Section 5 - Premarket Notification 510(k) Summary

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Date Prepared:	October 29, 2018
Trade Name:	DG Gel Essential Control
Classification:	Class II Quality control kit for blood banking reagents 21 CFR 864.9650
Product Code:	KSF
Predicate Device:	The subject device is substantially equivalent to the following device: DG Gel Extended Control
Device Description:	DG Gel Essential Control consists of 2x2 tubes containing human red blood cells as 15±2% suspensions in an antibody containing buffered isotonic, nutrient medium. Chloramphenicol and Neomycin Sulfate are added as preservatives. The tubes, with antibodies, are used as a quality control for DG Gel 8 technique and allow the regular control of materials, work procedures and instrument procedures. Each packaging of the product contains the following profiles: QC Tube 11: A Rh D neg, C-c+E-e+, K+, containing Anti-B and Anti-D in the supernatant; QC Tube 12: B Rh D pos, C+c+E+e+, K-, Fya-, containing Anti-A and Anti-Fya in the supernatant.
Indications For Use:	DG Gel Essential Control is intended to allow regular quality control of materials, work procedures and instrument procedures for: (i) the determination of the ABO, Rh and K antigens; (ii) the determination of the appropriate ABO blood group antibodies; and (iii) the detection of unexpected antibodies. For use with DG Gel 8 technique. For *in vitro* diagnostic use.
Functional and Safety Testing:	Not Applicable.

Substantial Equivalence Comparison

Parameter	Subject Device DG Gel Essential Control	Predicate DG Gel Extended Control
Indications for Use	DG Gel Essential Control is intended to allow regular quality control of materials, work procedures and instrument procedures for: the determination of the ABO, Rh and K antigens; the determination of the appropriate ABO blood group antibodies; and the detection of unexpected antibodies. For use with DG Gel 8 technique. For in vitro diagnostic use.	DG Gel Extended Control is intended to allow regular quality control of materials, work procedures and instrument procedures for: (i) the determination of the ABO, Rh and K antigens; (ii) the determination of the appropriate ABO blood group antibodies; (iii) the detection of unexpected antibodies; and (iv) ABO compatibility.
Principle of the test	DG Gel Essential Control is a simulated whole blood sample to be utilized with DG Gel 8 reagents and 0.8% Reagent Red Blood Cells for use with the DG Gel 8 technique.	SAME
Techniques	Manual Method: Ready-to-use for DG Gel 8 Technique.	SAME
	Automated Method: Ready-to-use for automated methods using column agglutination with DG Gel 8 technique.	SAME
Composition	Simulated Whole Blood: Reference Red Blood Cells and Testing Sera in same vial Human red blood cells (15+-2%) and antibodies in a buffered isotonic nutrient medium with neomycin and chloramphenicol as preservatives.	SAME
Number of tubes/vials	Simulated Whole Blood: 2 x 2 tubes (diameter: 16 mm; height 100 mm) containing cells (Reference Red Blood Cells) and antibodies (Reactivity Testing Sera)	Simulated Whole Blood: 4 tubes (diameter: 12 mm; height 100 mm) containing cells (Reference Red Blood Cells) and antibodies (Reactivity Testing Sera)
Profiles	QC Tube 11: A Rh D neg, C-c+E-e+, K+, containing Anti-B and Anti-D in the supernatant; QC Tube 12: B Rh D pos, C+c+E+e+, K-, Fya-, containing Anti-A and Anti-Fya in the supernatant.	QC Tube 1: A2 RhD neg, C-c+E-e+, containing Anti-B and Anti-D; QC Tube 2: B RhD pos, C+c-E-e+, containing Anti-A; QC Tube 3: O RhD pos, C-c+E+e-, K+, containing Anti-A and Anti-B; QC Tube 4: O RhD pos, C+c+E+e+, K-, Fya-, containing Anti-A, Anti-B and Anti-Fya.
Storage conditions	2-8 °C	SAME

Parameter	Subject Device DG Gel Essential Control	Predicate DG Gel Extended Control
Reagent preparation	The control reagents are provided ready to use.	SAME
Classification	Class II; 21 CFR 864.9650	SAME
Product Code	KSF	SAME
Common Name	Quality control kit for blood banking reagents	SAME

Differences:	DG Gel Essential Control is a basic quality control for daily routine quality control including only 2 types of tubes whereas the predicate device is a complete quality control including 4 different types of tubes. The predicate is additionally intended for ABO compatibility testing. None of these differences raise new concerns of safety and effectiveness.
Performance:	All required performance tests have been conducted with acceptable results. All performance comparison studies in this submission have demonstrated the device is safe and effective.
Conclusion:	Based on all information submitted, Medion Grifols Diagnostics concludes, that DG Gel Essential Control is substantially equivalent to the predicate device and has been demonstrated to be a safe and effective product to be marketed in the United States.