June 7, 2019

Ortho-Clinical Diagnostics, Inc.
Darlene Phillips
Manager, Regulatory Affairs
100 Indigo Creek Drive
Rochester, NY 14626

Re: K191316
Trade/Device Name: VITROS XT Chemistry Products ALB-TP Slides
Regulation Number: 21 CFR 862.1035
Regulation Name: Albumin test system
Regulatory Class: Class II
Product Code: CIX
Dated: May 14, 2019
Received: May 15, 2019

Dear Darlene Phillips:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k191316

Device Name
VITROS XT Chemistry Products ALB-TP Slides

Indications for Use *(Describe)*
Rx Only

For in vitro diagnostic use only

The ALB test within the VITROS XT Chemistry Products ALB-TP Slides quantitatively measures albumin (ALB) concentration in serum and plasma using the VITROS XT 7600 Integrated System. Albumin measurements are used 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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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
The assigned 510(k) number is**:** **k191316**

Submitter's Information

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
Phone: (585) 453-4253
Fax: (585) 453-3113

Contact Person:

Darlene J Phillips, RAC
Manager, Regulatory Affairs

Date of Preparation: May 14, 2019
Revised: May 30, 2019

Device Proprietary Name(s):

VITROS XT Chemistry Products ALB-TP Slides

Common Names:

Albumin assay

Classification Names

Test	Product Code	Class	Regulation Section	Panel
ALB	CIX	Class II	21 CFR 862.1035 Albumin test system	Clinical Chemistry (75)

Predicate Device(s)

Predicate Devices	FDA 510(k) Number
VITROS Chemistry Products ALB Slides	k023875

Intended Use Statement(s)

VITROS XT Chemistry Products ALB-TP Slides

Rx Only For *in vitro* diagnostic use only

The ALB test within the VITROS XT Chemistry Products ALB-TP Slides quantitatively measures albumin (ALB) concentration in serum and plasma using the VITROS XT 7600 Integrated System. Albumin measurements are used in the diagnosis and treatment of numerous diseases involving primarily the liver or kidneys.

Device Description

The new device, the VITROS XT Chemistry Products ALB-TP Slides is a single device that contains both an albumin test and a total protein test side by side separated by a plastic barrier sealed within a single slide frame. In this format, individual reactions occur and test results are generated for each analyte independently of the other analyte.

The ALB test is a multilayered, analytical element coated on a polyester support.

For the albumin measurement, a drop of patient sample is deposited on the slide and is evenly distributed by the spreading layer to the underlying layers. When the fluid penetrates the reagent layer, the bromcresol green (BCG) dye diffuses to the spreading layer and binds to albumin in the sample. This binding results in a shift in wavelength of the reflectance maximum of the free dye. The color complex that forms is measured by reflectance spectrophotometry. The amount of albumin-bound dye is proportional to the concentration of albumin in the sample.

Comparison to Predicate Devices

The following tables show similarities and differences between the new and predicate devices.

Summary of the technological characteristics of the device compared to the predicate device		
Device Characteristic	**New Device VITROS XT ALB-TP Slide [k191316] (New)**	**Predícate Device VITROS ALB Slide [k023875] (Current)**
Intended Use	No change For *in vitro* diagnostic use only. The ALB test within the VITROS XT ALB-TP Chemistry Products Slides measures albumin (ALB) concentration in serum and plasma.	For *in vitro* diagnostic use only. VITROS Chemistry Products ALB Slides quantitatively measure albumin (ALB) concentration in serum and plasma.
Device Description	No Change	Multilayered, analytical element coated on a polyester support
Basic Principle	No Change	Colorimetric

