CH2.03 – 510(k) Summary

Contact Details:

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Date of Summary:	June 13th, 2025

Device Name:

Trade Name:	Erytra Eflexis
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 Eflexis
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) Number:	BK230820
Device Class:	II
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Clearance Letter	June 22, 2023

Device Description:

Erytra Eflexis 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.
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, Erytra Eflexis 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.

Erytra Eflexis 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:

Erytra Eflexis is a fully automated analyzer designed to automate in vitro immunohematological testing of human blood utilizing DG Gel 8 cards 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), Erytra Eflexis 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 Eflexis (BK230820)	Subject Device Diagnostic Grifols S.A. Erytra Eflexis
General		
Indications for Use Statement	Erytra Eflexis is a fully automated analyzer designed to automate in vitro immunohematological testing of human blood utilizing DG Gel 8 cards 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), Erytra Eflexis automates test processing functions and data management requirements using DG Gel 8 cards and digital image processing.	Erytra Eflexis is a fully automated analyzer designed to automate in vitro immunohematological testing of human blood utilizing DG Gel 8 cards 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), Erytra Eflexis 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 Eflexis (BK230820)	Subject Device Diagnostic Grifols S.A. Erytra Eflexis
Positive identification of samples and reagents	Yes	Yes
Throughput	36 samples (ABO/Rh cards) per hour, including forward & reverse group	36 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	72 tubes simultaneously	72 tubes simultaneously
Reagent loading capacity	2 removable, independent, and random-access racks.	2 removable, independent, and random-access racks.
Sample/Reagent Dispensing (pipetting) Unit	1	1
Card loading capacity	200 cards	200 cards
Incubator	3 independent incubators	3 independent incubators
Centrifuge	2 independent centrifuges	2 independent centrifuges
System solution and waste containers	1 container for Grifols Wash Solution A 1 container for Grifols Wash Solution B 2 containers for waste solutions that can be configured to become Wash Solution containers if external drain is used. 1 disposable container for processed DG Gel 8 cards	1 container for Grifols Wash Solution A 1 container for Grifols Wash Solution B 2 containers for waste solutions that can be configured to become Wash Solution containers if external drain is used. 1 disposable container for processed DG Gel 8 cards

The differences between the Erytra Eflexis and its predicate device, the Erytra Eflexis (BK230820), are related to the Antibody Titration technique. The Erytra Eflexis uses an automated serial dilution method that allows for the preparation of dilutions up to 1/2048. Additionally, the Erytra Eflexis 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 Eflexis, 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 246 titrations were compared for serial dilution titration techniques and out of 76 samples were used for range titration techniques comparison. Additionally, a total of 364 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 Eflexis 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	116	100% (97.5%)
Ranges Technique	76	100% (96.1%)
Single Point	205	100% (98.5%)
Concordances Obtained for the Neutral Gel		
Serial Dilution Technique	130	99.2% (96.4%)
Ranges Technique	76	100% (96.1%)
Single Point	159	100% (98.1%)

The percent agreement (estimated with a 95% CI) between the three antibody titration techniques performed by Erytra Eflexis 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 results obtained in the Method comparison study supported the conclusion that the Erytra Eflexis 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 Eflexis in accordance to the following profile: 6 Samples x 3 Erytra Eflexis x 5 days x 2 runs (am/pm) x 2 replicates.

The study demonstrated that the Erytra Eflexis 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 Eflexis 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 Eflexis 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 Erytra Eflexis, when used for the defined indications for use, performs as well as or better than the legally marketed predicate device Erytra Eflexis (BK230820). In addition, all the requirements for a product to be marketed in the United States have been demonstrated.