

5.0 510(K) SUMMARY

Submitter's Name	Ortho-Clinical Diagnostics, Inc.
Address	1001 US Highway 202 North Raritan, NJ 08869-0606
Establishment Number	2250051
Telephone Number	(800) 523-6911
Fax Number	908-218-8168
Contact Person	Kristine Tkacs
Date:	February 21, 2013
Name of the Device	ORTHO [®] Summit System (OSS) with the ORTHO VERSEIA [®] Integrated Processor
Common or Usual Name	Test, Equipment, Automated Bloodborne Pathogen
Classification Name	Test, Equipment, Automated Bloodborne Pathogen Device Class: II Product Code: MZA Regulation Number: None
Performance Standards	There are no performance standards promulgated for this device.

Indications for Use	<p>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. Only assays licensed for use on the OSS may be used with this system.</p> <p>The ORTHO VERSEIA[®] Integrated Processor is an automated pipetting and processing system comprised of an ORTHO VERSEIA[®] Pipetter and an ORTHO[®] Summit Processor (OSP) joined together to enable integrated end-to-end pipetting and processing. The ORTHO VERSEIA[®] Integrated Processor is to be used with licensed blood screening tests distributed by Ortho-Clinical Diagnostics, Inc. for in vitro diagnostic use.</p>
Identification of the Legally Marketed Device (Predicate Device)	<p>ORTHO[®] Summit System (OSS) Classification Name: Test, Equipment, Automated Bloodborne Pathogen Device Class: II Product Code: MZA Regulation Number: None</p>

<p>Device Description</p>	<p>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. Only assays licensed for use on the OSS may be used with this system.</p> <p>The OSS consists of ORTHO® Assay Software (OAS), ORTHO® Summit Sample Handling System, ORTHO VERSEIA® Pipetter, ORTHO® Summit Processor (OSP), ORTHO® Assay Protocol Disks (OAPDs), and the AutoReader IV.</p> <p>The OSS, using the Networked OAS Software, can be used in one or more of the following operational modes:</p> <ul style="list-style-type: none"> • Manual: Manual Pipetting with Manual Processing • Semi-automated: Automated Pipetting Summit and/or Verseia with Manual Processing • Automated: Automated Pipetting Summit and/or Verseia with Summit Processor <p>The following ORTHO® Assay Protocol Disks (OAPDs) are currently cleared/approved for use on the OSS:</p> <ul style="list-style-type: none"> • Trypanosoma cruzi (<i>T. cruzi</i>) • Hepatitis C Virus V3.0 • Human Immunodeficiency Virus types 1 and 2 • Hepatitis B Core Antigen V3.0 • Antibody to Hepatitis B Antigen • HTLV-I and HTLV-II
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	<p>Predicate Device OSS BK120006</p>	<p>Modified Device OSS with VIP</p>
<p>Intended Use</p>	<p>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. Only assays licensed for use on the OSS</p>	<p>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. Only assays licensed for use on the OSS</p>

	Predicate Device OSS BK120006	Modified Device OSS with VIP
	may be used with this system.	may be used with this system.
Pipetter	<ul style="list-style-type: none"> Summit Firmware Version 4.1 Verseia V3.0 with Firmware Version 5.6S 	<ul style="list-style-type: none"> Summit Firmware Version 4.1 Verseia V4.0 with Firmware Version 7.1S
Microwell Plate Processor	ORTHO [®] Summit Processor (OSP) Version 2.1.3 or 2.1.4 if using (optional OSP MOD B3)	ORTHO [®] Summit Processor (OSP) User Software Version V2.2 Firmware version 6.8S
OAS Server	Red Hat Enterprise Linux V 5.3 Hardware Platform: 2.0 GHz	Red Hat Enterprise Linux V 5.3 Hardware Platform: 2.0 GHz
OAS Workstation	ORTHO [®] Assay Software v2.0.38	ORTHO [®] Assay Software S2.01
Microplate Reader	Version IV	Version IV
Assay Processing Software	<ul style="list-style-type: none"> Verseia Version V3.0 	<ul style="list-style-type: none"> Verseia V4.0
Assays Pipetted on the ORTHO VERSEIA[®] Pipetter	<ul style="list-style-type: none"> Trypanosoma cruzi (<i>T. cruzi</i>) Hepatitis C Virus V3.0 Human Immunodeficiency Virus types 1 and 2 Hepatitis B Core Antigen V3.0 Antibody to Hepatitis B Antigen HTLV-I and HTLV-II 	<ul style="list-style-type: none"> Trypanosoma cruzi (<i>T. cruzi</i>) Hepatitis C Virus V3.0 Human Immunodeficiency Virus types 1 and 2 Hepatitis B Core Antigen V3.0 Antibody to Hepatitis B Antigen HTLV-I and HTLV-II
OAPDs	<ul style="list-style-type: none"> ORTHO Trypanosoma cruzi (<i>T. cruzi</i>) Rev. 7 Hepatitis C Virus V3.0 Rev. 3 Human Immunodeficiency Virus types 1 and 2 Rev 2 Hepatitis B Core Antigen V3.0 Rev. 3 Antibody to Hepatitis B Antigen Rev 2 HTLV-I and HTLV-II Rev 4 	<ul style="list-style-type: none"> ORTHO Trypanosoma cruzi (<i>T. cruzi</i>) Rev. 7 Hepatitis C Virus V3.0 Rev. 3 Human Immunodeficiency Virus types 1 and 2 Rev 2 Hepatitis B Core Antigen V3.0 Rev. 3 Antibody to Hepatitis B Antigen Rev 2 HTLV-I and HTLV-II Rev 4

Device Features Comparison Table

	Predicate Device OSS BK120006	Modified Device OSS with VIP
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
Automated Plate Transfer (i-Swap)		X
Increased on-board Capacity of samples and plates on the ORTHO VERSEIA [®] pipetter		X

<p>Description of Testing</p>	<p>Non-clinical Testing: Non-clinical testing was performed for the ORTHO VERSEIA® Integrated Processor including feasibility testing; component level hardware testing; testing to verify the instrument precision and accuracy; sensitivity and specificity of the No Liquid Alarm functionality; software and system verification and validation activities that included unit, integration and system level software testing, and regression testing; Electromagnetic Compatibility (EMC) and product safety testing.</p> <p>Successful testing was performed on the ORTHO VERSEIA® Integrated Processor and the changes made to the OAS to verify this functionality as part of the OSS. Updated and new procedures/test cases in OCD published manuals, user's guides and/or validation guides were also verified.</p> <p>Comparison studies included reproducibility, analytical and clinical sensitivity and specificity studies. Additionally, studies evaluating cross contamination, on-board reagent/calibrator and sample stability were performed on the ORTHO VERSEIA® Integrated Processor only.</p>
<p>Conclusion of Testing</p>	<p>Conclusion: The successful non-clinical testing demonstrates the safety and effectiveness of the ORTHO® Summit System with the ORTHO VERSEIA® Integrated Processor 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.</p>