

CH2.03 – 510(k) Summary

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Date of Summary: March 7th, 2025

Device Name:

Trade Name: DG Gel 8 Neutral
Classification Name: Automated Blood Grouping and Antibody Test System
Device Class: II
Product Code: KSZ
Regulation Number: 21 CFR 864.9175

Legally Marketed Predicate Device:

Trade Name: DG Gel 8 Neutral
Classification Name: Automated Blood Grouping and Antibody Test System
510(k) Number: BK220754
Device Class: II
Product Code: KSZ
Regulation Number: 21 CFR 864.9175
Clearance Letter: November 1, 2022

Device Description:

DG Gel 8 Neutral card consists of a plastic support with eight (8) microtubes containing gel in a buffered medium. Each microtube is made of a chamber, also known as incubation chamber, at the top of a long and narrow microtube, referred to as the column. Buffered gel solutions have been prefilled into the microtubes of the plastic card. The microtubes, without antibodies, are used in techniques where antibodies react directly with the red blood cells.

Indications for Use:

The DG Gel 8 Neutral card is for the detection of antibodies to red blood cell antigens of human blood samples and for its use as a control microtube.

For use with the DG Gel System.

For in vitro diagnostic use.

Comparison to Predicate Device:

Parameter	Predicate Device Diagnostic Grifols S.A. DG Gel 8 Neutral (BK220754)	Subject Device Diagnostic Grifols S.A. DG Gel 8 Neutral
Indications for Use Statement	The DG Gel 8 Neutral card is for the detection of antibodies to red blood cell antigens of human blood samples and for its use as a control microtube. For use with the DG Gel System. For in vitro diagnostic use.	The DG Gel 8 Neutral card is for the detection of antibodies to red blood cell antigens of human blood samples and for its use as a control microtube. For use with the DG Gel System. For in vitro diagnostic use.
Classification	II	II
Product Code	KSZ	KSZ
Regulation number	21 CFR 864.9175	21 CFR 864.9175
Common name	Automated Blood Grouping and Antibody Test System	Automated Blood Grouping and Antibody Test System
Principle of the test	Immunoematology gel technique	Immunoematology gel technique
Techniques	Saline techniques: - Determination of the ABO reverse group - ABO compatibility test (immediate spin crossmatch test) - Antibody detection (at cold, room temperature and 37°C) - Antibody titration test - Use as a Control microtube Enzymatic techniques: Screening and/or identification of unexpected antibodies	Saline techniques: - Determination of the ABO reverse group - ABO compatibility test (immediate spin crossmatch test) - Antibody detection (at cold, room temperature and 37°C) - Antibody titration test (including single dilution titration test) - Use as a Control microtube Enzymatic techniques: Screening and/or identification of unexpected antibodies
Results	Report results as an agglutination grade, absence of agglutination or hemolysis.	Report results as an agglutination grade, absence of agglutination or hemolysis.
Storage conditions	2 - 25°C	2 - 25°C
Reagent preparation	Ready to use.	Ready to use.
Number of microtubes	8	8

Parameter	Predicate Device Diagnostic Grifols S.A. DG Gel 8 Neutral (BK220754)	Subject Device Diagnostic Grifols S.A. DG Gel 8 Neutral
Instruments for automated method	Erytra Eflexis, Erytra or WADiana Compact.	Erytra Eflexis, Erytra or WADiana Compact.
Instruments for manual method	DG Spin, DG Therm, DG Reader Net (optional) and DG Reader (optional)	DG Spin, DG Therm, DG Reader Net (optional) and DG Reader (optional)

The differences between the DG Gel 8 Neutral card and its predicate device, the DG Gel 8 Neutral (BK220754), are related to the Antibody Titration technique. The DG Gel 8 Neutral card allows performing a single dilution or a single point within antibody titration technique, when required by the user, in comparison to the predicate device. These differences do not raise new concerns of safety and effectiveness.

Performance:

All required performance tests have been conducted with acceptable results. The performance studies have demonstrated that performance of DG Gel 8 Neutral was not negatively impacted by allowing single dilution titration tests, when required by the user.

Conclusions:

Diagnostic Grifols S.A. concludes, based on all the information submitted and discussed in this submission and in this summary that DG Gel 8 Neutral, when used for the defined indications for use, performs as well as or better than the legally marketed predicate device DG Gel 8 Neutral (BK220754).