

510(K) SUMMARY

Submitter's Name	Ortho-Clinical Diagnostics, Inc.
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Date:	May 25, 2011
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Name of the Device	ORTHO [®] Summit System (OSS)
Common or Usual Name	Automated Bloodborne Pathogen Test Equipment
Classification Name	Automated Bloodborne Pathogen Test Equipment Device Class: II Product Code: MZA Regulation Number: None
Performance Standards	There are no performance standards promulgated for this device.
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510(k) Summary, continued

Indications for Use	The ORTHO [®] Summit System (OSS) is a modular, integrated system for use with licensed blood screening tests. Consisting of networked processors and instruments linked together via a local area network, assay-specific pipetting protocols and ORTHO [®] Assay Software (OAS), OSS automates many of the processing functions and data management requirements associated with ELISA (enzyme-linked immunosorbent assay) microplate testing.
Identification of the Legally Marketed Device (Predicate Device)	ORTHO [®] Summit System (OSS) Classification Name: Automated Bloodborne Pathogen Test Equipment Device Class: II Product Code: MZA Regulation Number: None

510(k) Summary, continued

Device Description

The ORTHO[®] Summit System (OSS) is a modular, integrated system for use with licensed blood screening tests. Consisting of networked processors and instruments linked together via a local area network, assay-specific pipetting protocols and ORTHO[®] Assay Software (OAS), OSS automates many of the processing functions and data management requirements associated with ELISA (enzyme-linked immunosorbent assay) microplate testing.

The OSS consists of ORTHO[®] Assay Software (OAS), ORTHO[®] Summit Sample Handling System (Summit), ORTHO VERSEIA[™] Pipetter (Verseia), ORTHO[®] Summit Processor (OSP), ORTHO[®] Assay Protocol Disks (OAPDs), and the AutoReader IV.

The OSS, using the Networked OAS Software, can be used in one or more of the following operational modes:

- **Manual:** Manual pipetting (Precision Pipettors) + Manual Processing (KVM Incubator, AutoWash 96, Precision Pipettors and AutoReader IV)
- **Semi-automated:** Automated Pipetting (ORTHO[®] Summit Sample Handling System and/or the ORTHO VERSEIA[™] Pipetter) + Manual Processing (KVM Incubator, AutoWash 96, Precision Pipettors and AutoReader IV)
- **Automated:** Automated Pipetting (ORTHO[®] Summit Sample Handling System and/or the ORTHO VERSEIA[™] Pipetter) + Automated Processing (ORTHO[®] Summit Processor)

The following ORTHO[®] Assay Protocol Disks (OAPDs) are currently cleared/approved for use on the OSS with the ORTHO[®] Summit Sample Handling System (Summit):

- ORTHO[®] *T. cruzi* ELISA Test System
- ORTHO[®] HCV Version 3.0 ELISA Test System
- GS HBsAg EIA 3.0
- GS HIV-1/HIV-2 *PLUS O* EIA
- ORTHO[®] HBc ELISA Test System

The ORTHO VERSEIA[™] Pipetter contains a single pipetting method that provides direction for pipetting the ORTHO[®] *T. cruzi* ELISA Test System, the ORTHO[®] HCV Version 3.0 ELISA Test System, the GS HBsAg EIA 3.0, and the GS HIV-1/HIV-2 *PLUS O* EIA using data table values specific for each assay. The ORTHO VERSEIA[™] Pipetter does not require the use of OAPDs for pipetting direction.

510(k) Summary, continued

Device Comparison Table

	Predicate Device ORTHO[®] Summit System	Modified Device ORTHO[®] Summit System
Intended Use	The ORTHO [®] Summit System (OSS) is a modular, integrated system for use with licensed blood screening tests. Consisting of networked processors and instruments linked together via a local area network, assay-specific pipetting protocols and ORTHO [®] Assay Software (OAS), OSS automates many of the processing functions and data management requirements associated with ELISA (enzyme-linked immunosorbent assay) microplate testing.	The ORTHO [®] Summit System (OSS) is a modular, integrated system for use with licensed blood screening tests. Consisting of networked processors and instruments linked together via a local area network, assay-specific pipetting protocols and ORTHO [®] Assay Software (OAS), OSS automates many of the processing functions and data management requirements associated with ELISA (enzyme-linked immunosorbent assay) microplate testing.
Pipetter	<ul style="list-style-type: none"> • ORTHO[®] Summit Sample Handling System (Summit) Firmware Version 4.1 • ORTHO VERSEIA[™] Pipetter Version V2.0 with Firmware Version 5.60 • Hamilton Microlab STAR IVD software v4.2.0 	<ul style="list-style-type: none"> • ORTHO[®] Summit Sample Handling System (Summit) Firmware Version 4.1 • ORTHO VERSEIA[™] Pipetter Version V2.0 with Firmware Version 5.60 • Hamilton Microlab STAR IVD software v4.2.0
Microwell Plate Processor	ORTHO [®] Summit Processor (OSP) User Software Version 2.1.3 or 2.1.4 if using optional OSP MOD B3	ORTHO [®] Summit Processor (OSP) User Software Version 2.1.3 or 2.1.4 if using optional OSP MOD B3
OAS Server	SCO UNIX Open Server Release 3.2.4 <ul style="list-style-type: none"> • OAS Version 2.0.1 • Informix Version 5.0 • JAM GUI 5.03 • Hardware Platform: 450 MHz Processor 	Red Hat Enterprise Linux Version 5.3 <ul style="list-style-type: none"> • OAS Version 2.1.0 • Informix Version 11.5 • JAM GUI 5.04h • Hardware Platform: 2.0 GHz Processor
OAS Workstation	<ul style="list-style-type: none"> • ORTHO[®] Assay Software version 2.0.38 • SCO UNIX 2.0.1 • Hardware Platform: 400 MHz Processor 	<ul style="list-style-type: none"> • ORTHO[®] Assay Software version 2.0.38 • SCO UNIX 2.0.1 • Hardware Platform: 400 MHz Processor
Microplate Reader	AutoReader IV	AutoReader IV
Assay Processing Software	<ul style="list-style-type: none"> • ORTHO VERSEIA[™] Pipetter Version V2.0 • ORTHO[®] Assay Protocol Disks 	<ul style="list-style-type: none"> • ORTHO VERSEIA[™] Pipetter Version V2.0 • ORTHO[®] Assay Protocol Disks

