

## **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 BK160058.

---

**Submitter:** Ortho-Clinical Diagnostics, Inc.

**Address:** 1001 US Route 202  
Raritan, NJ 08869-0606

**Telephone number** 908-218-8085  
**Fax number** 908-218-8168

**Contact Person:** Kristine Tkacs

**Preparation Date:** June 22, 2016

---

**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  
 Classification Name: Automated Blood Grouping and Antibody Test System  
 Device Class: II  
 Product Code: KSZ  
 Regulation Number: 21 CFR 864.9175

Device Comparison Table for 510(k) Summary

Characteristic	ORTHO VISION Analyzer (Predicate)	ORTHO VISION Max Analyzer (New Device)
<b>Intended Use:</b>		
Automated immunohematology instrument for in vitro diagnostic use	<p>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).</p>	<p>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).</p>
<b>Testing:</b>		
ABO and Rh Typing	X	Same
Monoclonal Rh Phenotyping	X	Same
Antibody Screen	X	Same

<b>Characteristic</b>	<b>ORTHO VISION Analyzer (Predicate)</b>	<b>ORTHO VISION Max Analyzer (New Device)</b>
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
<b>Specimen Types:</b>		
Plasma	X	Same
Serum	X	Same
Red Cells	X	Same
<b>Reagent Types:</b>		
ID-MTS™ Gel Cards	X	Same
Reagent Red Blood Cells	X	Same
Diluents	X	Same
Quality Control	X	Same
<b>Capacity:</b>		
Sample	42 tubes	84 tubes
ID-MTS™ Gel Cards	120 Cards (6 sleeves of 20 cards)	200 Cards (10 sleeves of 20 cards)

<b>Characteristic</b>	<b>ORTHO VISION Analyzer (Predicate)</b>	<b>ORTHO VISION Max Analyzer (New Device)</b>
Reagent	3 mL – 33 vials or 10 mL – 18 vials <i>Or various combinations</i>	3 mL – 66 vials or 10 mL – 36 vials <i>Or various combinations</i>
Diluent	2 – 10 mL bottles and 2 – 100 mL bottles	4 – 10 mL bottles and 4 – 100 mL bottles
Heated Incubator Card Capacity	12	Same
Room Temperature Incubator Capacity	16	24
Centrifuge	2	Same
Liquid Waste	5.4 liters or Optional Direct drain	Same or Option 10 liter External Bottle
Solid Waste	80 Cards	140 Card or Optional External
<b>Manual Entry of Sample Ids or Reagent Data:</b>		
Requires Double Blind Entry	X	Same
<b>Reagent Red Cell:</b>		
Suspension by Rotational Movement	X	Same
On Analyzer Storage of red blood cells	X	Same
<b>Metering:</b>		
Volume Verification	X	Same

<b>Characteristic</b>	<b>ORTHO VISION Analyzer (Predicate)</b>	<b>ORTHO VISION Max Analyzer (New Device)</b>
Probe for Reagent and Samples	1	4
<b>Results:</b>		
Digital Image Capture	X	Same
Digital Image Viewing Capability	X	Same
Color Image	X	Same
<b>Barcode Reading:</b>		
Sample Identification	X	Same
Reagent Lot No. and Expiration Date	X	Same
<b>Barcode Symbologies:</b>		
Codabar	X	Same
ISBT 128	X	Same
Code 128	X	Same
Code 3 of 9	X	Same
Code 2 of 5 (Interleaved)	X	Same
<b>Incubator:</b>		
Heated	X	Same
Room Temperature	X	Same
<b>Centrifuge:</b>		
Centrifuge	X	Same

Characteristic	ORTHO VISION Analyzer (Predicate)	ORTHO VISION Max Analyzer (New Device)
<b>Computer:</b>		
Microsoft Windows Operating System 7	X	Same
Master Computer Minimum speed	2.1 GHz	Same
User Password Protected	X	Same
Laboratory Information System Interface	X	Same

**New Feature:**

The ORTHO VISION Max analyzer instrument includes a Larger Capacity Throughput than the ORTHO VISION Analyzer.