510(k) Summary

510(k) #: BK251238

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Contact Details 21 CFR 807.92(a)(1)

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Device Name 21 CFR 807.92(a)(2)

Device Trade Name:

ORTHO VISION® Analyzer

ORTHO VISION Max® Analyzer

Common Name: ORTHO VISION® / ORTHO VISION® Max

Classification Name: System, Test, Automated Blood Grouping and Antibody

Regulation Number: 864.9175

Product Code(s): KSZ

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name	Product Code
BK210557	ORTHO VISION® Analyzer	KSZ
BK210564	ORTHO VISION® Max Analyzer	KSZ

Device Description Summary 21 CFR 807.92(a)(4)

ORTHO VISION® / VISION® Max Analyzer is a reusable multi-patient instrument designed to automate in vitro immunohematology testing of human blood utilizing ID-MTS™ gel card technology. ORTHO VISION® / VISION® Max Analyzer automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation, and data management requirements using cards and digital image processing. ORTHO VISION® / VISION® Max Analyzer can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).

The modification to the ORTHO VISION® Analyzer and ORTHO VISION® Max Analyzer is for the addition of the Immunohematology Anti-Human Globulin Anti-IgG (Rabbit)/Anti-C3b,-C3d (Murine Monoclonal)/DAT Control, MTS™ DAT Card (referred as the MTS™ DAT Card). The MTS™ DAT Card includes qualitative tests in the ID-MTS™ column agglutination technology (CAT) format for the differentiation of (patient or donor) human red blood cells sensitized in vivo by IgG type immunoglobulins or complement C3b and / or C3d components using the ORTHO® Workstation, ORTHO VISION®, and ORTHO VISION® Max platforms.

The addition of the MTS™ DAT Card test to the ORTHO VISION® Analyzer and ORTHO VISION® Max Analyzer test menu requires a modification to the analyzer Assay Data Disk (ADD). The ADD is a data file which contains processing parameters used by the analyzer software. There are no changes required to the analyzer software or hardware for this ADD modification. However, a new punch tool has been added to open the foil seal on the microtubes of the MTS™ DAT Card required for each sample to be tested. MTS™ Gel Cards have punch tools specific to microtubes that need to be accessed for pipetting sample required for the specific test to be performed.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

ORTHO VISION® / ORTHO VISION® Max Analyzer is an instrument designed to automate in vitro immunohematology testing of human blood utilizing ID-MTS™ gel card technology. ORTHO VISION® / ORTHO VISION® Max Analyzer automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation, and data management requirements using cards and digital image processing. ORTHO VISION® / ORTHO VISION® Max Analyzer can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).

Comparison to Predicate Devices 21 CFR 807.92(a)(6)

There are no changes required to the analyzer software or hardware for the addition of the MTS™ DAT Card to the test menu.

Device Characteristic	**Predicate Devices** ORTHO VISION® Analyzer (BK210557) ORTHO VISION® Max Analyzer (BK210564)	**Modified Devices** ORTHO VISION® Analyzer (BK210557) ORTHO VISION® Max Analyzer (BK210564) [Addition of the MTS™ DAT Card to the instrument test menu]
Intended Use	ORTHO VISION® / ORTHO VISION® Max Analyzer is an instrument designed to automate in vitro immunohematology testing of human blood utilizing ID-MTS™ gel card technology. ORTHO VISION® / ORTHO VISION® Max Analyzer automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation, and data management requirements using cards and digital image processing. ORTHO VISION® / ORTHO VISION® Max Analyzer can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).	Same

Device Characteristic	**Predicate Devices** ORTHO VISION® Analyzer (BK210557) ORTHO VISION® Max Analyzer (BK210564)	**Modified Devices** ORTHO VISION® Analyzer (BK210557) ORTHO VISION® Max Analyzer (BK210564) [Addition of the MTS™ DAT Card to the instrument test menu]
Classification	Name: Automated blood grouping and antibody test system Device Class: II Product Code: KSZ	Same
Test Method	Column agglutination technology (CAT) using ID-MTS™ Gel Cards and reagents	Same
Sample Types	• Centrifuged whole blood (anticoagulated) • Plasma or serum • Packed red blood cells • 3-5% red cell suspension (pre-diluted patient/donor) • 0.8% red cell suspension (pre-diluted patient/donor)	Same
Reaction Grading	Digital Image Capture and Analysis for reaction grading	Same
Result Interpretation	According to pre-defined rules as part of the software	Same
Measurement	Qualitative	Same
Image	High resolution color image	Same
Barcode Symbologies	• Codabar • ISBT 128 • Code 128 • Code 3 and 9 • Code 2 and 5 (Interleaved)	Same
Interface	Bidirectional Laboratory Information System (LIS) or standalone	Same
Automated Analysis	Instrument automates test processing functions including liquid pipetting, reagent handling, incubation, centrifugation, reaction grading and interpretation, and data management requirements.	Same
Test Menu	MTS™ DAT Card is not available	Addition of the MTS™ DAT Card to the test menu
Punch Tools	MTS™ DAT Card punch tool is not available	Addition of the MTS™ DAT Card punch tool

Non-Clinical and Clinical Tests Summary 21 CFR 807.92(b)

Non-Clinical Performance

Nonclinical tests were performed to support the safety, effectiveness, and performance of the MTS™ DAT Card on the ORTHO VISION® / VISION® Max Analyzer.

Testing demonstrated that environmental conditions, extreme to nominal ORTHO VISION® / ORTHO VISION® Max Analyzer specifications of temperature and humidity, have no impact on the assay performance of the MTS™ DAT Card. For both test platforms, repeatability within run and between analyzers across two validation lots of MTS™ DAT Cards resulted in 100% agreement and over 99% concordance at the lower bound of the 95% confidence limit. Testing also demonstrated that the current MTS™ Gel Card serological timeout restrictions for Anti-Human Globulin formulations used for direct antiglobulin testing (DAT) may be applied to the MTS™ DAT Card for use on the ORTHO VISION® and ORTHO VISION® Max Analyzers.

