CH2.03 – 510(k) Summary

Contact Details:

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Date of Summary:	February 27th, 2026

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:	BK251182
Device Class:	II
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Clearance Letter	June 17, 2025

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 (BK251182)	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 - 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 (BK251182)	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
Reading system	High-resolution color reading using a color CCD camera	New high-resolution color reading using a color CCD camera
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

Parameter	Predicate Device Diagnostic Grifols S.A. Erytra Eflexis (BK251182)	Subject Device Diagnostic Grifols S.A. Erytra Eflexis
Firmware/Software		
Interfaced with Laboratory Information System (LIS)	Yes - Unidirectional - Bidirectional	Yes - Unidirectional - Bidirectional
Capability to process STAT samples	Yes	Yes
QC procedures implemented	Yes	Yes
Automated results reading	Digital Image and Microtube Analysis incorporated in the Reader Module (DG-421)	Digital Image and Microtube Analysis incorporated in the Reader Module (DG-421)
Automated test interpretation	Yes. According to predefined rules stated in a definition file.	Yes. According to predefined rules stated in a definition file.

The differences between the Erytra Eflexis and its predicate device, the Erytra Eflexis (BK251182), are related to the digital camera installed in the reading module of the instrument. The Erytra Eflexis incorporates a new compatible high-resolution color reading camera due to the obsolescence of the current one, in comparison to the predicate device. These differences do not raise new concerns of safety and effectiveness.

Performance:
All new risks and associated hazard analysis related to the digital camera replacement have been performed and documented in accordance with ISO 14971 guidelines.

An in-house method comparison study was conducted with one Erytra Eflexis equipped with the current digital camera, and one Erytra Eflexis with the new digital camera. Both instruments performed automates testing using FDA-licensed Grifols Gel cards, 0.8% Reagent Red Blood Cells, and validated antisera reagents. The results obtained were then compared.

All immunohematology techniques covered in the device's intended use were evaluated in the method comparison study. A total of 822 positive samples, including weak reactions, and 707 negative samples were analyzed.

The results of the method comparison study supported the conclusion that the Erytra Eflexis, equipped with the new digital camera installed in the reading module of the instrument, yielded equivalent results to the comparative methods using FDA-licensed reagents.

In summary, the results of the in-house evaluation support the conclusion that the Erytra Eflexis, including the new camera, safely and effectively performs all immunohematology techniques using DG Gel 8 cards, Medion Grifols Diagnostics Reagent Red Blood Cells, and validated antisera reagents. Additionally, the evaluation demonstrated that the Erytra Eflexis is substantially equivalent when compared to results obtained using the same FDA-licensed reagents tested by the comparative method.

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 (BK251182). In addition, all the requirements for a product to be marketed in the United States have been demonstrated.