	Predicate Device ORTHO® Summit System	Modified Device ORTHO® Summit System
Assays Pipetted on the ORTHO® Summit Sample Handling System	<ul style="list-style-type: none"> • ORTHO® <i>T. cruzi</i> ELISA Test System • ORTHO® HCV Version 3.0 ELISA Test System • GS HBsAg EIA 3.0 • GS HIV-1/HIV-2 <i>PLUS O</i> EIA • ORTHO® HBc ELISA Test System 	<ul style="list-style-type: none"> • ORTHO® <i>T. cruzi</i> ELISA Test System • ORTHO® HCV Version 3.0 ELISA Test System • GS HBsAg EIA 3.0 • GS HIV-1/HIV-2 <i>PLUS O</i> EIA • ORTHO® HBc ELISA Test System
Assays Pipetted on the ORTHO VERSEIA™ Pipetter	<ul style="list-style-type: none"> • ORTHO® <i>T. cruzi</i> ELISA Test System • ORTHO® HCV Version 3.0 ELISA Test System • GS HBsAg EIA 3.0 • GS HIV-1/HIV-2 <i>PLUS O</i> EIA 	<ul style="list-style-type: none"> • ORTHO® <i>T. cruzi</i> ELISA Test System • ORTHO® HCV Version 3.0 ELISA Test System • GS HBsAg EIA 3.0 • GS HIV-1/HIV-2 <i>PLUS O</i> EIA

510(k) Summary, continued

Device Features Comparison Table

	Predicate Device OSS	Modified Device OSS
Support for multiple instruments	X	X
Centralized data storage and access	X	X
Centralized system administration	X	X
Industry standard network architecture support (TCP/IP, NFS and Ethernet)	X	X
Configurable to customer workflow needs	X	X
Automated bar code scanning for sample tubes and microplates	X	X
Automated sample and reagent pipetting onto microplates	X	X
Automated microplate reading and data collection	X	X
Automated plate and sample analysis	X	X
Automated sample tracking and interpretation	X	X
Capabilities for backup, restore and archive of data and on-line data review facility	X	X
Centralized user security by function, and by assay	X	X
Comprehensive User Audit Trail	X	X
Full featured, on-line training environment	X	X
Extensive report generation facilities	X	X
Result transmission to external host systems	X	X
Automated microplate processing (e.g., wash, reagent dispense, incubation)	X	X
Recording and tracking of automated plate processing data	X	X
Capacitance liquid level detection (cLLD) to detect the fluid level in sample tubes, wells, and other containers	X	X
Pressure detection to monitor the aspiration, dispense, and mix process steps	X	X
Remote device management application that connects OCD instruments and devices in the field to OCD technical support	X	X

510(k) Summary, continued

Description of Testing

Non-clinical Testing:

Non-clinical testing was performed on the ORTHO[®] Summit System (OSS) with the OAS Server that had the hardware and operating system upgrades. This testing included testing with the ORTHO[®] Summit Sample Handling System and the ORTHO VERSEIA[™] Pipetter. The software verification and validation activities included both static and dynamic activities including unit, integration, and system level: functional, regression, database management testing, media migration testing, stability/longevity/reliability, load/performance, stress/load testing, and validation for the OAS Server Hardware and Operating System Upgrade.

Clinical Testing (External Validation Testing):

No external clinical testing was required for this change.

Conclusion of Testing

The successful non-clinical testing demonstrates the safety and effectiveness of the modified ORTHO[®] Summit System when used for the defined indications for use and demonstrates that the device for which the 510(k) is submitted performs as well as or better than the legally marketed predicate device.