluated based on guidance from the Clinical Laboratory and Standards Institute (CLSI) document EP07-A2.

Interference effects were assessed by comparing test samples containing potentially interfering endogenous and exogeneous substances to reference samples.

Each test and reference sample were tested in a minimum of 12 replicates using 1 lot of reagent, 1 lot of calibrator and 1 lot of commercially available controls on 1 ARCHITECT c8000 System.

The following potentially interfering substances demonstrated interference within ± 7.5% for acetaminophen samples ≥ 20 µg/mL or within ± 1.50 µg/mL for acetaminophen samples < 20 µg/mL at the levels listed in the tables below:

Endogenous Substances:

Interferent	**Interferent Level**
Conjugated Bilirubin	≤ 14 mg/dL
Unconjugated Bilirubin	≤ 28 mg/dL
Hemoglobin	≤ 570 mg/dL
Intralipid	≤ 2000 mg/dL
Total Protein	≤ 10 g/dL
Triglycerides	≤ 933 mg/dL

Exogenous Substances:

Interferent	Interferent Level
Amitriptyline	≤ 0.048 mg/dL
Ampicillin	≤ 7.5 mg/dL
Benzocaine	≤ 560 mg/L
Cefoxitin	≤ 660 mg/dL
Codeine	≤ 0.141 mg/dL
Cyclosporine	≤ 0.18 mg/dL
Cysteamine	≤ 220 µmol/L
Dapsone	≤ 5.9 mg/L
Dipyrone/Metamizole	≤ 100 mg/L
2,5-Dihydroxybenzoic acid	≤ 117 µmol/L
Doxycycline	≤ 1.8 mg/dL
4-Ethoxyaniline	≤ 1.0 mmol/L
Ibuprofen	≤ 21.9 mg/dL
Imipramine	≤ 0.0315 mg/dL
L-Ascorbic Acid	≤ 170 µmol/L
L-Cysteine	≤ 18 mg/mL
Levodopa	≤ 0.75 mg/dL
L-Methionine	≤ 500 µg/mL
Methyldopa	≤ 2.25 mg/dL
Metoclopramide	≤ 1.5 µmol/L
Metronidazole	≤ 12.3 mg/dL
N-Acetylcysteine	≤ 1663 mg/L
N-Acetylprocainamide	≤ 16 µg/mL
p-Aminosalicylic acid	≤ 5.3 mmol/L
Phenacetin	≤ 14 µg/mL
Phenylbutazone	≤ 32.1 mg/dL
Procainamide	≤ 102 µmol/L
Rifampicin	≤ 80 µmol/L
Salicylic acid	≤ 4.4 mmol/L
Tetracycline	≤ 34 µmol/L
Theophylline	≤ 6.0 mg/dL

Method Comparison with Predicate Device

Method comparison testing was conducted based on CLSI EP09-A3 on 1 ARCHITECT c8000 analyzer using two lots of the Acetaminophen assay and two lots of Acetaminophen Calibrator and two lots of the predicate device Acetaminophen L3K reagent on 1 Hitachi 717 analyzer. Testing was completed on 119 patient specimens in duplicate over five operating days. Of the 119 samples, 114 were unaltered native samples and 5 (4% of the total) were contrived.

Method Comparison Representative Results:

Acetaminophen 3R74 on ARCHITECT c System vs Acetaminophen L3K 506 on Hitachi					
506-30 on Hitachi Sample Range (µg/mL)	3R74 on ARCHITECT Sample Range (µg/mL)	N	Slope	Intercept	Correlation Coefficient
3.50 – 356.26	3.58 – 375.28	119	1.042	-0.034	0.9993

Matrix Comparison

A matrix comparison study was performed to assess the Acetaminophen assay using serum and plasma. The study was performed using one lot of reagent and one lot of calibrator on one ARCHITECT c8000 instrument. The acetaminophen concentrations spanned the assay range. A set of seventy-eight matched specimen sets were collected and tested.

The following tube types were compared to serum tubes (without gel in plastic) and recovered within the stated acceptance criteria of within ± 7.5% for values ≥ 20 µg/mL or ± 1.50 µg/mL for values < 20 µg/mL and are, therefore, suitable specimens for analysis:

Serum
Lithium heparin
Lithium heparin mechanical separator
Lithium heparin (separator tube)
Serum (separator tube)
Sodium heparin

Automated and Manual Dilution

A study was performed to assess the ability of the Acetaminophen assay to accurately measure samples having concentrations above the analytical measuring interval after they have been automatically diluted or manually diluted.

This study was performed based on guidance from the Clinical and Laboratory Standards Institute (CLSI) document EP34, 1st ed. Five samples with Acetaminophen concentrations within the range of 450 µg/mL to 3,000 µg/mL tested. All dilutions were performed at a 1:10 dilution. Manual dilutions were performed using 0.9% (NaCl). The samples were tested in replicates of 42 for precision and dilution recovery testing using 1 lot of reagent, 1 lot of reagent, 1 lot of calibrator and 1 lot of commercially available controls on 1 ARCHITECT c8000 System.

The Acetaminophen assay demonstrated % difference results of 1.5% to 5.3% when measuring samples having concentrations above the analytical measuring interval by 1:10 autodilution vs manual dilution method.

Clinical studies

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

Not Applicable

Expected values/Reference Range

The package insert contains the following reference ranges cited from literature. (Burtis CA, Ashwood ER, Bruns DE, editors. *Tietz Textbook of Clinical Chemistry and Molecular Diagnostics.* 5th ed. St. Louis, MO:Elsevier; 2012:2176 and Rowden AK, Norvell J, Eldridge DL,et al. Acetaminophen poisoning. *Clin Lab Med* 2006;26(1):49-65.)

Therapeutic concentration: 10-30 µg/mL (66-199 µmol/L)

Toxic concentration:

4 hours > 150 µg/mL (> 993 µmol/L)

24 hours > 4.7 µg/mL (> 31 µmol/L)

These values are suggested guidelines. It is recommended that each laboratory establish its own expected range.

8. Conclusion

The results presented in these 510(k) premarket notifications demonstrate that the candidate assay (Acetaminophen, List No. 03R74) performance is substantially equivalent to the predicate assay (SEKURE Acetaminophen L3K, List No. 506-30).

The similarities and differences between the candidate assay and the predicate assay are presented in the table 5.6. The results presented in this 510(k) provide reasonable assurance that the Acetaminophen assay is safe and effective for the stated intended use. Any differences between the candidate assay and the predicate assay shown in the tables do not affect the safety and effectiveness of the candidate assay.

There is no known potential adverse effect to the operator when using this device according to the Acetaminophen package insert instructions.