



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002  
September 18, 2017

ORTHO CLINICAL DIAGNOSTICS  
DARLENE PHILLIPS  
MANAGER REGULATORY AFFAIRS  
100 INDIGO CREEK DRIVE  
ROCHESTER NY 14626

Re: K163433  
Trade/Device Name: VITROS Chemistry Products GLU Slides  
Regulation Number: 21 CFR 862.1345  
Regulation Name: Glucose test system  
Regulatory Class: II  
Product Code: CGA  
Dated: August 15, 2017  
Received: August 16, 2017

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. 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,

  
**Kellie B. Kelm -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

## Indications for Use

510(k) Number (if known)

k163433

Device Name

VITROS Chemistry Products GLU Slides

Indications for Use (Describe)

For in vitro diagnostic use only. VITROS Chemistry Products GLU Slides are used on VITROS Systems to quantitatively measure glucose (GLU) concentration in serum, plasma, urine and cerebrospinal fluid.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

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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## 1. 510(k) Summary

### Submitter Information

|                                         |                                                     |
|-----------------------------------------|-----------------------------------------------------|
| Name                                    | Ortho-Clinical Diagnostics, Inc.                    |
| Address                                 | 100 Indigo Creek Drive<br>Rochester, New York 14626 |
| Phone number                            | (585) 453-4253                                      |
| Fax number                              | (585) 453-3368                                      |
| Establishment<br>Registration<br>Number | 1319809                                             |
| Name of<br>contact person               | Darlene J Phillips                                  |
| Date prepared                           | September 18, 2017                                  |

### Name of devices

|                            |                                      |
|----------------------------|--------------------------------------|
| Trade or proprietary names | VITROS Chemistry Products GLU Slides |
| Common or usual name       | VITROS GLU Slides assay              |
| Common or usual name       | Glucose oxidase, glucose             |
| Classification name        | Glucose test system                  |
| Classification panel       | Clinical Chemistry                   |
| Regulation                 | 21 CFR 862.1345                      |
| Product Code               | CGA                                  |

### Legally marketed device(s) to which equivalence is claimed

The VITROS® Chemistry Products GLU Slides (modified) are substantially equivalent to the VITROS® Chemistry Products GLU Slides (current). The FDA cleared the VITROS® Chemistry Products GLU Slides on May 17, 1996 (k955286).

### Reason for 510(k) submission

The device modification is a proportional reduction in the amount of reagent used to manufacture each VITROS GLU Slide (or test). Each modified VITROS GLU Slide will have approximately 30% less ingredients compared to the current VITROS GLU Slide as a result of a smaller surface area. Since the reduction in ingredients per slide is due to a smaller surface area, the proportional concentration of ingredients of the modified VITROS GLU slide will be unchanged compared to the current VITROS GLU Slide. This device modification reduces the sample volume required per test from 10 µL per test to 6 µL per test.

### Device description

The VITROS GLU Slide is a multilayered, analytical element coated on a polyester support. A drop of patient sample is deposited on the slide and is evenly distributed

by the spreading layer to the underlying layers. The oxidation of sample glucose is catalyzed by glucose oxidase to form hydrogen peroxide and gluconate. This reaction is followed by an oxidative coupling catalyzed by peroxidase in the presence of dye precursors to produce a dye. The intensity of the dye is measured by reflected light.

### Intended Use/ Indications for Use

For *in vitro* diagnostic use only. VITROS Chemistry Products GLU Slides quantitatively measure glucose (GLU) concentration in serum, plasma, urine, and cerebrospinal fluid using VITROS Systems. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia and of pancreatic islet cell carcinoma.

Special Conditions for Use Statement: For prescription use only.

### Comparison with Predicate Devices:

#### Summary of the technological characteristics of the device compared to the predicate device

| Device Characteristic                                       | New Device<br>VITROS GLU Slide<br>(Modified)                                                                                                                                                                               | Predicate Device<br>VITROS GLU Slide[k955286]<br>(Current)                                                                                                                                                                 |
|-------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Intended Use                                                | No Change.                                                                                                                                                                                                                 | For <i>in vitro</i> diagnostic use only. VITROS® Chemistry Products GLU Slides quantitatively measure glucose (GLU) concentration in serum, plasma, urine, and cerebrospinal fluid.                                        |
| Sample volume                                               | 6 µL                                                                                                                                                                                                                       | 10 µL                                                                                                                                                                                                                      |
| Concentrations of Slide Reactive Ingredients per cm-squared | No Change                                                                                                                                                                                                                  | Glucose oxidase (Aspergillus sp.) 0.77 U; peroxidase (horseradish root) 3.6 U; 1,7- dihydroxynaphthalene (dye precursor) 67 µg and 4-aminoantipyrine hydrochloride (dye precursor) 0.11 mg.                                |
| Amount of Slide Reactive Ingredients per Slide (test)       | Glucose oxidase (Aspergillus sp.) <b>0.77 U</b> ; peroxidase (horseradish root) <b>3.6 U</b> ; 1,7- dihydroxynaphthalene (dye precursor) <b>67 µg</b> and 4-aminoantipyrine hydrochloride (dye precursor) <b>0.11 mg</b> . | Glucose oxidase (Aspergillus sp.) <b>0.99 U</b> ; peroxidase (horseradish root) <b>4.7 U</b> ; 1,7- dihydroxynaphthalene (dye precursor) <b>86 µg</b> and 4-aminoantipyrine hydrochloride (dye precursor) <b>0.14 mg</b> . |

