7.0 510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: BK190399

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Trade or Proprietary Name:	ORTHO VISION® Max Analyzer
Common Name:	Automated Blood Bank Analyzer
Classification Name:	Automated Blood Grouping and Antibody Test System Device Class**:** II Product Code: KSZ Regulation Number: 21 CFR 864.9175

Device Indication For Use:	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® 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® Max Analyzer can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).

Identification of the Legally Marketed Device (Predicate Device):	ORTHO VISION® Analyzer, BK190338 Classification Name: Automated Blood Grouping and Antibody Test System Device Class: II Product Code: KSZ Regulation Number: 21 CFR 864.9175

Device Features Controlled by Software

The system software controls the operation of the system. The primary functions of the ORTHO VISION® Max Analyzer software are listed below:

- Identify samples, reagents, diluents and cards
- Control operation of the system:
    - Identify materials (cards, reagents, diluents and system fluids) required to process tests and warn operators if insufficient quantities are detected
    - Verify positions of barcoded samples and reagents on the sample and reagent racks
    - Execute tests
    - Monitor hardware functions such as incubator temperatures, centrifugation speed and other critical operations
    - Track partially used cards for reuse prioritization
    - Identify and bring forward cards that require manual review
    - Liquid metering
    - Manage incubation time of cards
    - Manage centrifugation
- Interpret test results
- Grade test results
- Store data of test results in short-term and long-term archives
- Download test requests from LIS and update test results to LIS
- Track operator and system actions
- Inform operators of maintenance and quality control schedules

Device Comparison Table

Ortho is claiming that the ORTHO VISION® Max Analyzer is substantially equivalent to the currently marketed version of the ORTHO VISION® Analyzer originally cleared under 510(k) BK190338 on July 9, 2019.

Table 1 - Device Comparison Table

Characteristic	**ORTHO VISION® Analyzer (Predicate: BK190338)**	**ORTHO VISION® Max Analyzer (New Device)**
Intended Use: Automated immunohematology instrument for in vitro diagnostic use	ORTHO VISION® Analyzer is an instrument designed to automate in vitro immunohematology testing of human blood utilizing ID-MTS™ gel card technology. ORTHO VISION® 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® Analyzer can be used as a standalone instrument or interfaced to the customer's Laboratory Information System (LIS).	Same
Testing:		
ABO and Rh Typing	X	Same
Antibody Screen	X	Same
Antibody Identification	X	Same
Crossmatch	X	Same

Characteristic	ORTHO VISION® Analyzer (Predicate: BK190338)	ORTHO VISION® Max Analyzer (New Device)
Direct Antiglobulin	X	Same
Antigen Testing	X	*Same
QC Testing	X	Same
Serial Dilution for Titration Studies	X	Same
Specimen Types:		
Plasma	X	Same
Serum	X	Same
Red Cells	X	Same
Reagent Types:		
ID-MTS™ Gel Cards	X	Same
Reagent Red Blood Cells	X	Same
Reagent Sera	X	Same
Potentiator	X	Same
Decontaminating Fluid	X	Same
Diluents	X	Same
Quality Control	X	Same
Capacity:		
Sample	42 tubes	84 tubes
ID-MTS™ Gel Cards	120 Cards (6 sleeves of 20 cards)	200 Cards (10 sleeves of 20 cards)

Characteristic	ORTHO VISION® Analyzer (Predicate: BK190338)	ORTHO VISION® Max Analyzer (New Device)
Red Cell Reagent	3mL – 33 vials or 10mL – 18 vials *Or various combinations*	3mL – 66 vials or 10mL – 36 vials *Or various combinations*
Sera Blood Grouping Reagent	**Four – 5 mL vials per tray -up to 48 vials	Same
Diluent, Potentiator, Decontaminating Fluid	four – 10 mL bottles and four– 100 mL bottles	***Same
Heated Incubator	12 cards	Same
Room Temperature Incubator	24 cards	Same
Centrifuge	2 centrifuges; 10 cards per centrifuge	Same
Liquid Waste	5.4 liters or Optional Direct Drain	Same
Solid Waste	80 cards	140 cards Or Optional External
Manual Entry of Sample Ids or Reagent Data:		
Requires Double Blind Entry	X	Same
Reagent Red Cell:		
Suspension by Rotational Movement	X	Same

Characteristic	ORTHO VISION® Analyzer (Predicate: BK190338)	ORTHO VISION® Max Analyzer (New Device)
On Analyzer Storage of red blood cells	X	Same
Reagent Sera, Potentiator, Decontamination Fluid:		
On Analyzer Storage of sera	X	Same
On Analyzer Storage of potentiator	X	Same
On Analyzer Storage of decontaminating fluid	X	Same
Metering:		
Volume Verification	X	Same
Probe for Reagent and Samples	one	Four
Results:		
Digital Image Capture	X	Same
Digital Image Viewing Capability	X	Same
Color Image	X	Same
Barcode Reading:		
Sample Identification	X	Same
Reagent Lot No. and Expiration Date	X	Same
Barcode Symbologies:		

