November 23, 2021

Abbott Ireland Diagnostics Division
Suzanne Cheang
Regulatory Affairs Manager
Lisnamuck
Longford, Ireland

Re: K203248
Trade/Device Name: Albumin BCG2
Regulation Number: 21 CFR 862.1035
Regulation Name: Albumin Test System
Regulatory Class: Class II
Product Code: CIX
Dated: August 30, 2021
Received: August 31, 2021

Dear Suzanne Cheang:

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)*
K203248

Device Name
Albumin BCG2

Indications for Use *(Describe)*
The Albumin BCG2 assay is used for the quantitation of albumin in human serum or plasma on the ARCHITECT c System.

The Albumin BCG2 assay is to be used as an aid in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

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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Section 5: 510(k) Summary (Summary of Safety and Effectiveness)

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. 510(k) Number

k203248

II. Applicant Name

Abbott Ireland Diagnostics Division
Lisnamuck, Longford
Longford, IE

Primary contact person for all communications:

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Date Summary Prepared: November 15, 2021

III. Device Name

Albumin BCG2

Reagents

Trade Name: Albumin BCG2
Device Classification: Class II
Classification Name: Albumin test system
Governing Regulation Number: 21 CFR 862.1035
Product Code: CIX

IV. Predicate Device

Albumin BCG (k981758)

V. Description of Device

A. Principles of the Procedure

The Albumin BCG2 assay is an automated clinical chemistry assay. The Albumin BCG2 procedure is based on the binding of bromocresol green in the assay reagent specifically with albumin in the patient sample to produce a colored complex. The absorbance of the complex at 604 nm is directly proportional to the albumin concentration in the sample.

Methodology: Colorimetric (Bromocresol Green)

B. Reagents

The configurations of the Albumin BCG2 reagent kit are described below.

	List Number	
	04T3420	**04T3430**
Tests per cartridge	261	1000
Number of cartridges per kit	4	4
Tests per kit	1044	4000
Reagent 1 (R1)	25.5 mL	86.0 mL

Reagent 1 Active ingredient: bromocresol green 0.320 g/L. Inactive ingredients: Sodium hydroxide/succinic acid buffer (pH 4.2) and detergents/surfactants (1.6%). Preservative: ProClin 300.

VI. Intended Use of the Device

The Albumin BCG2 assay is used for the quantitation of albumin in human serum or plasma on the ARCHITECT c System.

The Albumin BCG2 assay is to be used as an aid in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

VII. Comparison of Technological Characteristics

The Albumin BCG2 assay (subject device) is an automated clinical chemistry assay for the quantitation of albumin in human serum or plasma on the ARCHITECT c System.

The similarities and differences between the subject device and the predicate device are presented in the following table.

Comparison of Subject Device Albumin BCG2 to Predicate Device Albumin BCG

Characteristics	Subject Device Albumin BCG2 (List No. 04T34)	Predicate Device Albumin BCG (k981758; List No. 7D53)
Platform	ARCHITECT c System	Same[a]
Intended Use and Indications for Use	The Albumin BCG2 assay is used for the quantitation of albumin in human serum or plasma on the ARCHITECT c System. The Albumin BCG2 assay is to be used as an aid in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.	The Albumin BCG assay is used for the quantitation of albumin in human serum or plasma.
Methodology	Colorimetric (Bromocresol Green)	Same
Specimen Type	Human serum or plasma	Same
Assay Principle / Principle of Procedure	The Albumin BCG2 procedure is based on the binding of bromocresol green in the assay reagent specifically with albumin in the patient sample to produce a colored complex. The absorbance of the complex at 604 nm is directly proportional to the albumin concentration in the sample.	The Albumin BCG procedure is based on the binding of bromocresol green specifically with albumin to produce a colored complex. The absorbance of the complex at 628 nm is directly proportional to the albumin concentration in the sample.
Standardization	ERM-DA470/IFCC	Same
Use of Calibrators	Yes	Same
Use of Controls	Yes	Same

[a] In accordance with FDA Guidance Document "Data for Commercialization of Original Equipment Manufacturer, Secondary and Generic Reagent for Automated Analyzers", issued June 10, 1996, the assay equivalency study on ARCHITECT c System vs. the original platform, AEROSET, was performed and submitted under K980367/A004 in May 2002.

