5. 510(k) SUMMARY

Applicant Information:

Date Prepared:	June 29, 2007
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Device Information:

Device Name:	Galileo®
Common Name:	Automated Blood Bank Analyzer
Classification:	21 CFR 864.9175, Class II (BK040013)
Classification Name:	Automated blood grouping and antibody test system

Predicate Devices:
Ortho ProVue
Olympus PK 7200

Device Description and Intended Use
The Galileo is a microprocessor-controlled instrument designed to fully automate immunohematology in vitro diagnostic testing of human blood. The Galileo automates test processing, result interpretation and data management functions. The Galileo is designed to automate standard immunohematology assays using a microplate-based platform. Assays include ABO grouping and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, red blood cell phenotyping, antigen screening and infectious disease screening such as syphilis and cytomegalovirus (CMV). The antigen screening assays provide guidelines for the user to select antisera or dilute commercial blood grouping reagents

as a mechanism to pre-screen for antigen negative blood units that can then be subjected to confirmation using a licensed method.

This 510(k) summary applies to use of the red blood cell phenotyping assays and antigen screening assays using the Galileo instrument.

The Galileo is a closed system intended for use only with the reagents specified in the Galileo Operator Manual. The only exception is for antigen screening, where the user selects antisera for use in the procedure.

All of Galileo's functions are fully automated, including: sample and reagent handling, pipetting, incubation, washing, shaking, centrifugation, reading and interpretation of results. Automated process controls and error detection mechanisms significantly reduce or eliminate potential opportunities for user error and invalidate suspect results.

Comparison to Predicate Devices:
A comparison between Galileo and predicate devices is presented in the table below. The devices are compared based on technological characteristics and intended use.

Comparison of Technological Characteristics & Intended Use

Intended Use	Galileo	Ortho ProVue	Olympus PK 7200
Automated immunohematology analyzer for in vitro diagnostic use	X	X	X
Tests Performed:			
ABO & Rh Typing	X	X	X
Antibody Screen	X	X	
Antibody Identification	X	X	
Crossmatch	X		
IgG Crossmatch	X	X	
Direct Antiglobulin	X	X	
Red Blood Cell Phenotyping	X	X	
RBC Antigen Screening	X		X
CMV Antibody Testing	X		X
Syphilis Testing	X		X
Read Test reactions by digital image analysis	X	X	X
Test Result Interpretation	X	X	X

Technical Characteristics Comparison

Technical Characteristics	Galileo	Ortho ProVue	Olympus PK 7200
User interface using computer workstation	X	X	X
System security requires user passwords for access	X	X	X
Testing performed on plasma	X		X
Testing performed on serum		X	X[1]
Barcode read on reagent and samples to confirm presence and location on the instrument	X	X	X[2]
Barcode read of reagent lot number and expiration date	X	X	
Manual entry of sample or reagent barcode requiring double blind entry	X	X	
Acceptable reagent vial size	10mL[3] and 57mL	3, 5 and 10mL[3]	
Sample and reagent volume verification at aspiration	X		X
Programmed to track volume or usage of each reagent vial or plate	X		
Prepares sample red cell suspension	X	X	X
Multiple vials of same reagent can be loaded on instrument. When empty instrument switches to second vial.	X	X	
Maintains red cell suspensions by agitation	X	X	X
Walk away testing capability	X	X	X
Instrument will discontinue operation if liquid waste is full	X	X	
Incubation duration and temperature are monitored	X	X	X
Centrifuge performed at a consistent rpm range and duration	X	X	
Error message for dispense verification discrepancy prior to result reading	X	X	X
Blood type test results interpreted against standard industry interpretation tables	X	X	X
Can be interfaced to laboratory information systems	X	X	X

[1] **CMV and Syphilis repeat only**
[2] **Samples only**
[3] **Reagent volume in 10mL vial may vary**

Summary of Clinical Tests

Red Blood Cell Phenotyping

The results of the clinical validation support the conclusion that the Galileo blood bank analyzer is safe and effective for the automated execution of the red blood cell phenotyping assays. The results of the clinical studies demonstrated that end users, with proper training, could use the Galileo to perform the in vitro diagnostic test defined for Galileo and that the testing with specified reagents on the Galileo would generate results comparable to established reference methods.

- The performance of the Galileo for phenotyping using the Immucor Rh (C, c, E, e) and Kell phenotyping assays was equivalent to the reference method. Agreement between the Galileo and reference method ranged between 99.1% and 99.5% for the various antigens tested.

Antigen Screening

Field studies were conducted for the antigen screening assays. The results of the field studies support the conclusion that use of these assays on the Galileo blood bank analyzer, are effective means for the automated execution of pre-screening blood units for red blood cell antigens. Field studies demonstrated negative predictive value (NPV) at levels of greater than 0.95 for all three assays based on the samples that received confirmatory testing.

In conclusion, these studies demonstrate that the Galileo is an effective automated method for performing the Immucor Rh(C, c, E, e) and Kell Phenotyping and antigen screening assays.