DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 20, 2016

ORTHO-CLINICAL DIAGNOSTICS, INC.
MARLENE HANNA
SENIOR REGULATORY AFFAIRS MANAGER
100 INDIGO CREEK DRIVE
ROCHESTER, NY 14626-5101

Re: K161140
Trade/Device Name: VITROS Chemistry Products Calibrator Kit 3
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator, multi-analyte mixture
Regulatory Class: II
Product Code: JIX
Dated: April 21, 2016
Received: April 22, 2016

Dear Marlene Hanna:

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 regulation (21 CFR Part 801), 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" (21CFR 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)*
k161140

Device Name

VITROS® Chemistry Products Calibrator Kit 3

Indications for Use *(Describe)*

For in vitro diagnostic use only. VITROS® Chemistry Products Calibrator Kit 3 is used to calibrate VITROS 250/350/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System for the quantitative measurement of ALT, ALKP, AMYL, AST, CK, GGT, LDH, and LIPA.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary of Safety and Effectiveness for the

VITROS® Chemistry Calibrator Kit 3

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.

1. **510(k) Number:** k161140
2. **Applicant:**

Contact: Marlene A. Hanna, RAC
Sr. Regulatory Affairs Manager
Address: Ortho Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, NY 14506
Phone: (585) 453-4041
(585) 453-3368 (Facsimile)

3. **Date:** April 21, 2016

4. **Proprietary and Established Names:**
VITROS® Chemistry Products Calibrator Kit 3

5. **Regulatory Information:**
Regulation section: 21 CFR §862.1150, calibrator, multi-analyte mixture
Classification: Class II
Product Code: JIX
Panel: Clinical Chemistry

6. **Purpose of the 510(k) Submission:**
The VITROS® Chemistry Products Calibrator Kit 3 is being modified by addition of nominal values and information to support traceability of lactate dehydrogenase (LDH) to the IFCC/L->P method and removal of value-assignment information for acid phosphatase (ACP). The VITROS ACP assay is no longer commercially available. There are no changes made to the other analytes (ALT, ALKP, AMYL, AST, CK, GGT and LIPA) the calibrator kit is used with.

7. **Predicate Device:**
Device Name: VITROS® Chemistry Products Calibrator Kit 3
510(k) Number: k001679
Manufacturer: Ortho-Clinical Diagnostics, Inc.

8. Intended Use:

See Indications for Use

9. Indications for Use:

For *in vitro* diagnostic use only. VITROS® Chemistry Products Calibrator Kit 3 is used to calibrate VITROS® 250/350/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System for the quantitative measurement of ALT, ALKP, AMYL, AST, CK, GGT, LDH and LIPA.

Special Conditions for Use Statement(s): For prescription use only.

10. Device Description:

VITROS® Calibrator Kit 3 contains three levels of calibrators: Calibrator 1, 2, and 3. The calibrators are lyophilized, multi-analyte products prepared from processed bovine serum to which enzymes, electrolytes, stabilizers, and preservatives have been added. VITROS Chemistry Products Calibrator Kit 3 contains four vials each of lyophilized calibrator 1, 2, and 3 and four vials each of calibrator diluent 1, 2, and 3.

11. Test Principle:

VITROS® Chemistry Products Calibrator Kit 3 is intended for in vitro diagnostic use in the calibration of ALT, ALKP, AMYL, AST, CK, GGT, LDH, and LIPA on VITROS® Chemistry and Integrated Systems.

12. Substantial Equivalence Information:

Predicate device name: VITROS® Chemistry Products Calibrator Kit 3
Predicate K number: k001679
Comparison with Predicate: Please see Table 1 below for Similarities and differences for the VITROS Calibrator Kit 3.

