DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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SEKISUI DIAGNOSTICS P.E.I. INC.
PENNY WHITE
REGULATORY AFFAIRS MANAGER
70 WATTS AVENUE
CHARLOTTETOWN C1E 2B9
CA

December 8, 2016

Re: K163078
Trade/Device Name: DC-UIBC-CAL Calibrator
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: II
Product Code: JIT
Dated: October 31, 2016
Received: November 8, 2016

Dear Ms. 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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k163078

Device Name
DC-UIBC-CAL

Indications for Use *(Describe)*

For IN VITRO diagnostic use as a calibrator in clinical chemistry assays for UIBC (Unsaturated Iron Binding Capacity). DC-UIBC-CAL may be used to check the linearity over the reportable patient range of UIBC assays.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary Safety and Effectiveness for the
DC-UIBC-CAL

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

1. **510(k) Number:** **K163078**

2. **Applicant Name and Address**

Contact Person:	Penny White Regulatory Affairs Manager
Company Name:	Sekisui Diagnostics P.E.I. Inc.
Address:	70 Watts Avenue Charlottetown, PE, C1E 2B9 Canada
Telephone:	902-628-0934 902-628-6504 (FAX)

3. **Date:** 2016-12-06

4. **Proprietary and Established Names**
   DC-UIBC-CAL

5. **Regulatory Information:**
   Regulation section: 21 CFR 862.1150, Calibrator, Secondary
   Classification: Class II
   Product Code: JIT
   Panel: Clinical Chemistry

6. **Purpose of the 510(k) submission**
   The DC-UIBC-CAL is being modified from a bovine and human serum matrix to strictly a human serum matrix.

7. **Predicate Device**
   Device Name: DC-UIBC- Cal, SE-090
   510(k) Number: K925877
   Manufacturer: Sekisui Diagnostics PEI Inc.

8. **Intended Use:**
   For IN VITRO diagnostic use as a calibrator in clinical chemistry assays for UIBC (Unsaturated Iron Binding Capacity). DC-UIBC-CAL may be used to check the linearity over the reportable patient range of UIBC assays.

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9. Indications for Use:

The DC-UIBC-CAL, used in conjunction with UIBC reagents, is intended for use in automated analyzers for the calibration of UIBC (Unsaturated Iron Binding Capacity). DC-UIBC-CAL may be used to check the linearity over the reportable patient range of UIBC assays.

10. Device Description

DC-UIBC-CAL is a human based, lyophilized serum intended for use as a calibrator with Sekisui Diagnostics UIBC Assays. The concentrations and activities of the UIBC (Unsaturated Iron Binding Capacity) is optimized for the calibration of clinical chemistry systems - Beckman Coulter AU® Systems, Roche/Hitachi®, Beckman Coulter SYNCHRON® Systems, and Cobas Mira®.

The DC-UIBC-CAL kit consists of the following:
Six vials with 10mL of lyophilized serum.
Human serum was used in the manufacture of this product. The human serum in this product has been prepared exclusively from the blood of donors tested individually and shown by FDA-approved methods to be free from HBsAg and antibodies to HCV and HIV. However, as no test method can rule out the potential risk of infection with absolute certainty, the material should be treated just as carefully as a patient sample. In the event of exposure, the directives of the responsible Health Authorities should be followed.

11. Test Principle

DC-UIBC-CAL is a human based, lyophilized serum intended for use as a calibrator with Sekisui Diagnostics UIBC methodologies. The concentrations and activities of the analyte UIBC is optimized for the calibration of clinical chemistry systems.

12. Substantial Equivalence Information

Predicate device name: DC-DC-UIBC-CAL, SE-090
Predicate number: K925877
Comparison with Predicate:

Similarities		
Characteristics	**DC-UIBC-CALSE-090**	**Predicate DC-UIBC-CAL SE-090**
Features	DC-UIBC-CALSE-090 Calibrator. Human Based Lyophilized serum	Same
Intended Use	For IN VITRO diagnostic use as a calibrator in clinical chemistry assays for UIBC (Unsaturated Iron Binding Capacity). DC-UIBC-CAL may be used to check the linearity over the reportable patient range of UIBC assays.	Same
Packaging Calibrator Diluent	6 x 10ml	Same
Format	Lyophilized	Same
Levels	1 Level	Same
Storage	2-8°C until expiration date	Same
Reconstituted Stability at 2-8°C	14 days	Same
Analytes	UIBC (Unsaturated Iron Binding Capacity).	Same
Traceability	The assigned values for the constituents are traceable to reference materials from NIST	Same

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Differences		
Characteristic	**DC-UIBC-CALSE-090**	**Predicate DC-UIBC-CAL SE-090**
Matrix	Calibrator is prepared from human serum and diluted with deionized water.	Calibrator is prepared from bovine and human serum and diluted with deionized water.

13. Standard/Guidance Document Reference

The following recognized standard and guidance documents were used:

- Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators
- ISO 17511:2003 - In vitro diagnostic medical devices -- Measurement of quantities in biological samples -- Metrological traceability of values assigned to calibrators and control materials
- CLSI EP25-A: Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline

14. Performance Characteristics

The following studies are not applicable for the purpose if this submission as outlined in Guidance for Industry – Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators

- *Precision/Reproducibility*
- *Linear/Assay Reportable Range*
- *Detection Limit*
- *Method and Matrix Comparison Studies*
- *Analytical Specificity*
- *Assay cut-off*
- *Expected Values/Reference Intervals*

Stability

Accelerated stability studies for shelf life and open vial claims have been conducted and acceptance criteria were met. The DC-UIBC-CAL is to be stored at 2-8 °C for 36 months or until the expiration date printed on each carton. Real time stability studies for shelf life are on-going. The final shelf life claims will be based on the completed real time study results. Reconstituted product is stable at 2-8 °C for 14 days. The reconstituted calibrator should be brought to room temperature (18-26 °C) before assaying.

Traceability and Value Assignment

Sekisui verifies that the Unsaturated Iron Binding Capacity is within the acceptable target range using the Sekisui protocol. DC-UIBC-CAL value assignments are completed using two reagent lots on instruments listed in the product insert. The Unsaturated Iron Binding Capacity in this calibrator is traceable using ISO 17511 to the reference material below:

Constituent	Material Reference
UIBC	NIST SRM 937

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Refer to the below table for representative target concentration for the UIBC in DC-UIBC- CAL kit.

UIBC-SL Reagent 153-10/30/50/90		
Instrument	**(µg/dL)**	**Target Range (µg/dL)**
Beckman Coulter AU Systems	238	208 – 312
Beckman Coulter SYNCHRON Systems	236	
Roche/Hitachi	237	
Cobas Mira	235	

15. Conclusion

The information presented in the premarket notification demonstrates that the performance of the Sekisui Diagnostics modified DC-UIBC-CAL is substantially equivalent to the cleared predicate device.

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