Assay performance of the Anti-IgG, Anti-C3b, -C3d, and DAT Control formulations is acceptable with samples collected in the anticoagulant recommended for DAT testing, ethylenediaminetetraacetic acid (EDTA), and processed on the ORTHO VISION® / VISION® Max Analyzer. Sample stability for patient and donor samples drawn into EDTA was confirmed to be consistent with the MTS™ Gel Card customer Instructions for Use, maintaining the recommendation to run samples within 24 hours of collection. Additionally, MTS™ DAT Card assay performance using hemolyzed samples was evaluated to confirm that hemolysis may interfere with the test interpretation when run on the ORTHO VISION® / VISION® Max Analyzer. The results confirmed that testing with heavily hemolyzed samples may result in interference with test interpretation. MTS™ DAT Card assay performance was also evaluated to demonstrate that cell washing does not affect test results when run on the ORTHO VISION® / VISION® Max Analyzer. There was 100% concordance between Test results and paired Control results. Assay performance was not compromised by washing cells with saline three times.

Internal testing was performed to verify acceptable agreement between the MTS™ DAT Card and comparator tube methods (ORTHO® Anti-IgG and BioClone® Anti-C3b, -C3d) when used on the ORTHO VISION® Analyzer and the ORTHO VISION® Max Analyzer.

Conclusion

All nonclinical testing results for the use of the MTS™ DAT Card on the ORTHO VISION® / VISION® Max Analyzer met their acceptance criteria. The successful nonclinical testing demonstrates that each MTS™ DAT Card formulation run on the ORTHO VISION® / VISION® Max Analyzer is substantially equivalent to the legally marketed predicate devices for the defined indications for use.

Clinical Performance

Clinical equivalency testing was performed at four sites (two external and two internal sites) that routinely perform immunohematology testing. Random clinical specimens including donors and patients (N=2778) were tested on the ORTHO VISION® / VISION® Max Analyzer.

Random sample results were assessed on a microtube-to-tube test basis using a paired sample comparison between the comparator tube method and the gel card microtube under evaluation. For reaction grades to be concordant between methods either both results had to be negative, or both had to be positive (any reaction grade 1+ through 4+). For the tube test method, a weak reaction was considered positive when comparing to the gel card microtube. The combined results from all sites are summarized in the following table. Percent agreement indicates concordance between the two assays and does not indicate which method gave the correct result. The results below do not reflect testing to resolve initial discrepant results between methods.

Anti-IgG and Anti-C3b,-C3d Microtube Concordance

Random Clinical Specimens									
All Sites Combined	**Total**			**Positive**			**Negative**		
Test	**N**	**Percent Agreement**	**Lower Bound of 95% CI**	**N***	**Percent Agreement**	**Lower Bound of 95% CI**	**N**	**Percent Agreement**	**Lower Bound of 95% CI**
Anti-IgG	2778	98%	98%	28	64%	47%	2750	99%	98%
Anti-C3b,-C3d	2778	99%	99%	9	56%	25%	2769	99%	99%
Control	All samples demonstrated negative results in the Control microtube.								

The combined total percent agreement and negative percent agreement (NPA) at the lower bound of the 95% confidence interval met the NPA requirement for direct antiglobulin tests of ≥ 95% agreement at the lower bound of the 95% confidence interval when testing random patient and donor samples on the ORTHO VISION® / VISION® Max Analyzer and in all microtube formulations.

The positive percent agreement (PPA) was 56% for the Anti-C3b,-C3d microtube formulation and 64% for the Anti-IgG microtube formulation for random patient and donor samples. There was a low frequency (1.3% to 1.4%) of random DAT positive patient and donor samples across the full study. If all random positive samples were concordant, the lower bound of the 95% CI would still not meet the minimal requirement of ≥ 95%.

Due to the small sample size of random positives, IgG and C3 contrived positive samples were used to support intended use for positive results. 203 well-characterized, contrived positive samples were tested and met a 100% point estimate agreement on the ORTHO VISION® and VISION® Max Analyzers. Testing of contrived positive samples coated with clinically significant IgG antibodies and components of complement across a range of reaction strengths further supports acceptable performance of the MTS™ DAT Card reagents.

Taking into consideration the clinical utility of the Direct Antiglobulin Test, as well as the fact that the DAT result is used in conjunction with patient history and other prognostic indicators, there is no expectation that the low PPA resulting from random donor and patient sampling encountered in the MTS™ DAT Card clinical trials would translate to a negative impact on patient care when used as intended for suspected hemolytic disease states and not as a random diagnostic immunohematology test.

The clinical evaluation study of the MTS™ DAT Card showed acceptable performance in the intended use environment.

Basis for Claim of Substantial Equivalence

This Traditional 510(k) is submitted to modify legally marketed devices (predicates). Ortho Clinical Diagnostics, Inc. is the holder of the 510(k)s for the predicate devices. The Indications for Use of the proposed devices are unchanged from the legally marketed devices (predicates). The intended use of the modified devices, as described in the labeling, has not changed as a result of the modifications. The fundamental scientific technology of the proposed devices is unchanged from the legally marketed devices

(predicates). There are no significant differences between the modified instruments and the predicates related to the Intended Use or Principle of Operation. With the exception of the addition of the MTS™ DAT Card to the test menu, the predicate and modified devices are identical.

The modified ORTHO VISION® and VISION® Max Analyzers are as safe and effective as the currently marketed predicates under BK210557 and BK210564, respectively.