**Summary of the technological characteristics of the device compared to the predicate device**

| <b>Device Characteristic</b>    | <b>New Device<br/>VITROS GLU Slide<br/>(Modified)</b> | <b>Predicate Device<br/>VITROS GLU Slide[k955286]<br/>(Current)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|---------------------------------|-------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Device Description              | No Change                                             | The VITROS GLU assay is performed using the VITROS Chemistry Products GLU Slides and the VITROS Chemistry Products Calibrator Kit 1 on the VITROS Systems. The VITROS GLU Slide is a multi-layered, analytical element coated on a polyester support. The method is based on an enzymatic detection. All reactions necessary for a single quantitative measurement of glucose take place within the multi-layered analytical element of a VITROS GLU Slide. A drop of sample fluid is metered onto the slide and a reaction occurs which ultimately results in the oxidation of dye precursors by peroxidase. The concentration of glucose in the sample is determined by measuring the intensity of the dye using reflectance spectrophotometry. |
| Basic Principle                 | No Change                                             | Enzymatic Endpoint test using reflectance spectrophotometry.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Sample type                     | No Change                                             | Serum, plasma, urine, and cerebrospinal fluid                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Assay Range                     | No Change                                             | Serum: 20.0-625.0 mg/dL<br>Urine and CSF: 20.0-650.0 mg/dL                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Incubation time and temperature | No Change                                             | 5 minutes at 37°C                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

## Non-Clinical Testing Analytical Performance:

### Method comparison Predicate vs Feature

To demonstrate substantial equivalence with the predicate, human serum, urine and CSF samples were tested with the modified VITROS Chemistry Products GLU Slides (feature) and the results obtained were compared to those obtained using the current VITROS Chemistry Products GLU Slides (predicate). Method Comparison testing followed CLSI Protocol EP09-A3, *Measurement Procedure Comparison and Bias Estimation Using Patient Samples*. The correlation between the predicate and the modified VITROS GLU Slides on the VITROS 4600 Chemistry System is summarized below.

|       | No. Obs. | Slope | y-intercept | Correlation |
|-------|----------|-------|-------------|-------------|
| Serum | 113      | 1.01  | -0.80       | 1.000       |
| Urine | 105      | 1.03  | -0.81       | 0.999       |
| CSF   | 165      | 1.04  | -2.74       | 1.000       |

Units (mg/dL)

### Precision

Long term precision testing followed CLSI Protocol EP05-A3, *Evaluation of Precision Performance of Quantitative Methods; Approved Guideline—Third Edition*, using the modified VITROS Chemistry Products GLU Slides on the VITROS Systems. The test included a minimum of 80 observations (2 replicates per run, 2 runs per day over 20 days) for serum, urine and CSF specimens. The long term precision of the modified VITROS GLU Slides on the VITROS 4600 Chemistry System is summarized below.

### Precision

| Serum        | Mean Conc. | Within day SD* | Within lab SD** | Within Lab CV% | No. Obs. | No. Days |
|--------------|------------|----------------|-----------------|----------------|----------|----------|
| Serum Pool 1 | 29.4       | 0.24           | 0.39            | 1.3            | 88       | 22       |
| PV I         | 90.3       | 0.63           | 1.47            | 1.6            | 88       | 22       |
| PV II        | 287.2      | 1.56           | 3.35            | 1.2            | 88       | 22       |
| Serum Pool 2 | 571.2      | 3.28           | 4.99            | 0.9            | 88       | 22       |

Units (mg/dL)

| Urine        | Mean Conc. | Within day SD* | Within lab SD** | Within Lab CV% | No. Obs. | No. Days |
|--------------|------------|----------------|-----------------|----------------|----------|----------|
| Control 1    | 31.6       | 0.34           | 0.47            | 1.5            | 88       | 22       |
| Control 2    | 301.4      | 2.84           | 4.48            | 1.5            | 88       | 22       |
| Urine Pool 1 | 574.5      | 4.05           | 5.46            | 1.0            | 88       | 22       |

