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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Date of Summary:	December 18, 2017

Name of Device

Trade Name:	IH-Basic QC
Classification Name:	Kit, Quality Control For Blood Banking Reagents
510(k) number:	BK170075
Device Class:	II
Product Code:	KSF
Regulation number:	21 CFR 864.9650

Identification of the Legally Marketed Device (Predicated Device)

Trade Name:	DG Gel Extended Control
Classification Name:	Kit, Quality Control For Blood Banking Reagents
510(k) number:	BK140092
Device Class:	II
Product Code:	KSF
Regulation number:	21 CFR 864.9650
Clearance Letter:	April 11, 2014

DESCRIPTION OF THE DEVICE

IH-Basic QC is intended as daily quality control of blood bank reagents on IH-1000 Analyzer (BK170019). The kit has similar characteristics as patient samples and therefore is treated identically. The reagents are preserved with 2.5 mg/L (0.01 mM) Trimethoprim and 47.5 mg/L (0.19 mM) Sulfamethoxazol.

IH-Basic QC

The IH-Basic QC is intended for daily quality control of blood bank reagents including Blood Grouping Reagents for ABO/Rh, Rh Phenotyping, K, Reagent Red Blood Cells and reagents for antibody detection.

IH-Basic QC Kit contains 8 x 2 vials of a 5 ml human whole blood suspension (Hematocrit 15.0 ± 2 %). The liquid portion of the samples contains serum with antibodies of human origin directed against red blood cell antigens.

- IH-Basic QC Sample 1:
  Group A RhD negative, ccee, K positive, containing Anti-B and Anti-D
- IH-Basic QC Sample 2:
  Group B RhD positive, CcEe, K negative, containing Anti-A and Anti-Fy^a

DEVICE COMPARISON

The Table 10-1 provides a comparison between IH-Quality Control Kit and the predicate device DG Gel Extended Control (BK140092). The devices are compared based on indications for use and material.

Table 10-1 IH-Basic QC - Substantial Equivalence Comparison

Parameter	**Predicate Device** **Medion Grifols Diagnostics AG** **DG Gel Extended Control**	**Subject Device** **Bio-Rad Laboratories** **IH-Basic QC**
Indications for Use	DG Gel Extended is intended to allow regular quality control of materials, work procedures and instruments procedures for: Determination of ABO, Rh, K antigens Determination of the appropriate ABO blood group antibodies Detection of unexpected antibodies ABO compatibility.	The IH-Basic QC is intended for daily quality control of blood bank reagents including Blood Grouping Reagents for ABO/Rh, Rh Phenotyping, K, Reagent Red Blood Cells and reagents for antibody detection. The IH-Basic QC is “Rx only”. For use with IH-Card Technique using the IH-1000 Analyzer.

	For use with the DG Gel 8 technique.	
Classification	Class II Kit, Quality Control For Blood Banking Reagents 21 CFR 864.9650	Class II Kit, Quality Control For Blood Banking Reagents 21 CFR 864.9650
Product Code	KSF	KSF
BK Number	140092	170075
Storage	2 to 8 °C	same
Reagent Preparation	Ready-to-use	Ready-to-use
Hematocrit	15.0 ± 2 %	15.0 ± 2 %
Tests performed	• Typing of ABO, RhD, Rh phenotyping and K antigens • Determination of ABO blood group antibodies • Detection of unexpected antibodies • Direct Antiglobulin Testing (DAT)	• Typing of ABO, RhD, Rh phenotyping and K antigens • Determination of ABO blood group antibodies • Detection of unexpected antibodies
Techniques	**Manual Method:** For DG Gel 8 Technique	**Not applicable**
	Automated Method: For automated methods including WADiana® Compact and Eryta® analyzers using column agglutination with DG Gel 8 technique.	**Automated Method:** For automated IH-1000 Analyzer, IH-Card Technique.
No. of vials	4 vials; containing cells (Reference Blood Cells) and antibodies (Reactivity Testing Sera)	2 vials (8 sets); containing cells (Reference Blood Cells) and antibodies (Reactivity Testing Sera)

PERFORMANCE TESTING

Performance evaluation studies were carried out to demonstrate that IH-Basic QC is safe and effective for its intended use. Testing was carried out at two external sites in the US. IH-reagents for ABO/D typing including ABO serum grouping, Rh/K phenotyping and AHG reagents were tested using IH-QC Kit, and the test results were assessed for concordance with the expected result according to the labeling of the QC kit. All tests were performed on the IH-1000. All required performance tests during the clinical testing have been conducted with acceptable results. The results confirm the satisfactory performance of IH-Basic QC and its suitability as control reagents for IH-Reagents.

Based on all information submitted, Bio-Rad concludes that IH-Basic QC is substantially equivalent to the predicate device and has been demonstrated to be safe and effective to be marketed in the U.S.A.