510(k) Summary

1. Submitter Name

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2. Contact Information

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3. Product Name
Trade name: Ortho ProVue™
Common Name: Automated blood grouping and antibody test system
Classification name: 21 CFR 864.9175

4. Device Description

Ortho ProVue™ is designed to allow for walkaway testing of direct agglutination, indirect antiglobulin, and direct antiglobulin tests utilizing the ID MTS/Gel cards. Ortho ProVue™ consists of:

- the instrument in which testing is conducted,
- a PC with the application software that allows the user to interface with the instrument,
- printer
- uninterrupted power supply (UPS)

5. Intended Use:

Ortho ProVue™ is a modular, microprocessor-controlled instrument designed to automate in vitro immunohematological testing of human blood utilizing the ID MTS/Gel Technology. As a standalone instrument or interfaced to the customer's laboratory information system (LIS), Ortho ProVue™ automates test processing functions and data management requirements using gel cards and digital image processing.

6. Predicate Devices

Immucor ABS2000, BK000024, BK010020
MTS SA™ Reader, BK000018

7. Comparison of technological characteristics

a. Intended Use Comparison

Function	Ortho ProVue™	ABS2000	Reader SA™
Automated bench top analyzer to perform in vitro serological analysis of blood specimens.	X	X	
Test Analysis includes:			
ABO and Rh Typing	X	X	
Antibody screening and identification, IgG Crossmatching)	X	X	
Antibody identification	X		
Crossmatch	X	X	
Direct Antiglobulin	X		
Antigen Typing	X		
Read test reactions by digital image capture	X		X
Test result interpretation	X	X	X

b. Technical Characteristics Comparison

Technical Characteristic	Ortho ProVue™	ABS2000	Reader SA™
Workstation utilized for instrument/user interface	X	X	X
System security requiring user password for system access	X	X	X
Testing performed on plasma	X	X	
Testing performed on serum	X		
Barcode read on reagent and samples to confirm presence and location on the instrument.	X	X	
Barcode read of reagent lot number and expiration date	X		

Technical Characteristic	Ortho ProVue™	ABS2000	Reader SA™
Manual entry of sample IDs or reagent data requiring double blind entry	X		
Acceptable reagent vial size	3 ml, 5ml, and 10 ml	10 ml	
Sample and reagent volume verification determined at aspiration.	X	X	
Prepare sample red cell suspension	X	X	
Two vials of same reagent can be loaded on instrument. When one empty instrument switches to second vial.	X	X	
Maintains reagent red cell suspension by rotational movement.	X		
Walk away testing capability	X	X	
Instrument will discontinue operation if liquid waste is full.	X		
Incubation temperature and duration monitored.	X	X	
Centrifugation performed at a consistent rpm range and duration	X	X	X
Dispense verification performed prior to result reading	X		
Reaction analysis of microtube well digital image capture and analysis	X		X
Reaction analysis of microtube by spectrophotometric method		X	
Blood type test results interpreted against standard industry interpretation tables.	X	X	X
Interface to laboratory information systems	X	X	X

8. Summary of non-clinical tests

A summary of the test type (direct agglutination, direct and indirect agglutination), percent concordance, lower 95% confidence bound for percent concordance from alpha testing is provided in in Table 1 below.

Table 1: Non-Clinical Indirect and Direct Antiglobulin Tests
Comparison of Results: Individual Tests

Test	Number of Tests	% Concordance	Lower 95% Confidence Bound
ABD/Reverse	636	100.00	99.53
ABD	180	100.00	98.35
Anti-C, Anti-E, Anti-c, Anti-e	81	100.00	96.37
Overall Direct Agglutination	**897**	**100.00**	**99.67**
Two-Cell Antibody Screen	250	99.60	98.12
Three-Cell Antibody Screen	291	99.60	98.97
Pooled Cell Antibody Screen	50	98.00	90.86
Panel A Antibody Screen	220	100.00	98.65
Crossmatch	34	100.00	91.57
DAT	21	100.00	86.70
Overall Direct and Indirect Antiglobulin	**866**	**99.31**	**98.64**
All Data	**1,763**	**99.66**	**99.33**

There were a total of 1,763 wells tested for the direct agglutination and direct and indirect Antiglobulin tests. The overall percent concordance was 99.66% with a lower 95% confidence bound of 99.33%. These data support the conclusion that Ortho ProVue™ performance is equivalent to the manual test method for both direct agglutination tests and direct and indirect antiglobulin tests.

9. Summary of clinical tests

A summary of the test type (direct agglutination, direct and indirect agglutination), percent concordance, lower 95% confidence bound for percent concordance from beta testing is provided in Table 2 below.

Table 2: Clinical Indirect and Direct Antiglobulin Tests
Comparison of Results: Individual Tests

Test	Number of Tests	% Concordance PVs vs Manual	Lower 95% Confidence Bound
ABD/Reverse	1830	99.67	99.35
ABD	537	100	99.44
Anti-C, Anti-E, Anti-c, Anti-e	140	100	97.88
Overall Direct Agglutination	**2507**	**99.76**	**99.53**
Two-Cell Antibody Screen	234	99.15	97.33
Three-Cell Antibody Screen	375	100	99.20
Pooled Cell Antibody Screen	227	100	98.69
Panel A Antibody Screen	253	98.42	96.42
Crossmatch	113	100	97.38
DAT(IgG)	215	97.21	94.57
DAT(IgGC3d)	176	99.43	97.33
Overall Direct and Indirect Antiglobulin	**1593**	**99.18**	**98.70**
All Data	**4100**	**99.54**	**99.32**

There were a total of 4100 wells tested for the direct agglutination and direct and indirect Antiglobulin tests. The overall percent concordance was 99.54% with a lower 95% confidence bound of 99.32%. These data support the conclusion that Ortho ProVue™ performance is equivalent to the manual test method for both direct agglutination tests and direct and indirect antiglobulin tests.

10. Conclusions drawn from testing

Verification testing demonstrates that the design outputs meet the design inputs fulfilling all design specifications. Alpha and Beta testing demonstrate that the intended use is met, the functional requirements are fulfilled, and the device is safe and effective.