5. 510(k) SUMMARY

Applicant Information:

Date Prepared:	January 31, 2006
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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:

Olympus PK 7200, Software Version 3.7 (BK930024)

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 and infectious disease screening such as syphilis and cytomegalovirus (CMV). This 510(k) summary applies to use of the Capture-S screening assay using the Galileo instrument.

The Galileo is a closed system intended for use only with the reagents specified in the Galileo Operator Manual.

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 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.

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

Technical Characteristics	Galileo	Olympus PK 7200
User interface using computer workstation	X	X
System security requires user passwords for access	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	X	

Technical Characteristics	Galileo	Olympus PK 7200
number and expiration date		
Manual entry of sample or reagent barcode requiring double blind entry	X	
Acceptable reagent vial size	10mL and 57mL	
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
Multiple vials of same reagent can be loaded on instrument. When empty instrument switches to second vial.	X	
Maintains red cell suspensions by agitation	X	X
Walk away testing capability	X	X
Instrument will discontinue operation if liquid waste is full	X	
Incubation duration and temperature are monitored	X	X
Centrifuge performed at a consistent rpm range and duration	X	
Error message for dispense verification discrepancy prior to result reading	X	X
Blood type test results interpreted against standard industry interpretation tables	X	X
Can be interfaced to laboratory information systems	X	X

Summary of Clinical Tests

Comparison of the test results by the Galileo method to the reference method was performed for the Capture-S screening assay. 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 Immucor Capture-S assay. 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 detection of IgG+IgM antilipid antibodies using the Immucor Capture-S assay was equivalent to the reference method.
    - The detection rate for reactive samples was 98.4% as compared to a 98.1% detection rate demonstrated by the reference method.
    - The detection rate for non-reactive samples was 99.9% as compared to a 99.1% detection rate demonstrated by the reference method
- Additionally, test results from the challenge samples show that the performance of the Galileo is reproducible.

In conclusion, these studies demonstrate that the Galileo is an effective automated method for performing the Immucor Capture-S in vitro diagnostic testing assay.