Summary of the technological characteristics of the device compared to the predicate device		
Device Characteristic	**New Device VITROS XT ALB-TP Slide [k191316] (New)**	**Predicate Device VITROS ALB Slide [k023875] (Current)**
Incubation time and temperature	No Change	Approximately 2.5 minutes 37°C (98.6° F)
Sample type	No Change	Serum and plasma
Amount of Slide Reactive Ingredients per cm^2 (test)	No Change The composition of the analytical element of each test within the VITROS XT Slide will remain the same as that used in each predicate device	Bromcresol green dye 104 µg.
Assay Range	No Change	1.0 – 6.0 g/dL
Calibrators	No Change	VITROS Chemistry Products Calibrator Kit 4
Controls	No Change	VITROS Chemistry Products Performance Verifier I and II
Differences		
Instrumentation	VITROS XT 7600 Integrated System	VITROS 250/350, 5,1 FS and 4600 Chemistry Systems VITROS 5600 and XT 7600 Integrated Systems
Sample volume	4.2 µL	5.5 µL

Non-Clinical Testing Analytical Performance

Method Comparison

Method Comparison testing followed CLSI Protocol EP09-A3, *Measurement Procedure Comparison and Bias Estimation Using Patient Samples.* Serum samples were evaluated on the VITROS XT Chemistry Products ALB-TP Slides using the VITROS XT 7600 Integrated System and on VITROS Chemistry Products ALB Slides using the VITROS 5600 Integrated System. The correlation between the predicate and the ALB test within the VITROS XT ALB-TP Slides on the VITROS XT 7600 Integrated System is summarized below.

Ordinary Deming regression was performed to determine the correlation for the ALB test within the VITROS XT ALB-TP Slides.

Summary of Method Comparison Regression Analysis Data						
Test	**N**	**Slope**	**Intercept**	**Corr. Coeff.**	**Test Range**	**Measuring range**
ALB (g/dL)	127	1.00	-0.03	0.999	1.0 – 5.9	1.0 – 6.0

Matrix comparison:

To demonstrate equivalence between serum and plasma samples, serum (glass red top, plastic red top and SST) and plasma (Na-heparin, Li-heparin, and PST) specimen collection tubes were evaluated to verify acceptable performance.

All collection devices were compared to the red top plastic serum tube using Weighted Deming regression. The regression assessments use the mean of the red top plastic serum tube (two replicates) versus the replicates of the feature tube (two replicates).

Sample Type	Slope	Intercept
Na Hep vs. Serum Plastic	0.96	0.098
Li Hep vs. Serum Plastic	0.96	0.088
PST vs. Serum Plastic	0.95	0.107
SST vs. Serum Plastic	0.99	0.033
Serum Glass vs. Serum Plastic	1.00	- 0.007

Precision

Precision was evaluated with patient pools and quality control materials following CLSI Protocol EP05-A3, *Evaluation of Precision Performance of Quantitative Methods; Approved Guideline—Third Edition*, using the VITROS XT Chemistry Products ALB-TP Slides on the VITROS XT 7600 Integrated System. The test included 80 observations (2 replicates per run, 2 runs per day over 20 days) using three lots of VITROS XT ALB-TP Slides. The ALB test long term precision analysis for a representative lot is summarized below.

The data presented are a representation of test performance and are provided as a guideline. Variables such as sample handling and storage, reagent handling and storage, laboratory environment, and system maintenance can affect reproducibility of test results.

Conventional Units (g/dL Albumin)							No. of Obs.	No. of Days
Mean Concentration	Repeatability		Within Day		Within Lab			
	SD*	%CV	SD**	%CV	SD***	%CV		
1.6	0.02	1.2	0.02	1.2	0.02	1.4	80	20
2.7	0.02	0.9	0.02	0.9	0.03	1.2	80	20
3.4	0.03	0.8	0.03	0.9	0.04	1.1	80	20
4.1	0.04	1.0	0.04	1.0	0.05	1.3	80	20
4.4	0.03	0.7	0.03	0.8	0.04	0.9	80	20
5.2	0.05	0.9	0.05	1.1	0.06	1.2	80	20

*Repeatability (formerly called within-run precision) was determined using two replicates per run.

**Within Day precision was determined using two runs per day with two replicates per run

***Within Lab precision was determined using a single lot of slides and a single calibration

Detection Limits

Detection capability studies for the ALB test within the VITROS XT ALB-TP Slides were evaluated according to CLSI EP17-A2: *Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures.*

LoQ determination was set on pre-defined Total Error (TE) goals based on the Westgard model. The Total Error goal used to accept the LoQ was ≤ 0.2 g/dL.

