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: BK190400

Submitter:	Ortho-Clinical Diagnostics, Inc.
Address:	1001 US Route 202 Raritan, NJ 08869-0606
Telephone number **Fax number**	585-453-4041 585-453-3368
Contact Person:	Marlene Hanna
Preparation Date:	December 13, 2019

Trade or Proprietary Name:	MTS™ Buffered Gel Card
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:	For the detection of antibodies to red blood cells For the detection of antigens to red blood cells For *in vitro* diagnostic use only For use with the ID-Micro Typing System™
Identification of the Legally Marketed Device (Predicate Device):	MTS™ Buffered Gel Card, BK190339 Classification Name: Automated Blood Grouping and Antibody Test System Device Class: II Product Code: KSZ Regulation Number: 21 CFR 864.9175

Device Comparison Table

Ortho is claiming that the MTS™ Buffered Gel Card for use on the ORTHO VISION® Max Analyzer is substantially equivalent to the currently marketed version of the MTS™ Buffered Gel Card for use on the ORTHO VISION Analyzer cleared under 510(k) BK190339 on July 8, 2019.

Table 1: Device Comparison Table – MTS™ Buffered Gel Card

Characteristic	MTS™ Buffered Gel Card (Predicate Device) (BK190339)	MTS™ Buffered Gel Card (Modified Device)
Analyzer	ORTHO VISION Analyzer	ORTHO VISION Max Analyzer
Intended Use	For the detection of antibodies to red blood cells by separation of agglutinated/non-agglutinated red blood cells.	For the detection of antibodies and antigens to red blood cells by separation of agglutinated/non-agglutinated red blood cells.
Physical format	separation occurs in a reagent medium contained within a molded plastic device	Same
Constitution	does not contain biological reagents	Same
Separation method	require centrifugation	Same

Reason for the Submission:

The changes described in this Special 510(k) are limited to an update to the Instructions for Use for the MTS Buffered Gel Card for use with the ORTHO VISION Max Analyzer. No changes have been made to the Intended Use aside from clarifying the use for detection of antigens to red blood cells. No changes have been made to the physical cards themselves.

Device Description

The MTS Buffered Gel Card does not contain any biological active ingredients. Each microtube contains a (b) (4) gel suspended in a (b) (4) buffer that does not contain antibodies, red cells, or potentiators. Typical use of this device would be Reverse ABO Blood Grouping and as a control test when using specific antibody cards. All the specific antibody cards are subject to separate product license approval.

Testing Summary

All verification and validation activities as required by a risk analysis demonstrated that predetermined acceptance criteria were met.

ORTHO™ Sera assay migration testing with ORTHO VISION® Max Analyzer was conducted to demonstrate that assays utilizing ORTHO™ Sera Blood Grouping Reagents and ORTHO™ Sera Papain manufactured by QUOTIENT and supported for use by manual MTS CAT (Column Agglutination Technology) test methods with MTS Buffered Gel Cards are suitable for migration to the ORTHO VISION® Max Analyzer.

Comparative testing was performed using the same ORTHO™ Sera reagents on the ORTHO VISION® Analyzer as per the product labeling. Results generated by manual tests were compared for equivalence in terms of positive or negative result to those from the same tests performed on ORTHO VISION® Max Analyzer.

The concordance of ORTHO™ Sera results between the ORTHO VISION® Analyzer (comparator System) and the ORTHO VISION® Max Analyzer (test system) are summarized in Table 2.

Table 2: MTS ORTHO Sera Migration Testing –ORTHO VISION® Max Analyzer Results Summary

	Number of Samples Tested (Positive Results)	% Agreement	One-sided 95% lower confidence limit (%)	Number of Samples tested (Negative Results)	% Agreement	One-sided 95% lower confidence limit (%)
ORTHO Sera Anti-D (DVI)	650	100.0	99.5	696	100.0	99.6
ORTHO Sera Anti-K	308	100.0	99.0	695	99.7	99.1
ORTHO Sera Anti-Jka	636	99.8	99.3	610	100.0	99.5
ORTHO Sera Anti-Jkb	689	100.0	99.6	697	99.9	99.3
ORTHO Sera Anti-Lea	602	100.0	99.5	659	99.7	99.1
ORTHO Sera Anti-Leb	713	100.0	99.6	603	99.2	98.3
ORTHO Sera Anti-N	690	100.0	99.6	609	99.7	99.0

Results from ORTHO™ Sera Assay Migration testing demonstrate consistent and reliable performance of the ORTHO™ Sera Blood Grouping Reagents with the MTS Buffered Gel Card when used on ORTHO VISION® Max Analyzer.

Substantial Equivalence Conclusion

The MTS™ Buffered Gel Card has the same Intended Use as the legally marketed predicate device, and there are no differences in technological characteristics. Data

demonstrates the MTS™ Buffered Gel Card on the ORTHO VISION® Max is substantially equivalent to the cleared predicate device, the MTS Buffered Gel Card on the ORTHO VISION® Analyzer, BK190339. The Instructions for Use were modified to add information to support the use of the MTS Buffered Gel Card on the ORTHO VISION Max Analyzer.