Characteristic	ORTHO VISION® Analyzer (Predicate: BK190338)	ORTHO VISION® Max Analyzer (New Device)
Codabar	X	Same
ISBT 128	X	Same
Code 128	X	Same
Code 3 of 9	X	Same
Code 2 of 5 (Interleaved)	X	Same
Incubator:		
Heated	37˚C	Same
Room Temperature	24˚C +/- 3˚C	Same
Centrifuge:		
Centrifuge	Speed : 1014 RPM	Same
Computer:		
Operating System	Windows Embedded Standard 7 SP1 (64 Bit)	Same
Master Computer	Minimum speed: 2.1 GHz	Same
User Password Protected	X	Same
Laboratory Information System Interface	X	Same

* Antigen Typing for the Predicate Device is executed using pre-filled cards, where the active antibodies of particular specificity are pre-filled in card columns, requiring only the addition of sample red blood cells for the reaction. For the New Device, those same assays are available, however, thirteen new antigen typing tests are added to the menu by means of dispensing ORTHO™ Sera Blood Grouping Reagents of a particular specificity to columns filled with either ID-MTS™ IgG or buffered gel cards, followed by the addition of sample red blood cells.

** ORTHO™ Sera Blood Grouping Reagents are loaded on the ORTHO™ Sera Reagent rack, which has a capacity for four 5 mL vials. ORTHO™ Sera Reagent Racks can be loaded in any one or more of six loading sectors on the Load Station outer rotor. Additionally, the potentiator and decontaminating fluid required for some of the ORTHO™ Sera tests can be loaded in the ORTHO™ Sera Reagent Rack.

*** The potentiator and decontaminating fluid required for some of the ORTHO™ Sera tests can be loaded in the 10 mL locations of the Diluent Rack, in addition to the ORTHO™ Sera Reagent Rack.

Performance Testing Summary

Appropriate types of non-clinical and clinical testing were performed for the ORTHO VISION® Max Analyzer with ORTHO™ Sera.

Non-clinical Testing

Electromagnetic compatibility (EMC) testing was conducted according to FCC Part 15 Class A and IEC 61326 Standard. Product safety testing was conducted according to UL/CSA/IEC 61010 Standard. Transportation studies were conducted using established methods. Software testing included unit, integration and requirements based (system level) testing. Performance testing included on analyzer stability of reagent red blood cells and diluents, interference, serial dilution, repeatability/reproducibility, and environmental testing.

Clinical Testing

An external assay migration evaluation was performed at three (3) sites. Testing was specifically designed to exercise intended use and instrument functionality. A total of 16,034 samples were successfully assayed on the ORTHO VISION® Max Analyzer, representing a total of 16,034 microtubes. Specimens represented diverse population groups in broad geographic areas and were composed of samples sourced through the sites, representing patient and blood donors.

Performance Testing

ORTHO™ Sera comprise a range of 13 blood grouping reagents developed by Alba Bioscience Limited (Alba) and marketed by Ortho Clinical Diagnostics (Ortho). These reagents are intended for manual use on the ID-Micro Typing System™ (ID-MTS™) Gel Test (MTS™ Gel Cards) and automated use on the ORTHO VISION® Max Analyzer. Acceptable assay performance of ORTHO™ Sera Blood Grouping Reagents has been demonstrated on ORTHO VISION® Analyzer at an external field trial conducted at three sites. Data from this trial have previously been submitted and approved for use by FDA. To support the use of ORTHO™ Sera reagents on the ORTHO VISION® Max Analyzer, performance testing (bench) was executed at Alba Bioscience Limited and performance testing (clinical) was executed at 3 external sites in the United States.

Verification and validation data supporting the use of the ORTHO™ Sera Blood Grouping Reagents on the ORTHO VISION® Max Analyzer, has been generated through the execution of the following performance testing studies:

- Reagent carryover verification
- On Analyzer Stability (OAS) verification
- Serological Timing Restrictions (STR) verification, incorporating assay temperature sensitivity

These studies were conducted for the ORTHO VISION® Max Analyzer using Ortho reagents (Reagent Red Blood Cells [RRBC] and diluents), ORTHO™ Sera Blood Grouping Reagents and ID-MTS™ Gel Cards and demonstrated that;

- No carryover was observed using the final wash protocol designs and met the acceptance criteria.
- After exposure to environmental conditions that are expected to be worst case for ORTHO™ Sera stability (i.e. high temperature (35 °C) and low humidity (15% RH), the reagents remained stable and performed as expected at all test points. Exposure of the ORTHO™ Sera Blood Grouping Reagents to the increased temperature and low humidity environment did not impact performance through repeated cycles of on-board use.
- The STR assessment of the ORTHO™ Sera reagents on ID-MTS™ Gel Cards met the acceptance criteria. The STR values which were established and subsequently verified during this study, were incorporated into the analyzer software update utilized for the migration of the ORTHO™ Sera Blood Grouping Reagents to the ORTHO VISION® Max Analyzer.

