DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 18, 2016

ORTHO-CLINICAL DIAGNOSTICS, INC.
DARLENE PHILLIPS
MANAGER REGULATORY AFFAIRS
100 INDIGO CREEK DRIVE MC00881
ROCHESTER NY 14626

Re: K160495
Trade/Device Name: VITROS® Automation Solutions
Regulation Number: 21 CFR 862.1700
Regulation Name: Total thyroxine test system
Regulatory Class: II
Product Code: KLI, JJE, KLT, LCD
Dated: August 19, 2016
Received: August 22, 2016

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,

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)*
K160495

Device Name
VITROS® Automation Solutions

Indications for Use *(Describe)*
VITROS® Automation Solutions is intended to automate pre-analytical and post-analytical sample processing in the clinical laboratory. VITROS® Automation Solutions allows the consolidation of software, automation modules and clinical analyzers, such as VITROS® Systems into a unified workstation to perform a variety of assays such as total T4, carbamazepine and gentamicin.

Carbamazepine measurements are used to monitor patient compliance and therapy, and to diagnose potential overdose. Gentamicin measurements are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to ensure appropriate therapy. Total thyroxine (T4) measurements are used to aid in the differential diagnosis of thyroid disease.

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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510(k) Summary

Submitter Information

Name	Ortho-Clinical Diagnostics, Inc.
Address	100 Indigo Creek Drive Rochester, New York 14626
Phone number	(585) 453-4253
Fax number	(585) 453-3368
Establishment Registration Number	1319681
Name of contact person	Darlene J Phillips
Date prepared	October 6, 2016

Name of devices

Trade or proprietary names	VITROS® Automation Solutions
Common or usual name	Laboratory Automation System

Classification Name	Regulation number	Product code	Device class	Review panel
Carbamazepine test system	862.3645	KLT	II	Toxicology
Gentamicin test system	862.3450	LCD	II	Toxicology
Total thyroxine test system	862.1700	KLI	II	Clinical Chemistry
Discrete photometric chemistry analyzers for clinical use	862.2160	JJE	I	Clinical Chemistry

Legally marketed device(s) to which equivalence is claimed

Ortho claims that VITROS® Automation Solutions is substantially equivalent to the enGen™ Laboratory Automation System with VITROS® 5,1 FS Chemistry System K063144

Device description

VITROS® Automation Solutions is a configurable, scalable laboratory automation system (LAS) designed to streamline pre and post analytical processes in the clinical laboratory. VITROS® Automation Solutions is comprised of personal computer (PC) Kit(s) (including software and hardware), sample conveyors with turns, parallel and perpendicular bypasses, storage module, single-tube entry, rack entry and exit, centrifuge, de-capper modules and clinical analyzers.

In the basic configuration, patient sample tubes are loaded onto the automation track to be centrifuged, de-capped, and sorted for further processing on clinical analyzers such as the VITROS® Systems. Additional modules may be added to enable aliquot capability, sample capping, and refrigerated storage.

Parallel and perpendicular bypasses are extensions of the automation track that link with an analyzer's existing laboratory automation system (LAS) interface. These bypasses support on-track metering at the analyzer based on point-in-space pipetting technology and robotic interface module (RIM). With point in space pipetting, the automation performs the sample bar code read function, presents the sample identification to the connected analyzer, and then signals for direct sampling of the open tube by the connected analyzer at an aspiration point on the automation track. With robotic interface modules, the sample tube is transferred to the analyzer and the analyzer will read the bar code to identify the sample, aspirate sample from the tube and perform the test(s) requested and then return the tube to the LAS.

VITROS® Automation Solutions allows the establishment of a connection with clinical analyzers such as VITROS® Systems to enable sample routing based on reagent and calibration status. The clinical analyzers, such as VITROS® Systems, will perform all functions with respect to result generation, including sample metering, assay processing and reporting for the assays.

The VITROS® Systems are fully automated, computer controlled, clinical chemistry and immunodiagnostic analyzers intended for the *in vitro* determination of a variety of general chemistries, therapeutic drugs, drugs of abuse, proteins, infectious diseases, as well as cardiac, metabolic, thyroid, anemia, and oncology markers in biological fluids such as serum, plasma, urine and cerebral spinal fluid.

The VITROS® Systems operate in conjunction with VITROS® Immunodiagnostic and Chemistry Products, reagents, calibrators and controls designed for use with the systems in the MicroSlide, MicroTip or MicroWell format. Representative assays (carbamazepine, gentamicin and total thyroxine) are used to demonstrate acceptable performance.

Intended Use/ Indications for Use

VITROS® Automation Solutions is intended to automate pre-analytical and post-analytical sample processing in the clinical laboratory. VITROS® Automation Solutions allows the consolidation of software, automation modules and clinical analyzers, such as VITROS® Systems into a unified workstation to perform a variety of assays such as total T4, carbamazepine and gentamicin.

Carbamazepine measurements are used to monitor patient compliance and therapy, and to diagnose potential overdose. Gentamicin measurements are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to ensure appropriate therapy. Total T4 measurements are used to aid in the differential diagnosis of thyroid disease.

