7.0 510(k) Summary

Date Prepared

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510(k) Owner

Immucor, Inc.
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Establishment Registration Number: 1034569

Contact Information

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Device Name

Trade/Device Name:	Echo Lumena®	Galileo Echo®
Common Name:	Automated Blood Bank Analyzer	Automated Blood Bank Analyzer
Classification Name:	Automated blood grouping and antibody test system	Automated blood grouping and antibody test system
Unique Device Identifier (UDI):	10888234002338	10888234001584

Device Class

Trade/Device Name:	Echo Lumena®	Galileo Echo®
Regulatory Class:	II	II
Product Code:	KSZ	KSZ
Regulation Number:	21CFR§864.9175	21CFR§864.9175
Classification Advisory Committee:	Hematology	Hematology
Review Advisory Committee:	Hematology	Hematology

Predicate Device Information

Trade/Device Name:	Echo Lumena®	Galileo Echo®
Clearance:	BK200483	BK200483
Date Cleared:	June 22, 2020	June 22, 2020

Device Description

Galileo Echo (v.2.0) is an upgrade of the Galileo Echo to bring that instrument up to the design and performance specifications of the Echo Lumena by replacement of camera and software components; both instruments are technologically and functionally identical.
The Galileo Echo (v.2.0) and Echo Lumena (hereafter “Echo” will refer to either instrument) are designed to automate standard immunohematology assays and to operate as walk-away systems, meaning you can leave the Echo to operate independently for periods of time. Several unified principles have been integrated into the Echo system to support and simplify the system’s overall operation.
The Echo uses two (2) basic methods of blood testing, namely hemagglutination and solid phase red cell adherence (SPRCA). Hemagglutination is used for red blood cell typing assays which includes ABO and Rh(D) typing and red blood cell phenotyping. Solid phase is used for antibody detection and identification assays, compatibility testing and weak D.
The Echo is a closed system and can only be used with specified Immucor products. The Echo is a robotic instrument programmed to move micro-well 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 Echo micro-well reader uses a CCD camera to capture an image of the micro-well. The Echo software calculates a reaction value for each well based on a multi-feature image analysis. The 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 Echo uses software to drive its mechanics and data processing. The operator uses hardware in combination with the software to operate and maintain the Echo.

Intended Use

The intended use of the modified devices, as described in the labeling, has not changed as a result of the modifications.

Echo Lumena:
The Echo Lumena is a microprocessor-controlled instrument designed to fully automate immunohematology in vitro diagnostic testing of human blood. The Echo Lumena automates test processing, result interpretation, and data management functions. The Echo Lumena is designed to automate standard immunohematology assays using a micro-well strip-based platform. Assays include ABO and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, and red blood cell phenotyping. The Echo Lumena is a closed system intended for use only with the reagents described in the Echo Lumena Operator Manual, Regional Attachment – North America- Echo Lumena Assay Reagents and Cutoffs.

Galileo Echo:
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 and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing and red blood cell phenotyping.
The Galileo Echo is a closed system intended for use only with the reagents described in the Galileo Echo Operator Manual, Regional Attachment – North America- Galileo Echo Assay Reagents and Cutoffs.

Technological Comparison to Predicate Device

Below is a summary of the technological characteristics of modified Echo Lumena and Galileo Echo (proposed devices) compared to the predicate devices (BK200483).

Properties/Features/ Characteristics	Predicates (BK200483)	Modified Echo Lumena and Galileo Echo	Comparison
Common Name	Automated Blood Bank Analyzer	Automated Blood Bank Analyzer	Identical
Classification	Class II	Class II	Identical
Regulation	21 CFR 864.9175	21 CFR 864.9175	Identical
Intended Use	Automated immunohematology analyzer for in vitro diagnostic use	Automated immunohematology analyzer for in vitro diagnostic use	Identical

