CH2.03 – 510(k) Summary

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Date of Summary:	June 13th, 2025

Device Name:

Trade Name:	Erytra
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:	Erytra
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) Number:	BK220751
Device Class:	II
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Clearance Letter	November 1, 2022

Device Description:

The Erytra is designed to automate all necessary operations and procedures to process gel immunohematology tests, allowing laboratories to:

1. Create test profiles and optimize profile implementation in the shortest time and with the most accurate results possible.
2. Increase process safety and traceability by eliminating possible identification and transcription errors.

3. Increase analytical reliability by standardizing all steps, eliminating possible handling, and processing errors, and interpreting the results with objective criteria.
4. Reduce the danger of contamination for Operators by reducing Operator interaction with the samples and reagents during the analytical process. Operator interaction is limited to the loading and unloading of the analyzer.

In addition, the Erytra adapts to the needs and differing operational workflows in immunohematology laboratories, donation centers, transfusion centers, and clinical testing laboratories, as well as different work rhythms (routine, emergency) and the flow of samples processed over different shifts.

The Erytra automates the following gel immunohematology tests:

ABO Red Cell and Serum Grouping.

Rh(D) Typing.

Antigen Typing.

Antibody detection.

Antibody identification.

Antibody titration.

Direct Antiglobulin test.

Compatibility Tests (Crossmatching).

Indications for Use:

The Erytra is a fully automated high-throughput analyzer designed to automate *in vitro* immunohematological testing of human blood utilizing DG Gel 8 card technology, including Blood Grouping, Antigen Typing, Antibody Screening, Antibody Identification, Antibody Titration, Compatibility Tests, and Direct Antiglobulin Tests.

As a standalone analyzer or interfaced to the customer's Laboratory Information System (LIS), the Erytra automates test processing functions and data management requirements using DG Gel 8 cards and digital image processing.

Comparison to Predicate Device:

Parameter	Predicate Device Diagnostic Grifols S.A. Erytra (BK220751)	Subject Device Diagnostic Grifols S.A. Erytra
General		
Indications for Use Statement	The Erytra is a fully automated high-throughput analyzer designed to automate *in vitro* immunohematological testing of human blood utilizing DG Gel 8 card technology, including Blood Grouping, Antigen Typing, Antibody Screening, Antibody Identification, Antibody Titration, Compatibility Tests, and Direct Antiglobulin Tests. As a standalone analyzer or interfaced to the customer's Laboratory Information System (LIS), the Erytra automates test processing functions and data management requirements using DG Gel 8 cards and digital image processing.	The Erytra is a fully automated high-throughput analyzer designed to automate in vitro immunohematological testing of human blood utilizing DG Gel 8 card technology, including Blood Grouping, Antigen Typing, Antibody Screening, Antibody Identification, Antibody Titration, Compatibility Tests, and Direct Antiglobulin Tests. As a standalone analyzer or interfaced to the customer's Laboratory Information System (LIS), the Erytra automates test processing functions and data management requirements using DG Gel 8 cards and digital image processing.
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
Test performed	- ABO Red Cell and Serum Grouping - Rh(D) Typing - Antigen Typing - Antibody detection - Antibody identification - Antibody titration - Direct Antiglobulin test - Compatibility Tests (Crossmatching)	- ABO Red Cell and Serum Grouping - Rh(D) Typing - Antigen Typing - Antibody detection - Antibody identification - Antibody titration (including Single Point and Range Titration techniques) - Direct Antiglobulin test - Compatibility Tests (Crossmatching)
Primary components	Analyzer Computer Software Optional hand-held bar code scanner Optional printer	Analyzer Computer Software Optional hand-held bar code scanner Optional printer
Specimen Types	Plasma, Serum and Red Blood Cells.	Plasma, Serum and Red Blood Cells.
Reagents	Erytra Eflexis is used with Diagnostic Grifols DG Gel 8 cards, Medion Grifols Diagnostics Reagent Red Blood Cells and Validated Antisera Reagents.	Erytra Eflexis is used with Diagnostic Grifols DG Gel 8 cards, Medion Grifols Diagnostics Reagent Red Blood Cells and Validated Antisera Reagents.