An external Assay Migration Study demonstrated that performance of the ORTHO™ Sera Blood Grouping Reagents on the ORTHO VISION® Max Analyzer is substantially equivalent to the ORTHO VISION® Analyzer.

Testing was performed in an intended use environment at three external US test sites to demonstrate that assays performed using ORTHO™ Sera Blood Grouping Reagents on the ORTHO VISION® Max Analyzer returned comparable assay performance to that achieved with the ORTHO VISION® Analyzer. Testing on the ORTHO VISION® Analyzer was used as the direct comparator (predicate) method.

Results from the migration study are summarized in Table 2 below and demonstrate substantial equivalence for ORTHO™ Sera Blood Grouping Reagents used on the ORTHO VISION® Max Analyzer, as compared to the ORTHO VISION® Analyzer.

Table 2 - ORTHO™ Sera Migration Study

ORTHO™ Sera	Antigen Positive/Negative	Number of Samples Tested	Comparator Analysis	
			% Agreement	One sided 95% CI
ORTHO™ Sera Anti-N	Positive	690	100.0	99.6
	Negative	609	99.7	99.0
ORTHO™ Sera Anti-Le[a]	Positive	602	100.0	99.5
	Negative	659	99.7	99.1
ORTHO™ Sera Anti-Le[b]	Positive	713	100.0	99.6
	Negative	603	99.2	98.3[1]
ORTHO™ Sera Anti-D (DVI)	Positive	650	100.0	99.5
	Negative	696	100.0	99.6
ORTHO™ Sera Anti-D (IAT)	Positive	609	100.0	99.5
	Negative	636*	99.4	98.6
ORTHO™ Sera Anti-Fy[a]	Positive	630	100.0	99.5
	Negative	618*	99.7	99.0
ORTHO™ Sera Anti-Fy[b]	Positive	607	100.0	99.5
	Negative	613*	99.0	98.1
ORTHO™ Sera Anti-Jk[a]	Positive	636	99.8	99.3
	Negative	610	100.0	99.5
ORTHO™ Sera Anti-Jk[b]	Positive	689	100.0	99.6
	Negative	697	99.9	99.3
ORTHO™ Sera Anti-S	Positive	618	100.0	99.5
	Negative	611*	99.7	99.0
ORTHO™ Sera Anti-s	Positive	675	100.0	99.6
	Negative	300	100.0	99.0
ORTHO™ Sera Anti-K	Positive	308	100.0	99.0
	Negative	695	99.7	99.1
ORTHO™ Sera Anti-P1	Positive	659*	99.4	98.6[2]
	Negative	601	99.8	99.2

CI = Confidence Interval

[1] Five discordant results occurred during ORTHO Sera Anti-Le^b (Murine Monoclonal) Assay Migration for which a root cause could not be determined, (see P0171_D0072 for root cause investigation). All five results are included in ORTHO Sera Anti-Le^b (Murine Monoclonal) percentage concordance analysis. The one-sided exact 95% LCL of negative percent agreement (NPA) was 98.3% based on the comparison of interpreted results.

[2] Discordant resolution testing determined that one sample had a weak expression of the P1 antigen which was detected on the ORTHO VISION® Analyzer. A root cause could not be determined for the discordant results between test platforms for two samples (see P0171_D0073 for root cause investigation). The one-sided exact 95% LCL of negative percent agreement (NPA) was 98.6% based on the comparison of interpreted results.

* Number of samples includes the following samples which tested as DAT positive: Anti-D(IAT) – 3; Anti-Fy^a – 2; Anti-Fy^b – 5; Anti-S – 2; Anti- P1 – 2.

Reproducibility/repeatability testing was performed at the same three external US trial sites as the migration testing to demonstrate precision performance under established conditions. The performance of all 13 ORTHO™ Sera specificities was assessed on the ORTHO VISION® Max Analyzer.

Reproducibility and repeatability across all assays was 99.4% and 99.6% for negative percent agreement (NPA) and positive percent agreement (PPA), respectively, at the one-sided exact 95% LCL. Any variation in the returned positive sample reaction grades was no greater than 1 grading unit, confirming the suitability of ORTHO™ Sera Blood Grouping Reagents for use on the ORTHO VISION® Max Analyzer.

Substantial Equivalence Conclusion

The successful non-clinical testing and clinical testing demonstrates the ORTHO VISION® Max Analyzer with ORTHO™ Sera is substantially equivalent to the legally marketed ORTHO VISION® Analyzer predicate device for the claimed indications for use.