The results of this analysis are summarized below:

	ALB (g/dL)
LOB	0.24
LOD	0.27
LOQ	0.60
Claimed LOQ	1.0

Linearity

Linearity studies were performed according to CLSI EP06-A, *Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach Approved Guideline (2003).* VITROS XT ALB-TP Slides were tested on the VITROS XT 7600 Integrated System. A series of seventeen proportionally related admixtures of low and high test fluids were tested to verify linearity of the ALB test; each sample was tested in quadruplicate. The linearity study supports the claimed measuring range for the ALB test within the VITROS XT ALB-TP Slides.

Assay	**Measuring Range**	**Linear Range**
ALB	1.0 – 6.0 g/dL	0.5 – 7.1 g/dL

A least squares regression was performed on the data collected, y = 1.01x-0.19 with R^2 = 1.00.

Serum and plasma samples with values greater than the ALB test measuring range may be diluted with 10 parts sample and 1 part diluent. Reagent-grade water and isotonic saline are acceptable diluents for the ALB test within the VITROS XT Chemistry Products ALB-TP Slides.

Expected Values

The expected values of the ALB test within the VITROS XT ALB-TP Slides are not changed from that of the predicate assay. Each laboratory should confirm the validity of these intervals for the population it serves.

ALB Reference Interval [†]

ALB Test Expected Values
3.5–5.0 g/dL

Each laboratory should confirm the validity of these intervals for the population it serves.

[†] Peters T. *All about Albumin* San Diego: Academic Press; 256; 1996.

Specificity

The ALB test within the VITROS XT Chemistry Products ALB-TP Slide was screened for interfering substances following CLSI document EP07-A3, Interference Testing in Clinical

Chemistry. The supplemental tables in CLSI document EP37 were referenced for recommended testing concentrations for analytes and endogenous substances that may interfere in clinical chemistry measurement procedures.

Point estimates of the effects of potential interferents on the ALB test within the VITROS XT ALB-TP Slides were made using the paired difference method. Dose-response analysis was conducted to characterize the degree of interference for each substance that exceeded the acceptance criterion in the initial screening test, and expected bias was reported at the lowest test level which did not meet acceptance criteria for bias as shown in the product claims.

Two (2) substances were found to interfere with the ALB test in VITROS XT Chemistry Products ALB-TP Slides. The substances listed in the table, when tested at the concentrations indicated, caused the bias shown. The bias is an estimate of the maximum bias observed.

It is possible that other interfering substances may be encountered. These results are representative; however, your results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed might not be predictable.

Known Interferences ALB test			
Interferent	**Interferent Concentration (Conv. Units)**	**Albumin Concentration (g/dL)**	**Bias* (g/dL)**
Dextran 40	6 g/dL	3.8	-0.38
	4 g/dL	4.8	-0.58
Hemoglobin	300 mg/dL	3.8	0.32
	200 mg/dL	4.6	0.37

* The bias is an estimate of the maximum bias observed

Forty-seven (47) test substances, when tested at the concentrations indicated, were found not to interfere with the ALB test within VITROS XT ALB-TP Slides, bias < 0.24 g/dL at approximately 3.6 g/dL albumin and bias < 0.30 g/dL at approximately 4.5 g/dL albumin.

Other Limitations

Certain drugs and clinical conditions are known to alter albumin concentrations in vivo. For additional information, refer to the published summaries.

Young DS. *Effects of Drugs on Clinical Laboratory Tests*. ed. 4. Washington D.C.: AACC Press; 1995.

Friedman RB. Young DS. *Effects of Disease on Clinical Laboratory Tests*. Washington, D.C.: AACC Press; 1990.

Conclusion

The conclusions drawn from the nonclinical tests (discussed above) demonstrate the ALB test within the VITROS XT Chemistry Products ALB-TP Slides for use on the VITROS XT 7600 Integrated System is as safe, effective, and performs as well as the predicate device. The information submitted in the premarket notification is complete and supports a substantial equivalence decision.