Units (mg/dL)

| CSF          | Mean Conc. | Within day SD* | Within lab SD** | Within Lab CV% | No. Obs. | No. Days |
|--------------|------------|----------------|-----------------|----------------|----------|----------|
| CSF Pool 1   | 37.2       | 0.29           | 0.56            | 1.5            | 88       | 22       |
| Liquid PV I  | 49.2       | 0.45           | 0.64            | 1.3            | 88       | 22       |
| Liquid PV II | 88.9       | 0.58           | 1.11            | 1.2            | 88       | 22       |
| CSF Pool 2   | 283.0      | 1.69           | 3.55            | 1.3            | 88       | 22       |
| CSF Pool 3   | 609.3      | 2.58           | 4.03            | 0.7            | 88       | 22       |

Units (mg/dL)

\* Within Day precision was determined using two runs per day with two replications.

\*\* Within Lab precision was determined using a single lot of slides and calibrating weekly.

### Limit of Blank, Detection and Quantitation (LoB/LoD/LoQ)

The Limit of Blank (LOB), Limit of Detection (LOD), and Limit of Quantitation (LOQ) of the VITROS GLU assay were determined according to CLSI EP17-A2: Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures. The following limits of the modified VITROS GLU Slides assay are summarized below:

### Limit of Blank, Detection and Quantitation Calculated

| Fluid Type | LOB (mg/dL) | LOD (mg/dL) | LOQ (mg/dL) |
|------------|-------------|-------------|-------------|
| Serum      | 1           | 2           | 9           |
| Urine      | 7           | 8           | 18          |
| CSF        | 4           | 5           | 20          |

The Limit of Quantitation is defined as the lowest amount of analyte in the sample that can be quantitatively determined with stated acceptable precision and trueness, under stated experimental conditions. A properly operating VITROS System should exhibit a LoQ value of 20 mg/dL with serum, plasma, urine and CSF specimens.

### Linearity

Linearity was determined following CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: a Statistical Approach: Approved Guideline. A high GLU pool was intermixed with a low pool to generate 14 concentration levels each tested in six replicate determinations for each body fluid type, serum, urine and CSF. Linear results were compared to 2nd and 3rd order polynomial fits against a pre-specified allowable error. Analysis by linear regression indicated that the assay is linear across the measuring range of each fluid type.

### Matrix Comparison

The performance of plasma specimens were compared to serum using a paired serum/plasma blood draw.

The results indicated that serum (stored removed from the clot), EDTA, both sodium and lithium heparin, and sodium fluoride/potassium oxalate plasma are suitable for use with the VITROS Chemistry Products GLU Slides assay.

### Measuring Range and Expected Values

The modification does not impact the measuring range and expected values of the modified VITROS GLU Slides assays. Current claims will apply as summarized below. Each laboratory should confirm the validity of these intervals for the population it serves.

#### Measuring (Reportable or Dynamic) Range

|       |                    |
|-------|--------------------|
| Serum | 20.0 – 625.0 mg/dL |
| Urine | 20.0 – 650.0 mg/dL |
| CSF   | 20.0 – 650.0 mg/dL |

#### Expected Values

|                |                |
|----------------|----------------|
| Serum          |                |
| Fasting Adults | 74 – 106 mg/dL |
| Urine          |                |
| Random         | < 30 mg/dL     |
| 24-hour        | < 500 mg/day*  |
| CSF            | 40 – 70 mg/dL  |

\*Glucose concentration (mg/dL) x 24-hour volume (dL) = mg/day

## **Interfering Substances**

Specimens Not Recommended

Urine with the following preservatives:

- Acetic acid
- Hydrochloric acid

The VITROS Chemistry Products GLU Slide assay was screened for interfering substances following CLSI Protocol EP07-A2, Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition.

The presence of N-Acetylcysteine, cholesterol, glutathione, dextran and total protein in serum are known to cause bias in assay results.

High levels of ascorbic acid in urine will cause a large negative bias, potentially resulting in values less than the measuring range. The degree of bias is proportional to the ascorbic acid concentration.

The presence of hemoglobin in CSF is known to cause a positive bias in assay results.

Substances exhibiting bias less than the stated acceptance criteria have been cited as substances that do not interfere. It is possible that other interfering substances may be encountered. These results are representative; however results may differ somewhat due to test-to-test variation. The degree of interference at concentrations other than those listed may not be predictable.

## **Conclusion:**

The conclusions drawn from the nonclinical tests (discussed above) demonstrate the modified VITROS Chemistry Products GLU Slides assay is as safe, effective, and perform as well as the predicate device, current VITROS Chemistry Products GLU Slides assay. The information submitted in the premarket notification is complete and supports a substantial equivalence decision.