Comparison with Predicate Devices:

Similarities Table		
Attribute	**Predicate device** **enGen™ Laboratory Automation System with VITROS® 5,1 FS Chemistry System** **K063144**	**New device** **VITROS® Automation Solutions (sample and data processing modules, software and clinical analyzers, such as VITROS® Systems)**
Intended Use	A clinical laboratory automation system that is intended to perform automated pre-analytical and post-analytical sample and data management. The System automates sample handling and data management through the use of middleware, automation, driver software and a configuration file. The System is interfaced mechanically and electronically to analyzers and a Laboratory Information System (LIS).	Same
System Design	Each installation of the System requires a baseline configuration file determined by the unique combination of modules and clinical analyzers and the supported test menu that will be integrated with each installation of the System.	Same
Sample Transfer Method	Supports both “Point-in-space” and the physical transfer of the sample tube/rack from the automation track to the analyzer’s sample load and identification area using automation interface modules.	Same
Fundamental Technology	Outboard analyzer connections accessed by track bypass modules and/or robotic interface	Same

Attribute	Predicate device enGen™ Laboratory Automation System with VITROS® 5,1 FS Chemistry System K063144	New device VITROS® Automation Solutions (sample and data processing modules, software and clinical analyzers, such as VITROS® Systems)
System Modules	Instrument Manager Hardware/software TCAutomation Software TCAutomation Modules including but not limited to: • Rack Entry/Exit Modules, Single Tube Entry Modules • Conveyors and turns • Centrifuges (operating as a single cluster) • Decappers • Aliquoter • Recappers • Bypasses for analyzers such as VITROS® Systems and 3rd party analyzers • ES Flex Module	Same
Chemistry Analyzer Connection	Clinical analyzers such as, VITROS® 5,1 FS Chemistry System VITROS® 4600 Chemistry System VITROS® 3600 Immunodiagnostics Systems VITROS® 5600 Integrated Systems	Same
VITROS® Products Assays Performed	VITROS® Chemistry and Immunodiagnostic Products Assays such as VITROS® CRBM Slides assay VITROS® GENT Reagent assay VITROS® Total T4 Reagent assay	Same
Sample Identification	Sample bar code read by automation linked to Transport carriers identified on the system by Radio-frequency identification (RFID) tags, presented to instrument via Bypass Module	Same
Sample Handling	The ability to interface with a LIS device to receive patient identification and test requests via a communications protocol to provide sample tracking via bar code labeling and RFID. Processes multiple tube sizes/types simultaneously; sorts and maps samples for routing, storage, and retrieval; performs intelligent sample routing based on system status	Same

Attribute	Predicate device enGen™ Laboratory Automation System with VITROS® 5,1 FS Chemistry System K063144	New device VITROS® Automation Solutions (sample and data processing modules, software and clinical analyzers, such as VITROS® Systems)
Software Components	Data Innovations • Instrument Manager™ Core with drivers Thermo Fisher Scientific • TCAutomation software communicates to IM and track	Same Same

Difference Table

Attribute	Predicate device enGen™ Laboratory Automation System with VITROS® 5,1 FS Chemistry System K063144	New device VITROS® Automation Solutions (sample and data processing modules, software and clinical analyzers, such as VITROS® Systems)
Software Components	Developed and provided by Ortho enGen configuration file (gsb) • sample routing and reprocessing • includes Autoverification	Developed and provided by Data Innovations • Incorporated into Automation Driver, Instrument Driver, Universal LIS Driver and Out of Service driver • Optional VITROS Autoverification Rules set – developed by Data Innovations

Performance Summary:

Non-Clinical Testing Analytical Performance:

Assay performance characteristics were established in VITROS® CRBM assay K980283, VITROS® GENT assay K042479 and VITROS® Total T4 assay K964721. These performance characteristics are dependent on the assay and the VITROS® Systems which have not changed.

Method Comparison

To establish equivalence between results for samples manually introduced to the analyzer versus automated sample introduction and identification to the analyzer, a method comparison has been performed using the VITROS® CRBM, GENT and Total T4 assays.

The comparison study was performed using patient samples processed through the appropriate laboratory protocol using a representative configuration of VITROS® Automation Solutions (on-track) followed by manual load directly to the VITROS® System (off track).

The linear regression analysis demonstrates comparable performance across the range of sample concentrations tested for each representative assay.

Assay	Sample Range	N	Slope	Intercept	R^2
CRBM (µg/mL)	3.09 – 17.12	70	1.04	-0.0905	0.9796
GENT (µg/mL)	0.63 – 9.72	55	1.00	0.0075	0.9989
Total T4 (nmol/L)	12.70 – 288.70	57	1.01	-1.1936	0.9969

The test results showed no clinically significant difference in assay performance between the two sample processing methods. This data demonstrates substantial equivalence between VITROS® Automation Solutions and the stand-alone analyzer, VITROS® Systems.

Conclusion

The information submitted demonstrates substantial equivalence between VITROS® Automation Solutions and the predicate, enGen™ Laboratory Automation System.