ERM = European Reference Materials Standard Reference Material

IFCC - International Federation of Clinical Chemistry and Laboratory Medicine

Comparison of Subject Device Albumin BCG2 to Predicate Device Albumin BCG (Continued)

Characteristics	**Subject Device Albumin BCG2 (List No. 04T34)**	**Predicate Device Albumin BCG (k981758; List No. 7D53)**
Assay Range	Analytical Measuring Interval: 0.3 – 9.4 g/dL Reportable Interval: 0.3 – 9.4 g/dL	Measuring Interval: 0.4 – 10.5 g/dL
Precision	Samples with albumin concentrations between 0.4 g/dL and 9.4 g/dL demonstrated standard deviations ranging from 0.00 g/dL to 0.07 g/dL and % Coefficient of Variation (%CV) values ranging from 0.0% to 1.9%.	Samples with albumin concentrations between 2.7 g/dL and 4.1 g/dL demonstrated %CV values ranging from 1.4% to 1.5%
Lower Limits of Measurement	Limit of Blank: 0.0 g/dL Limit of Detection: 0.3 g/dL Limit of Quantitation: 0.3 g/dL	Limit of Detection: 0.3 g/dL Limit of Quantitation: 0.31 g/dL
Tube Types	Serum: - Serum tubes - Serum separator tubes Plasma: - Dipotassium EDTA tubes - Lithium heparin tubes - Lithium heparin separator tubes - Sodium heparin tubes	Serum: - Glass or plastic tubes with or without gel barrier Plasma: - Glass or plastic lithium heparin tubes (with or without gel barrier) - Glass or plastic sodium heparin tubes

VIII. Summary of Nonclinical Performance

A. Reportable Interval

Based on the limit of detection (LoD), limit of quantitation (LoQ), precision, and linearity, the ranges over which results can be reported are provided below according to the definitions from Clinical and Laboratory Standards Institute (CLSI) EP34, 1st ed.*

	g/dL
Analytical Measuring Interval (AMI)[a]	0.3 – 9.4
Reportable Interval[b]	0.3 – 9.4

[a] AMI: The AMI extends from the LoQ to the upper limit of quantitation (ULoQ). This is determined by the range of values in g/dL that demonstrated acceptable performance for linearity, imprecision, and bias.

[b] The reportable interval extends from the LoD to the upper limit of the AMI.

NOTE: The default Low Linearity value of the assay file corresponds to the lower limit of the Analytical Measuring Interval (AMI).

* Clinical and Laboratory Standards Institute (CLSI). *Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking.* 1st ed. CLSI Document EP34. Wayne, PA: CLSI; 2018.

B. Within-Laboratory Precision

A study was performed based on guidance from CLSI EP05-A3.* Testing was conducted using 3 lots of the Albumin BCG2 reagent, 3 lots of the Consolidated Chemistry Calibrator, 1 lot of commercially available controls, and 3 instruments. Two controls and 3 human serum panels were tested in duplicate, twice per day on 20 days on 3 reagent lot/calibrator lot/instrument combinations, where a unique reagent lot and a unique calibrator lot is paired with 1 instrument. The performance from a representative combination is shown in the following table.

			Within-Run (Repeatability)		Within-Laboratory[a]	
Sample	**n**	**Mean (g/dL)**	**SD**	**%CV**	**SD (Range[b])**	**%CV (Range[b])**
Control Level 1	80	4.1	0.05	1.2	0.06 (0.05 – 0.06)	1.5 (1.3 – 1.6)
Control Level 2	80	2.6	0.03	1.3	0.04 (0.04 – 0.05)	1.4 (1.4 – 1.9)
Panel 1	80	0.4	0.00	0.0	0.00 (0.00 - 0.00)	0.0 (0.0 – 0.0)
Panel 2	80	5.7	0.06	1.0	0.06 (0.05 – 0.06)	1.0 (0.9 – 1.0)
Panel 3	80	9.4	0.07	0.8	0.07 (0.06 – 0.07)	0.8 (0.7 – 0.8)

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

[b] Minimum and maximum SD or %CV across all reagent lot and instrument combinations.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition*. CLSI Document EP05-A3. Wayne, PA: CLSI; 2014.

C. Accuracy

A study was performed to estimate the bias of the Albumin BCG2 assay relative to a standard reference material European Reference Materials Standard Reference Material - DA470k/ International Federation of Clinical Chemistry and Laboratory Medicine [ERM - DA470k/IFCC]). Testing was conducted using 2 lots of the Albumin BCG2 reagent, 2 lots of the Consolidated Chemistry Calibrator, and 1 instrument. The bias was within ± 2.4%.

