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: BK190338

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Trade or Proprietary Name:	ORTHO VISION® 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® 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).

Identification of the Legally Marketed Device (Predicate Device):	ORTHO VISION® Analyzer 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 for 510(k) Summary

The system software controls the operation of the system. The primary functions of the ORTHO VISION® 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 for 510(k) Summary

Ortho is claiming that the ORTHO VISION® Analyzer is substantially equivalent to the currently marketed version of the ORTHO VISION® Analyzer originally cleared under 510(k) BK140207 on August 14, 2015.

The ORTHO VISION® Analyzer has the same Intended Use as the legally marketed predicate device. The differences in technological characteristics do not raise different questions of safety and effectiveness. Non-clinical performance testing included on analyzer stability of reagent red blood cells and diluents, interference, serial dilution, repeatability/reproducibility, and environmental testing. A clinical evaluation was performed at three (3) external sites. Testing was specifically designed to exercise intended use and instrument functionality. Specimens represented diverse population groups in broad geographic areas and were composed of samples sourced through the sites, representing patient and blood donors. The successful non-clinical testing and clinical testing demonstrate the ORTHO VISION® Analyzer is substantially equivalent to the legally marketed predicate device for the defined indications for use.

Table 1 - Device Comparison Table

Characteristic	**ORTHO VISION® Analyzer (Predicate: BK140207)**	**ORTHO VISION® 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 the 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

Characteristic	ORTHO VISION® Analyzer (Predicate: BK140207)	ORTHO VISION® Analyzer (New Device)
Testing:		
ABO and Rh Typing	X	Same
Antibody Screen	X	Same
Antibody Identification	X	Same
Crossmatch	X	Same
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	Not available	X
Potentiator	Not available	X
Decontaminating Fluid	Not available	X
Diluents	X	Same
Quality Control	X	Same

Characteristic	**ORTHO VISION® Analyzer (Predicate: BK140207)**	**ORTHO VISION® Analyzer (New Device)**
Capacity:		
Sample	42 tubes	Same
ID-MTS™ Gel Cards	120 Cards (6 sleeves of 20 cards)	Same
Red Cell Reagent	3mL – 33 vials or 10mL – 18 vials *Or various combinations*	Same
Sera Blood Grouping Reagent	Not available	**Four – 5 mL vials per tray
Diluent, Potentiator, Decontaminating Fluid	Two – 10 mL bottles and Two – 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	Same
Manual Entry of Sample Ids or Reagent Data:		
Requires Double Blind Entry	X	Same
Reagent Red Cell:		

Characteristic	**ORTHO VISION® Analyzer (Predicate: BK140207)**	**ORTHO VISION® Analyzer (New Device)**
Suspension by Rotational Movement	X	Same
On Analyzer Storage of red blood cells	X	Same
Reagent Sera, Potentiator, Decontamination Fluid:		
On Analyzer Storage of sera	Not available	X
On Analyzer Storage of potentiator	Not available	X
On Analyzer Storage of decontaminating fluid	Not available	X
Metering:		
Volume Verification	X	Same
Single Probe for Reagent and Samples	X	Same
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

Characteristic	ORTHO VISION® Analyzer (Predicate: BK140207)	ORTHO VISION® Analyzer (New Device)
Barcode Symbologies:		
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.