Properties/Features/ Characteristics	Predicates (BK200483)	Modified Echo Lumena and Galileo Echo	Comparison
Indications for Use	Microprocessor controlled instrument designed to fully automate immunohematology in vitro diagnostic testing of human blood. Automates test processing, result interpretation, and data management functions. Designed to automate standard immunohematology assays using a micro-well strip-based platform. Assays include ABO and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, and red blood cell phenotyping.	Microprocessor controlled instrument designed to fully automate immunohematology in vitro diagnostic testing of human blood. Automates test processing, result interpretation, and data management functions. Designed to automate standard immunohematology assays using a micro-well strip-based platform. Assays include ABO and Rh (D) typing, detection/identification of IgG red blood cell antibodies, compatibility testing, and red blood cell phenotyping.	Identical
Tests Performed	ABO & RH Typing Antibody Screen Antibody Identification IgG Crossmatch Direct Antiglobulin Antigen Typing	ABO & RH Typing Antibody Screen Antibody Identification IgG Crossmatch Direct Antiglobulin Antigen Typing	Identical
Test Reactions Reading	Digital Image Analysis	Digital Image Analysis	Identical
User Interface	By Computer Workstation	By Computer Workstation	Identical
System Security requires user passwords for access	Yes	Yes	Identical
Testing performed on Plasma	Yes	Yes	Identical
Testing performed on serum	Yes	Yes	Identical
Barcode read on reagent and samples to confirm presence and location on the instrument	Yes	Yes	Identical
Barcode read of reagent lot number and expiration date	Yes	Yes	Identical
Manual entry of sample or reagent barcode requiring double blind entry	Yes	Yes	Identical
Acceptable reagent vial size	10 mL	10 mL	Identical
Sample and reagent volume verification at aspiration	Yes	Yes	Identical
Programmed to track volume or usage of each reagent vial or plate	Yes	Yes	Identical
Prepares sample red cell suspension	Yes	Yes	Identical
Multiple vials of same reagent can be loaded on instrument. When empty instrument switches to second vial	Yes	Yes	Identical
Maintains Reagent Red Cell suspensions by agitation	Yes	Yes	Identical
Walk away testing capability	Yes	Yes	Identical
Instrument will discontinue operation if liquid waste is full	Yes	Yes	Identical
Incubation duration and temperature are monitored	Yes	Yes	Identical

Properties/Features/ Characteristics	Predicates (BK200483)	Modified Echo Lumena and Galileo Echo	Comparison
Centrifuge performs at a consistent rpm range and duration	Yes	Yes	Identical
Can be interfaced to laboratory information systems	Yes	Yes	Identical
Camera Model/ module	Lumenera Camera	Lumenera Camera	Identical
Software Operating System	Microsoft Windows 10	Microsoft Windows 10	Identical
Algorithm interpretation and thresholds	Interpretation by camera imaging	Interpretation by camera imaging	Identical
Automated C3d DAT Assay	No	Yes	New

Clinical Performance

Method comparison studies were performed externally at two sites and internally at Immucor, Inc. Specimens were tested with the Automated C3d DAT assay on Galileo Echo/Echo Lumena and the comparator method. Samples with initial equivocal results were retest and the results used for calculations. Test results were evaluated for agreement with the comparator method. Results are summarized in the following tables:

Note: Agreement between methods does not indicate which method is correct.

Initial C3d_DAT		Comparator		Agreement	
		Positive	Negative		
Galileo Echo# & Echo Lumena	Positive	99*	7	Positive % Agreement	95.17%
				PPA (95% Lower 1-sided CI)	90.16%
	Negative	5	1,032	Negative % Agreement	99.32%
				NPA (95% Lower 1-sided CI)	98.73%

Galileo Echo software version 2.1. Positive samples include 86 C3d-positive contrived samples.

* One contived sample tested repeat equivocal and was removed from PPA calculation.

Resolved C3d_DAT		Comparator		Agreement	
		Positive	Negative		
Galileo Echo# & Echo Lumena	Positive	99	7	Positive % Agreement	100%
				PPA (95% Lower 1-sided CI)	97.70%
	Negative	0*	1,035	Negative % Agreement	99.33%
				NPA (95% Lower 1-sided CI)	98.74%

Galileo Echo software version 2.1.

* Excludes 3 samples reacting 1+ or weaker with the comparator reagent per limitation in Operator Manuals.

Basis for Claim of Substantial Equivalence

This Traditional 510(k) is submitted to modify legally marketed devices (predicates). Immucor, Inc. is the holder of the 510(k)s for the predicate devices. The Indications for Use of the proposed devices are unchanged from the legally marketed devices (predicates). The intended use of the modified devices, as described in the labeling, has not changed as a result of the modifications. Finally, fundamental scientific technology of the proposed devices is unchanged from the legally marketed devices (predicates). There are no significant differences between the modified

instruments and the predicates as relates to Intended Use or Principle of Operation. With the exception of the addition of the automated C3d DAT Assay, the predicate and modified devices are identical.

The modified Echo Lumena and Galileo Echo instruments are as safe and effective as the currently marketed predicates under BK200483.