D. Lower Limits of Measurement

A study was performed based on guidance from CLSI EP17-A2.* Testing was conducted using 3 lots of the Albumin BCG2 reagent kit on each of 2 instruments over a minimum of 3 days. The maximum observed limit of blank (LoB), limit of detection (LoD), and limit of quantitation (LoQ) values are summarized below.

	g/dL
LoB[a]	0.0
LoD[b]	0.3
LoQ[c]	0.3

[a] The LoB represents the 95th percentile from n ≥ 60 replicates of zero-analyte samples.

[b] The LoD represents the lowest concentration at which the analyte can be detected with 95% probability based on n ≥ 60 replicates of low-analyte level samples.

[c] The LoQ is defined as the lowest concentration at which a maximum allowable precision of 20% CV was met and was determined from n ≥ 60 replicates of low-analyte level samples.

E. Linearity

A study was performed based on guidance from CLSI EP06-A.† The assay was demonstrated to be linear across the analytical measuring interval of 0.3 to 9.4 g/dL.

* Clinical and Laboratory Standards Institute (CLSI). *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition*. CLSI Document EP17-A2. Wayne, PA: CLSI; 2012.

† Clinical and Laboratory Standards Institute (CLSI). *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline*. CLSI Document EP06-A. Wayne, PA: CLSI; 2003.

F. Potentially Interfering Endogenous and Exogenous Substances

A study was performed based on guidance from CLSI EP07-A2.* Each substance was tested at 2 levels of the analyte (approximately 3.5 g/dL and 5.0 g/dL).

Potentially Interfering Endogenous Substances

No significant interference (interference within ± 10%, based on 95% confidence intervals) was observed at the following concentrations.

Potentially Interfering Substance	Interferent Level
Conjugated Bilirubin	60 mg/dL
Unconjugated Bilirubin	60 mg/dL
Hemoglobin	750 mg/dL
Triglycerides	3000 mg/dL

* Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition.* CLSI Document EP07-A2. Wayne, PA: CLSI; 2005.

Potentially Interfering Exogenous Substances

No significant interference (interference within ± 10%, based on 95% confidence intervals) was observed at the following concentrations.

Potentially Interfering Substance	**Interferent Level**
Acetaminophen	250 mg/L
Acetylcysteine	1663 mg/L
Acetylsalicylic Acid	1000 mg/L
Aminosalicylic Acid	80 mg/dL
Ampicillin-Na	1000 mg/L
Ascorbic Acid	300 mg/L
Calcium Dobesilate	200 mg/L
Cefotaxime	31 mg/dL
Cefoxitin	2500 mg/L
Cyclosporine	5 mg/L
Desacetylcefotaxime	6 mg/dL
Doxycycline	50 mg/L
Ibuprofen	500 mg/L
Levodopa	20 mg/L
Methyldopa	20 mg/L
Metronidazole	200 mg/L
Penicillin	18,000 mg/L
Phenylbutazone	400 mg/L
Rifampicin	60 mg/L
Sodium Heparin	10 U/mL
Theophylline (1,3-dimethylxanthine)	100 mg/L

G. Method Comparison

A study was performed based on guidance from CLSI EP09-A3* using the Passing-Bablok regression method. The study compared the Albumin BCG2 assay to the Albumin BCG assay (List Number 7D53).

Albumin BCG2 vs Albumin BCG on the ARCHITECT c System

	n	Units	Correlation Coefficient	Intercept	Slope	Concentration Range
Serum	128	g/dL	1.00	0.03	1.03	0.4 – 8.1

* Clinical and Laboratory Standards Institute (CLSI). *Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition*. CLSI Document EP09-A3. Wayne, PA: CLSI; 2013.

H. Tube Type

A study was performed to evaluate the suitability of specific blood collection tube types for use with the Albumin BCG2 assay. Samples were collected from a minimum of 40 donors and evaluated across tube types. The following blood collection tube types were determined to be acceptable for use with the Albumin BCG2 assay:

- Serum tubes
- Serum separator tubes
- Dipotassium EDTA tubes
- Lithium heparin tubes
- Lithium heparin separator tubes
- Sodium heparin tubes

IX. Summary of Clinical Performance

This section does not apply.

X. Conclusion Drawn from Nonclinical Laboratory Studies

The results presented in this 510(k) premarket notification demonstrate that the performance of the subject device, Albumin BCG2 (List No. 04T34), is substantially equivalent to the predicate device, Albumin BCG (List No. 7D53, k981758).

The similarities and differences between the subject device and predicate device are presented in Section 5-VII.

There is no known potential adverse effect to the operator when using this *in vitro* device according to the Albumin BCG2 reagent package insert instructions.