510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

k160495

B. Purpose for Submission:

The submission is to obtain clearance for the VITROS Automation Solution, a laboratory automation system used as an accessory to clinical laboratory analyzers such as the VITROS 5, 1 FS Chemistry System, VITROS 5600 Chemistry System, VITROS 4600 Chemistry System and 3600 Immunodiagnostics System.

The manufacturer uses the performance of VITROS® Chemistry Products CRBM Reagent, VITROS® Chemistry Products GENT Reagent and the VITROS® Immunodiagnostic Products Total T4 Reagent to demonstrate the VITROS Automation Solution is equivalent to the manual sample introduction on the analyzer.

C. Manufacturer and Instrument Name:

Ortho-Clinical Diagnostics, VITROS® Automation Solutions

D. Type of Test or Tests Performed:

Quantitative, immunoassay

E. System Descriptions:

1. 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.

The connection between the automation software of the VITROS® Automation Solutions allows the establishment of a connection with the laboratory information system (LIS) and the clinical analyzers such as VITROS® Systems to enable sample routing based on reagent and calibration status.

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.

2. Principles of Operation:

   The Carbamazepine assay is based on an enzyme heterogeneous, competitive immunoassay.

   The Gentamicin assay is a homogenous enzyme immunoassay.

   The Total T4 assay is a competitive immunoassay.

3. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ___X_____ or No _____

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___X_____

4. Specimen Identification:

   Barcode identification of patient samples. Sample bar code read by VITROS Automation Solutions linked to Transport carriers identified on the system by Radio-frequency identification (RFID) tags, presented to instrument via Bypass Module.

5. Specimen Sampling and Handling:

   The patient's sample tubes are loaded onto the VITROS Automation Solutions automated track to be centrifuged, de-capped and sorted for processing on clinical analyzers. The sample bar codes are read to direct the sample to a specific analyzer.

6. Calibration:

   Provided in VITROS CRBM (carbamazepine) k980283, VITROS GENT (Gentamicin) k042479, and VITROS TT4 (Total T4) k964721

7. Quality Control:

   Provided in VITROS CRBM (carbamazepine) k980283, VITROS GENT (Gentamicin) k042479, and VITROS TT4 (Total T4) k964721

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes___X_____ or No_____

F. Regulatory Information:

Classification name	Product Code	Classification	Regulatory Section	Panel
Carbamazepine test system	KLT	class II	21 CFR 862.3645	Toxicology 91
Gentamicin test system	LDC	class II	21 CFR 862.3450	Toxicology 91
Total thyroxine test system	KLI	class II	21 CFR 862.1700	Chemistry 75
Discrete photometric chemistry analyzers for clinical use	JJE	class I	21 CFR 862.2160	Chemistry 75

G. Intended Use:

1. Indication(s) 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 thyroxine (T4) measurements are used to aid in the differential diagnosis of thyroid disease.

2. Special Conditions for Use Statement(s):

   For prescription use only

   For in vitro diagnostic use

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:
   enGen™ Laboratory Automation System with VITROS 5, 1 FS Chemistry System – k063144

2. Comparison with Predicate Device:

Similarities / Differences		
Item	VITROS® Automation Solution Candidate Device (k160495)	enGen™ Laboratory Automation System Predicate Device (k063144)
Intended Use	Automate pre-analytical and post-analytical sample processing in the clinical laboratory	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
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

Similarities / Differences		
Item	VITROS® Automation Solution Candidate Device (k160495)	enGen™ Laboratory Automation System Predicate Device (k063144)
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
Software Components	Data Innovations • Instrument Manager™ Core with drivers Thermo Fisher Scientific • TCAutomation software communicates to IM and track	Same
Software Components	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	Developed and provided by Ortho enGen configuration file (gsb) • sample routing and reprocessing • includes Autoverification

I. Special Control/Guidance Document Referenced (if applicable):

- EN ISO 14971: 2009 Medical devices – Application of risk management to medical devices
- EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices
- EN ISO 18113 – 1:2011 In vitro diagnostic medical devices-Information supplied by the manufacturer (labeling)-Part1: Terms, definitions and general requirements
- EN ISO 18113-3:2011 In vitro diagnostics medical devices-Information supplied b the manufacturer (labeling)-Part 3: Instruments for professional use.
- EN ISO 13485:2012 Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 15223-1:2012 Medical devices – Symobols to be used with medical device labels, labelling and information to be supplied – Part 1: General reqirements
- EN 61326-2-6 Electrical equipment for measurement, control and laboratory use-EMC requirements
- EMC: IEC 61010-2-101 Medical Electrical Equipment – Part 1: General Requirements for Safety
- EC 61010-1 Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

J. Performance Characteristics*:*

1. Analytical Performance:

a. Accuracy:

Provided in VITROS CRBM (carbamazepine) k980283, VITROS GENT (Gentamicin) k042479, and VITROS TT4 (Total T4) k964721

b. Precision/Reproducibility:

Provided in VITROS CRBM (carbamazepine) k980283, VITROS GENT (Gentamicin) k042479, and VITROS TT4 (Total T4) k964721

c. Linearity:

Provided in VITROS CRBM (carbamazepine) k980283, VITROS GENT (Gentamicin) k042479, and VITROS TT4 (Total T4) k964721

d. Carryover:

Not applicable

e. Interfering Substances:

Provided in VITROS CRBM (carbamazepine) k980283, VITROS GENT

(Gentamicin) k042479, and VITROS TT4 (Total T4) k964721

2. Other Supportive Instrument Performance Data Not Covered Above:

a. Method comparison with predicate device:

A comparison study was performed to demonstrate equivalence between results for samples delivered to the VITROS System analyzers via the VITROS Automation Solutions (on-track) and samples manually placing on the VITROS System analyzers by the operator (off-tack). A total of 70 samples were tested for carbamazepine, 13 samples were spiked (18%) with a stock solution of carbamazepine using the VITROS® 5,1 FS Chemistry System. A total of 55 native samples were tested for gentamicin using the 5600 Integrated System and a total of 51 native samples and an additional 6 diluted samples (10% spiked) were tested for Total T4 using the 3600 Immunodiagnostic System. The samples were split into pairs: one sample processed through the VITROS Automation Solutions (on-track) and delivered to the VITROS chemistry analyzer and the other was processed by manually loading directly to the VITROS chemistry analyzers systems (off-track). The samples were tested in three replicates per sample both on and off the track. The first replicate from each sample was used to generate the regression statistics. The regression analysis for each assay are summarized in the tables below:

Assay	Sample Range	N	Slope	Intercept	R^2
CRBM (µg/mL) (5,1 FS Chemistry System)	3.09 – 17.12	70	1.04	-0.0905	0.9796
GENT (µg/mL) (5600 Integrated System)	0.63 – 9.72	55	1.00	0.0075	0.0989
Total T4 (nmol/L) (3600Immunodiagnostic)	12.70 – 288.70	57	1.01	-1.1936	0.9969

b. Software/Hardware Verficaiton and Validation

FDA has reviewed the applicant's software validation and verification documentation for this product and found it to be acceptable.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.