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

Name:	Bio-Rad Medical Diagnostics GmbH
Address:	Industriestrasse 1, 63303 Dreieich, Germany
Telephone number:	+49 (0) 6103 3130-442
Fax number:	+49 (0) 6103 3130-646
Establishment Registration Number:	9610824
Contact Person:	Dr. Rolf Vornhagen
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Name of Device

Trade Name:	IH-Incubator L
Classification Name:	Manual Blood Grouping and Test Systems
510(k) number:	BK170066
Device Class:	II
Product Code:	PBC
Regulation number:	21 CFR 864.9175

Identification of the Legally Marketed Device (Predicated Device)

Trade Name:	MTS Incubator II
Classification Name:	Supplies, Blood Bank
510(k) number:	BK010021
Device Class:	I
Product Code:	KSS
Regulation number:	21 CFR 864.9050
Clearance Letter:	October 1, 2001

Device Description

IH-Incubator L is a stand-alone incubator intended for the manual processing of IH-Cards for detection of blood group antigen-antibody reactions. IH-Incubator L will be used for incubation of IH-Cards containing Anti-Human Globulin (AHG) (AHG Anti-IgG, AHG Anti-IgG,-C3d) for weak D testing, antibody detection and identification of red blood cell alloantibodies, AHG crossmatching and auto control.

IH-Incubator L contains a heating system allowing incubation of IH-Cards. IH-Cards can be placed in the Head 24 Cards centrifuge head (24 IH-Cards) or in three racks (12 IH-Cards per rack) at a temperature of 37 °C. The main heating chamber is protected by a lid. A microprocessor controls the incubator's function and monitors incubation time and temperature. An operating panel (4.3" color touch display) indicates the operating status of IH-Incubator L.

Intended Use

The IH-Incubator L is intended for incubation of IH-System gel cards and/or test tubes for in vitro immunohematology testing of human blood. In the USA, IH-Incubator L is "Rx only".

The IH-Incubator L may only be operated by trained personnel and is not intended for use in a direct patient environment.

Use of the IH-Incubator 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-Incubator L and being applicable to a Biologics License Application (BLA) are listed below. BLA supplements including the Package Inserts for the extension of the Intended Use were subject of the companion Prior Approval Supplement (PAS) submission and were revised according to FDA's Information Request (November 17, 2017), through a PAS amendment submitted on November 28, 2017.

BLA	Product Name	STN BL
Blood Grouping Reagent	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	

Comparison to Predicate Device

The following device comparison table identifies MTS Incubator II (Ortho-Clinical Diagnostics), FDA-cleared under BK010021, as predicate device.

Parameter	Predicate Device Ortho-Clinical Diagnostics MTS Incubator II	Subject Device Bio-Rad Laboratories IH-Incubator L
Indications for Use	The MTS Incubator is a precision top instrument controlled by solid state electronics that has been designed to provide a 37°C incubation of MTS Gel Cards and tubes, for the purpose of performing routine blood banking procedures.	The IH-Incubator L is intended for incubation of IH-System gel cards and/or test tubes for in vitro immunohematology testing of human blood. In the USA, IH-Incubator L is “Rx only”. The IH-Incubator L may only be operated by trained personnel and is not intended for use in a direct patient environment. Use of the IH-Incubator 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.
Classification	Class I Supplies, Blood Bank 21 CFR 864.9050	Class II Manual Blood Grouping and Test Systems 21 CFR 864.9175
Product Code	KSS	PBC
Dimensions	H: 105 mm (4.15 in) W: 270 mm (10.7 in) D: 315 mm (12.5 in)	H: 230mm (9.06 in) W: 380mm (15.0 in) D: 500mm (19.7 in)
Power Requirements (Frequency)	110V~ (50/60 Hz)	100-240V~ (50/60 Hz)
Capacity	24 gel cards	24 gel cards (Head 24 cards) 36 gel cards (3 card racks)
Temperature	37°C	37°C
Temperature Tolerance	± 2°C	± 1°C
Incubation Time	Preset to 15 minutes, modifiable (5 to 60 min)	Preset to 15 minutes (programmable 00:01 to 99:59 min)
Display	• Time • Temperature	• Time (3 timers) • Temperature • Maintenance counter • Basic information line (Date/Time/Instr. name) • Setting interface button
Acoustic (and visual) Alarm	• none	• End of incubation cycle • Warnings • 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-Incubator L and the IH-Centrifuge 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-Incubator L (and IH-Centrifuge L) is safe and effective.
The yielded results demonstrate that end users, with proper training, could use IH-Incubator L for incubation of IH-Cards containing AHG (AHG Anti-IgG, AHG Anti-IgG, -C3d) for weak D testing, antibody detection and identification of red blood cell alloantibodies and AHG cross matching. Testing with the specified IH reagents on IH-Incubator L (and IH-Centrifuge L) does generate results comparable to established FDA licensed reference reagents and FDA-cleared predicate.

Bio-Rad concludes, based on all information submitted and discussed in this submission and this summary that IH-Incubator 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.