Section 4 – 510(k) Summary

Submitter's Details

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Date of Summary:	January 21st, 2020

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:	BK180260
Device Class:	II
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Clearance Letter	December 20, 2018

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.

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, 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® (BK180260)**	**Subject Device** **Diagnostic Grifols S.A.** **Erytra Eflexis®**
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.	Same
Primary components	Analyzer Computer Software Optional hand-held bar code scanner Optional printer	Same
Specimen Types	Plasma, Serum and Red Blood Cells.	Same
Reagents	Erytra Eflexis is used with Diagnostic Grifols DG Gel 8 cards and Medion Grifols Diagnostics Reagent Red Blood Cells.	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® (BK180260)	Subject Device Diagnostic Grifols S.A. Erytra Eflexis®
Positive identification of samples and reagents	Yes	Same
Throughput	36 samples (ABO/Rh cards) per hour, including forward & reverse group	Same
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.	Same
Sample loading capacity	72 tubes simultaneously	Same
Reagent loading capacity	2 removable, independent and random-access racks.	Same
Sample/Reagent Dispensing (pipetting) Unit	1	Same
Card loading capacity	200 cards	Same
Incubator	3 independent incubators	Same
Centrifuge	2 independent centrifuges	Same
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	Same

Performance:

Erytra Eflexis® was tested in parallel at three clinical sites with the FDA-licensed reagent anti-D (IgM clones P3x61 and P3x21223 B10 and IgG clones P3x290 and P3x35) and FDA cleared instruments.

More than 3,000 individual unique specimens representing diverse population groups in broad geographic areas and composed of approximately 60.43% hospital patients and 39.57% blood donors were successfully tested with the Erytra Eflexis®.

The results obtained in the Method Comparison studies supported the conclusion that the Erytra Eflexis® with its DG Gel® 8 cards and anti-D (IgM clones P3x61 and P3x21223 B10 and IgG clones P3x290 and P3x35) yielded equivalent results to FDA licensed reagents and Erytra® instruments. The percentages of agreement met the acceptance criteria for anti-D (IgM clones P3x61 and P3x21223 B10 and IgG clones P3x290 and P3x35) testing.

In summary, the results of the method comparison study support a conclusion that the Erytra Eflexis® is safe and effective and is substantially equivalent to the FDA-licensed reagents and FDA-cleared instruments used in the study.

Conclusions:

Diagnostic Grifols S.A. concludes, based on all 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® (BK180260).