510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR§807.92.

Applicant Information

Date Prepared:	July 17, 2018
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Device Information

Trade Name:	Galileo Echo®
Model Number:	Product Code 0087000
Software Version:	1.4 SP1
Common Name:	Automated Blood Bank Analyzer
Classification Name:	Automated blood grouping and antibody test system
Regulation Number:	21CFR§864.9175
FDA Product Code:	KSZ

Predicate Device

Galileo Echo®, 510(k) number BK070016, cleared on June 14, 2007.

Device Description

The Galileo Echo is designed to automate standard immunohematology assays and to operate as a walk-away system, meaning the operator can leave the Galileo Echo to operate independently for periods of time. This leaves the operator free to carry out other tasks in the laboratory. Several unified principles have been integrated into the Galileo Echo system to support and to simplify the overall system operation.

The Galileo Echo is a closed system and can only be used with specified Immucor products.

The Galileo Echo is an ergonomically friendly and easy-to-use system. Features of the Galileo Echo system have been designed to maximize operator efficiency and thereby minimize result errors.

The Galileo Echo is a robotic instrument programmed to move micro-strips, liquid reagent fluids, and blood sample fluids to different processing areas for a given assay in the correct sequence, such as the incubator, the micro-well washing station, the centrifuge, and the reader.

The Galileo Echo microwell reader uses a CCD camera to capture an image of the microwell. The Galileo Echo software calculates a reaction value for each well based on a multi-feature image analysis. The Galileo Echo then assigns a result and interpretation to the well based on predefined criteria associated with the calculated reaction value. Some assay protocols require multiple test wells for a given blood sample interpretation, such as ABO and Rh (D) typing.

The Galileo Echo uses software to drive its mechanics and data processing. The operator uses hardware in combination with the software to operate and maintain the Galileo Echo.

All of Galileo Echo's functions are 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.

Intended Use

The Galileo Echo® is a microprocessor-controlled instrument designed to fully automate immunohematology *in vitro* diagnostic testing of human blood. The Galileo Echo automates test processing, result interpretation and data management functions. The Galileo Echo is designed to automate standard immunohematology assays using a micro-well strip-based platform. Assays include ABO grouping and Rh (D) typing, detection/ identification of IgG red blood cell antibodies, compatibility testing and red blood cell phenotyping.

The Galileo Echo® is for *in vitro* diagnostic use.

Comparison to Predicate Device's Technological Characteristics

A comparison between the proposed Galileo Echo and its predicate Galileo Echo (BK070016) is presented in the table below. There are no changes related to the technological characteristics of the instrument and no change to the intended use.

Technological Characteristics	**Galileo Echo (BK070016)**	**Galileo Echo (Proposed)**
Intended Use The Galileo Echo® is a microprocessor-controlled instrument designed to fully automate	**X**	**Same, no change**

immunohematology *in vitro* diagnostic testing of human blood. The Galileo Echo automates test processing, result interpretation and data management functions. The Galileo Echo is designed to automate standard immunohematology assays using a microstrip-based platform. Assays include ABO grouping and Rh (D) typing, detection/ identification of IgG red blood cell antibodies, compatibility testing and red blood cell phenotyping.		
Tests Performed:		
ABO & RhD Typing	**X**	**X**
Antibody Screen	**X**	**X**
Antibody Identification	**X**	**X**
IgG Crossmatch	**X**	**X**
Direct Antiglobulin Test	**X**	**X**
RH and Kell Phenotyping	**X**	**X**
Read test reactions by digital image analysis	**X**	**X**
Test result interpretation	**X**	**X**
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**	**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**	**X**
Manual entry of sample or reagent barcode requiring double blind entry	**X**	**X**
Acceptable reagent vial size	**10 mL**	**10 mL**
Sample and reagent volume verification at aspiration	**X**	**X**
Programmed to track volume or usage of each reagent vial or plate	**X**	**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**	**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**	**X**
Incubation duration and temperature are monitored	**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**
Blood type test results interpreted against standard	**X**	**X**

industry interpretation tables		
Can be interfaced to laboratory information systems	**X**	**X**

Nonclinical Performance Testing

As required, non-clinical studies were conducted in-house at Immucor to verify that the Galileo Echo's performance was not negatively impacted by the changes described in this submission.

Statement of Substantial Equivalence

In summary, the Galileo Echo described in this submission is substantially equivalent to the predicate device.