SIMILARITIES		
Item	**New Device**	**Predicate Device**
Intended Use	For *in vitro* diagnostic use only. VITROS® Chemistry Products Calibrator Kit 3 is used to calibrate VITROS® 250/350/5,1 FS and 4600 Chemistry Systems and the VITROS 5600 Integrated System for the quantitative measurement of ALT, ALKP, AMYL, AST, CK, GGT, LDH and LIPA.	Same

SIMILARITIES		
Item	**New Device**	**Predicate Device**
Measured Analytes (Value assigned)	Alanine Aminotransferase (ALT) Alkaline Phosphatase (ALKP) Amylase (AMYL) Aspartate Aminotransferase (AST) Creatine Kinase (CK) Gamma Glutamyltransferase (GGT) Lactate Dehydrogenase (LDH) Lipase (LIPA)	Same
Form	Lyophilized	Same
Analyte Source	ALT: Porcine Heart ALKP: Porcine Kidney AMYL: Porcine Pancreas AST: Porcine Heart CK: Porcine Heart GGT: Porcine Kidney LDH: Chicken Heart LIPA: Porcine Pancreas	Same
Number of Levels	Three	Same
Target Concentrations (U/L)	ALT: 20, 250, 900 ALKP: 20, 150, 1450 AMYL: 35, 360, 1000 AST: 11, 243, 775 CK: 40, 700, 1650 GGT: 25, 125, 1360 LIPA: 30, 200, 1950	Same
Stability	Unopened: Frozen: $\leq$ -18°C (< 0°F): for 24 months Reconstituted (Refrigerated): 2- 8°C (36-46°F): $\leq$ 24 hours	Same

DIFFERENCES		
Item	**New Device**	**Predicate Device**
Target Concentrations (U/L) for LDH	LDH: 225, 800, 2000 LDH: 90, 320, 800	LDH: 225, 800, 2000
Traceability for LDH	Buhl method and IFCC method	Buhl method

13. Standard/Guidance Document Reference

The following recognized standard and guidance documents were used:

- CEN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry – *Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators*

14. Performance Characteristics

The following studies are not applicable for the purpose of this submission:

- *Precision/Reproducibility*
- *Linearity/Assay Reportable Range*
- *Detection limit*
- *Method and Matrix Comparison Studies*
- *Analytical Specificity*
- *Assay cut-off*
- *Expected Values/Reference Interval*

Summary of Stability:

Real-time stability studies for shelf-life and open-vial claims have been conducted and acceptance criteria were met. VITROS Chemistry Products Calibrator Kit 3 is to be stored frozen at less than or equal to -18^{o}C for 24 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 products should be used immediately or stored refrigerated at 2-8^{o}C for less than or equal to 24 hours.

Summary of Traceability and Value Assignment

Values assigned to the VITROS Chemistry Products Calibrator Kit 3 for lactate dehydrogenase LDHI Slides are traceable to the IFCC recommended reference method as described in *IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37 C. Part 3. Reference procedure for the measurement of catalytic concentration of lactate dehydrogenase* .[1]

The process by which Supplementary Assigned Values (SAV) are assigned to VITROS Chemistry Products Calibrator Kit 3 is analogous to the value transfer process described by Broughton and Eldjarn (*P.M.G. Broughton and L. Eldjarn, Methods of assigning accurate values to reference serum, Part 1. The use of reference laboratories and consensus values, with an evaluation of a procedure transferring values from one reference serum to another, Ann. Clin. Biochem. 22: 625-634, 1985*). The major difference is that instead of transferring values from one serum pool to another, reference method values are transferred to product calibrator fluids, using a panel of human samples as an intermediate Working Calibrator.

The assigned values of the VITROS Calibrator Kit 3 are traceable as listed in the following table:

Product	**Analyte**	**Traceability**
VITROS® Calibrator Kit 3	ALT	IFCC/NRSCL RS4-A/37 °C
	ALKP	IFCC/37 °C
	AMYL	PG5/37 °C
	AST	IFCC/NRSCL RS2-A/37 °C
	CK	IFCC/NRSCL RS14-P/37 °C
	GGT	IFCC/NRSCL RS17-P/37 °C
	LDH	NCCLS/P->L/37 °C
	LDHI	IFCC/L->P/37 °C
	LIPA	pH Stat

Refer to the below table for representative target concentrations for LDH in VITROS Calibrator Kit 3.

VITROS Calibrator Kit 3	Nominal Calibrator Value LDH (U/L)
Calibrator Vial 1	90
Calibrator Vial 2	320
Calibrator Vial 3	800

16. Conclusions

Based on the testing and the comparisons with the predicate device, the VITROS Calibrator Kit 3 (Modified) is substantially equivalent to the VITROS Calibrator Kit 3 cleared under k001679.