Parameter	Predicate Device Diagnostic Grifols S.A. Erytra (BK220751)	Subject Device Diagnostic Grifols S.A. Erytra
Positive identification of samples and reagents	Yes	Yes
Throughput	67 samples (ABO/Rh cards) per hour, including forward & reverse group	67 samples (ABO/Rh cards) per hour, including forward & reverse group
Useful life	7 years, considering 8 hours a day of continuous operation at maximum throughput (using ABO/Rh DG Gel 8 cards), 250 days a year.	7 years, considering 8 hours a day of continuous operation at maximum throughput (using ABO/Rh DG Gel 8 cards), 250 days a year.
Hardware		
Reagent Red Cell suspension	Maintained by Rotation Movement	Maintained by Rotation Movement
Barcode Symbologies	- Interleaved 2 of 5. - Code 3 of 9. - Codabar. - EAN 8 / EAN 13 / JAN 8 / JAN 13. - Codes 128 A, B & C (ISBT 128). - Others under configuration.	- Interleaved 2 of 5. - Code 3 of 9. - Codabar. - EAN 8 / EAN 13 / JAN 8 / JAN 13. - Codes 128 A, B & C (ISBT 128). - Others under configuration.
Sample loading capacity	96 tubes distributed in four drawers.	96 tubes distributed in four drawers.
Reagent loading capacity	54 vials (36 of them agitated) distributed in two drawers.	54 vials (36 of them agitated) distributed in two drawers.
Sample/Reagent Dispensing (pipetting) Unit	2	2
Card loading capacity	400 cards	400 cards
Incubator	4 independent incubators for 12 cards each.	4 independent incubators for 12 cards each.
Centrifuge	2 independent centrifuges for 12 cards each.	2 independent centrifuges for 12 cards each.
System solution and waste containers	1 container for Grifols Wash Solution A 1 container for Grifols Wash Solution B 2 containers for waste solution 1 container for processed DG Gel 8 card disposal Option to double the capacity of Grifols Wash Solution A and B with the liquid waste drainage configuration activated	1 container for Grifols Wash Solution A 1 container for Grifols Wash Solution B 2 containers for waste solution 1 container for processed DG Gel 8 card disposal Option to double the capacity of Grifols Wash Solution A and B with the liquid waste drainage configuration activated

The differences between the Erytra and its predicate device, the Erytra (BK220751), are related to the Antibody Titration technique. The Erytra uses an automated serial dilution method that allows for the preparation of dilutions up to 1/2048. Additionally, the Erytra supports both single point and range titration techniques within antibody titration tests, when required by the user, in comparison to the predicate device. These differences do not raise new concerns of safety and effectiveness.

Performance:
All new risks and hazard analysis related to the automated serial dilution method, and single dilution and range titration techniques, have been performed and documented per ISO 14971 guidelines.

An in-house method comparison study was conducted with three Erytra, and with DG Gel 8 Anti-IgG (Rabbit) and DG Gel 8 Neutral cards, and 0.8% Reagent Red Blood Cells. The following methods were used as comparative methods:

> Serial dilution titration technique: the current FDA approved automated single direct dilution method was used as comparative for titers up to 64, and the manual serial double dilution method was used as comparative for titers higher than 64.
> Single dilution and range titration techniques: the manual serial double dilution method was used as comparative for high range titrations.

A total of 243 titrations were compared for serial dilution titration techniques and out of 76 samples were used for range titration techniques comparison. Additionally, a total of 356 single dilution tests were compared with the manual method.

The percent agreements and the lower limits of 95% one-side confidence interval (CI) for Erytra and antibody titration technique are indicated in the following table:

Antibody Titration	Nº of samples	Percent Agreement (Lower 95% CI)
Concordances Obtained for Anti-Human Globulin		
Serial Dilution Technique	115	100% (97.4%)
Ranges Technique	74	100% (96.0%)
Single Point	201	100% (98.5%)
Concordances Obtained for the Neutral Gel		
Serial Dilution Technique	128	100% (97.7%)
Ranges Technique	75	100% (96.1%)
Single Point	155	97.4% (94.2%)

The percent agreement (estimated with a 95% CI) between the three antibody titration techniques performed by Erytra and with the respective comparative methods met all the acceptance criteria previously established as ≥ 95% for DG Gel 8 Anti-IgG (Rabbit) and for DG Gel 8 Neutral cards. The discrepancies found caused the single point antibody titration technique for the Neutral Gel to not meet the acceptance criteria. However, the 4 discrepancies were resolved in favor of the Erytra.

The results obtained in the Method comparison study supported the conclusion that the Erytra including the new automated serial dilution method, and single dilution and range titration techniques, yielded equivalent results to the comparative methods using FDA licenses reagents and instruments.

In addition, an internal reproducibility and repeatability study was conducted. The study was done using three Erytra in accordance to the following profile: 6 Samples x 3 Erytra x 5 days x 2 runs (am/pm) x 2 replicates.

The study demonstrated that the Erytra consistently obtained the expected results and the reproducibility and repeatability of the results for these techniques was deemed demonstrated.

In summary, the results of the in-house evaluation supported the conclusion that the Erytra including the new automated serial dilution method, and single dilution and range titration techniques, can perform antibody titrations with its DG Gel 8 cards and Medion Grifols Diagnostics Reagent Red Blood Cells, safely and effectively. In addition, it is concluded that the Erytra is substantially equivalent when compared to the results obtained using the same DG Gel 8 cards and Medion Grifols Diagnostics Reagent Red Blood Cells tested by the comparative methods.

Conclusions:

Diagnostic Grifols S.A. concludes, based on all the information submitted and discussed in this submission and in this summary that the Erytra, when used for the defined indications for use, performs as well as or better than the legally marketed predicate device the Erytra (BK220751). In addition, all the requirements for a product to be marketed in the United States have been demonstrated.