510(k) SUMMARY

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

Submitter´s Details

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Name of Device

Trade Name:	IH-Centrifuge L
Classification Name:	Manual Blood Grouping and Test Systems
510(k) number:	BK170065
Device Class:	II
Product Code:	PBC
Regulation number:	21 CFR 864.9175

Identification of the Legally Marketed Device (Predicated Device)

Trade Name:	MTS Centrifuge
Classification Name:	Centrifuge, Cell-Washing, Automated For Immuno-Hematology
510(k) number:	BK960013
Device Class:	II
Product Code:	KSN
Regulation number:	21 CFR 864.9285
Clearance Letter:	April 15, 1996

Device Description

IH-Centrifuge L is a standard centrifuge intended for the centrifugation of manually processed IH-Cards for ABO+D blood grouping (including weak D and partial D testing), Rh phenotype and Kell blood grouping, antibody detection and identification of red blood cell alloantibodies, AHG crossmatching, auto control and direct antiglobulin testing.

IH-Centrifuge L can be loaded with interchangeable heads allowing centrifugation of IH-Cards. The Head 24 Card holds 24 IH-Cards and is used to carry out the centrifugation of processed IH-Cards. The Head 2 Rack is designed for post-transportation centrifugation of 2 racks of IH-Cards (12 IH-Cards per rack) prior to testing. The head used in IH-Centrifuge L is identified automatically.

An operating panel (4.3" color touch screen display) on the IH-Centrifuge L indicates current centrifugation status. After starting, centrifugation is fully automatic and does not need to be supervised by operating personnel.

Intended Use

The IH-Centrifuge L is intended for centrifugation of IH-System gel cards and/or test tubes for in vitro immunohematology testing of human blood. In the USA, IH-Centrifuge L is "Rx only".
The IH-Centrifuge L may only be operated by trained personnel and is not intended for use in a direct patient environment.
Use of the IH-Centrifuge L is only permitted in conjunction with the corresponding software or in a configuration authorized by Bio-Rad.
The use of any material not specified in the User Manual (e.g. non-authorized substances) is under users' responsibility.

List of Reagents to be used with the Subject Device

Reagents to be used with the IH-Centrifuge L and being applicable to a Biologics License Application (BLA) are listed below.

BLA	Product Name	STN BL
Blood Grouping Reagent	IH-Card ABO/D(DVI-)+RevA1,B	125094*, 125532
	IH-Card ABO/D(DVI+)+RevA1,B	125094*, 125532

	IH-Card ABO/RhD(DVI+)	125094*, 125529, 125532
	IH-Card Group A,B	125094*
	IH-Card Group ABO	125094*, 125532
	IH-Card ABD(DVI-)-Conf	125094*, 125532
	IH-Card ABD(DVI+)-Conf	125094*, 125532
	IH-Card Rh-Phenotype+K	125094*
	IH-Card Anti-C	125094*
	IH-Card Anti-E	125094*
	IH-Card Anti-c	125094*
	IH-Card Anti-e	125094*
	IH-Card Anti-D (DVI+)	125094*
	IH-Card Anti-D (DVI-)	125094*
	IH-Card Anti C-E-K	125094*
	IH-Card Anti-K	125094*
	IH-Card RhD(DVI-) +Phenotype	125094*
	IH-Anti-D Blend	125533
Anti-Human Globulin	IH-Card AHG Anti-IgG,-C3d	125529
	IH-Card AHG Anti-IgG	125098
Reagent Red Blood Cells	IH-Cell I-II	125208
	IH-Cell I-II-III	
	IH-Cell Pool	
	IH-Panel 11	
	IH-Panel 11 Papain	
	IH-Panel Plus 6	

* Trans-BLA STN BL 125094

Comparison to Predicate Device

The following device comparison table identifies MTS Centrifuge (Ortho-Clinical Diagnostics), FDA-cleared under BK960013, as predicate device.

Parameter	Predicate Device Ortho-Clinical Diagnostics MTS Centrifuge	Subject Device Bio-Rad Laboratories IH-Centrifuge L
Indications for Use	The MTS Centrifuge is a precision bench top, single speed instrument designed specifically for the ID-Micro Typing System. The MTS Centrifuge is intended for centrifugation of the MTS Gel Card.	The IH-Centrifuge L is intended for centrifugation of IH-System gel cards and/or test tubes for in vitro immunohematology testing of human blood. In the USA, IH-Centrifuge L is “Rx only”. The IH-Centrifuge L may only be operated by trained personnel and is not intended for use in a direct patient environment. Use of the IH-Centrifuge L is only permitted in conjunction with the corresponding software or in a configuration authorized by Bio-Rad. The use of any material not specified in the User Manual (e.g. non-authorized substances) is under users’ responsibility.
Device Classification	Class II, 21 CFR 864.9285 Centrifuge, Cell-Washing, Automated For Immuno-Hematology	Class II, 21 CFR 864.9175 Manual Blood Grouping and Test Systems
Product Code	KSN	PBC
Dimensions	H: 144 mm (5.75 in) W: 338 mm (13.50 in) D: 481 mm (19.25 in)	H: 230 mm (9 in) W: 380 mm (15 in) D: 500 mm (19.7 in)
Power Requirements (Frequency)	110-120V~ (50/60 Hz)	100-240V~ (50/60 Hz)
Spin Heads	Removable and exchangeable	Removable and exchangeable
Capacity	24 cards	24 cards
Speed	895 ± 25 rpm (80-90 rcf)	Head 24 Cards 910 rpm ± 0.5% (85 ± 0.5% rcf) Head 2 Racks 842 rpm ± 0.5% (85 ± 0.5% rcf)
Cycle Time	600 s	Head 24 Cards 600s ± 1 Head 2 Racks 300s ± 1

Display	• Time and Speed	Same, plus • Type of head loaded • Timer area • Start / Stop cycle • Maintenance counter • Power off • Open lid • Acceleration area • Settings
Alarms	• None	• Warnings • Errors • Maintenance is needed

Performance Testing

Clinical studies were performed at five (5) US sites and one (1) internal site using Bio-Rad Medical Diagnostics licensed IH-reagents and FDA licensed comparator methods. Testing of the IH-reagents included the use of the IH-Centrifuge L and IH-Incubator L. Comparative methods included FDA cleared instruments and FDA licensed reagents for immunhematology testing. Samples were collected from both blood donors and patients at these six (6) sites. Study included more than 17,050 tests from a diverse population in broad geographical areas.

The results of this clinical trial support the conclusion that the testing of IH-Cards for Blood Grouping and Anti-Human Globulin Testing and the corresponding Reagent Red Blood Cells tested on the IH-Centrifuge L is safe and effective.

The yielded results demonstrate that end users, with proper training, could use the IH-Centrifuge L (together with IH-Incubator L) to perform ABO+D cellular and serum grouping, Rh+K phenotyping, weak D testing, detection and identification of unexpected antibodies, DAT and AHG crossmatching and that the testing with the specified IH reagents on the instruments does generate results comparable to established FDA licensed reference reagents and FDA cleared predicates.

Bio-Rad concludes, based on all information submitted and discussed in this submission and this summary that IH-Centrifuge L is safe, effective and substantially equivalent to the predicate device and has been demonstrated to meet all requirements for a product to be marketed in the U.S.A.