Section 5 – 510(k) Summary

Submitter's Details:

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Date of Summary:	August 3rd, 2022

Name of Device:

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

Identification of the Legally Marketed Device (Predicated Device):

Trade Name:	Erytra Eflexis
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) Number:	BK200467
Device Class:	II
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Clearance Letter	April 23rd, 2020

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 (BK200467)**	**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, 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.

Parameter	Predicate Device Diagnostic Grifols S.A. Erytra Eflexis (BK200467)	Subject Device Diagnostic Grifols S.A. Erytra Eflexis
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 - 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.
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.
Hardward		
Reagent Red Cell suspension	Maintained by Rotation Movement	Maintained by Rotation Movement
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.

Parameter	Predicate Device Diagnostic Grifols S.A. Erytra Eflexis (BK200467)	Subject Device Diagnostic Grifols S.A. Erytra Eflexis
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

Performance:
All new risks and hazard analysis related to the addition of the antibody titration technique into the DG Gel System have been performed and documented per ISO 14971 guidelines.

Erytra Eflexis was tested in parallel at three (3) clinical sites with FDA-licensed Anti-IgG reagents, FDA-cleared Neutral cards, and three 0.8 % Reagent Red Blood Cells products. The manual method using DG Gel 8 Anti-IgG and Neutral cards, DG Spin and DG Therm instruments was used as comparative method. The data obtained in the Method Comparison studies included 793 comparison tests.

The clinical study geographic diversity included both the deep-South and Southwest regions of the United States. This regional mixture also resulted in a very diverse ethnicity which distinctly encompassed a percentage of non-Caucasian samples.

The results obtained in the Method Comparison study supported the conclusion that the Erytra Eflexis with its DG Gel 8 cards and Medion Grifols Diagnostics Reagent Red Blood Cells yielded equivalent results to the manual DG Gel method using FDA licensed reagents and instruments.

In addition, each of the three (3) clinical study sites was assigned to perform reproducibility study.

The study was done using the same reproducibility panel shipped to the three clinical study sites in accordance to the following profile: 1 lot of test cards x 3 sites x 5 days (during 20 days) x 2 runs (AM/PM) x 2 replicates using the Erytra Eflexis at each site.

The study demonstrated that Erytra Eflexis consistently obtained the expected results in all the repetitions.

In summary the results of this clinical evaluation supported a conclusion that the Erytra Eflexis can perform antibody titrations with its DG Gel 8 cards and Medion Grifols Diagnostics Reagent Red Blood Cells, safely and effectively and 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 manual DG Gel 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 (BK200467). In addition, all the requirements for a product to be marketed in the United Stated has been demonstrated.