Section 5 – 510(k) Summary

Submitter's Details

Name	Diagnostic Grifols S.A.
Address	Passeig Fluvial, 24, Parets del Valles Barcelona, 08150, Spain
Establishment Registration Number:	3002772505
Contact Person:	Joaquín Alberto Tamparillas Technical Director at Diagnostic Industrial Group of Grifols, S.A. joaquin.alberto@grifols.com Phone: (34) 670-924-632
Date of Summary:	September 21th, 2018

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®
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) Number:	BK17013
Device Class:	II
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Clearance Letter	October 30, 2017

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
- Antigen Typing
- Antibody Screening
- Antibody Identification
- Compatibility Tests

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:

	Predicate Device **Erytra® BK170130**	**Subject Device** **Erytra Eflexis®**
General		
Intended Use	The Erytra is a fully-automated high throughput analyzer designed to automate in vitro immunohematological testing of human blood utilizing the DG Gel 8 card 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), the Erytra® 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, 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

	Predicate Device **Erytra® BK170130**	**Subject Device** **Erytra Eflexis®**
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 - Antigen Typing - Antibody Screening - Antibody Identification - Compatibility Tests - Direct Antiglobulin Tests	- ABO Red Cell and Serum Grouping - Antigen Typing - Antibody Screening - Antibody Identification - Compatibility Tests - Direct Antiglobulin Tests
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 type	Plasma, Serum and Red Blood Cells.	Plasma, Serum and Red Blood Cells.
Reagents	Erytra 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 and Medion Grifols Diagnostics Reagent Red Blood Cells.
Positive identification of samples and reagents	Yes	Yes
Throughput	67 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	- Codabar. - Code 3 of 9. - Code 2 of 5 interleaved. - Code 128 A, B & C (ISBT 128).. - EAN8/EAN13/JAN8/JAN13 (without supplemental encodation).	- Codabar. - Code 3 of 9. - Code 2 of 5 interleaved. - Code 128 A, B & C (ISBT 128). EAN8/EAN13/JAN8/JAN13 (without supplemental encodation).
Sample Loading capacity	96 tubes simultaneously	72 tubes simultaneously

	Predicate Device **Erytra® BK170130**	**Subject Device** **Erytra Eflexis®**
Reagents loading capacity	4 removable holders in two independent, random-access drawers	2 removable, independent and random-access racks
Sample/Reagent Dispensing Unit	2	1
Card loading capacity	350 cards	200 cards
Incubator	4 independent incubators	3 independent incubators
Centrifuge	2 independent centrifuges	2 independent centrifuges
System solutions 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
Computer	Erytra contains an industrial embedded computer based on ASRock IMB-150.	Erytra Eflexis contains an industrial embedded computer based on based on ASRock IMB-150.
Reader	Color camera (Guppy F-033-C) connected to the computer through IEEE1394	Color camera (Guppy F-033-C) connected to the computer through IEEE1394
Software		
Operating system	Windows Embedded Standard 7	Windows Embedded Standard 7
Software applications	Erytra program, Importer, Technical Service, Diagnostic, System tools and Diana Server.	Executor, Manager, Importer, Technical Service, Diagnostic, System tools and Diana Server.
Capability process STAT samples	Yes	Yes
QC procedures implemented	Yes	Yes
Barcode Reading	Sample Identification Reagent Nº and Expiration Date	Sample Identification Reagent Nº and Expiration Date
Manual Entry of Sample IDs	Requires Double Blind Entry	Requires Double Blind Entry
Incubator temperature	Incubators can be set up independently at 37ºC or 24ºC. Temperature accuracy at 37ºC: ±1ºC Temperature accuracy at 24ºC: ±3ºC	Incubators can be set up independently at 37ºC or 24ºC. Temperature accuracy at 37ºC: ±1ºC Temperature accuracy at 24ºC: ±3ºC
Relative centrifugal force	127g ± 12g at 4.6mm from the bottom of the microtube.	127g ± 12g at 4.6mm from the bottom of the microtube.

	Predicate Device Erytra® BK170130	Subject Device Erytra Eflexis®
Centrifugation time	The centrifugation time is 540 s ± 30 s to meet the requirements of the DG-Gel 8 cards.	The centrifugation time is 540 s ± 30 s to meet the requirements of the DG-Gel 8 cards.
Automated results reading	Yes. Microtube Digital Image Analysis. (Reactions graded according to the definitions given in the DG Gel 8 Package Insert).	Yes. Microtube Digital Image Analysis. (Reactions graded according to the definitions given in the DG Gel 8 Package Insert).
Automated test interpretation	Yes. According to predefined rules stated in a definition file.	Yes. According to predefined rules stated in a definition file.
Interfaced with Laboratory Information System (LIS)	Yes - Unidirectional. - Bidirectional.	Yes - Unidirectional. - Bidirectional.
Access control	User access limited to authorized individuals with specific privileges. Every user is unique and has a user identifier and specific password. Complies with 21CFR11.	User access limited to authorized individuals with specific privileges. Every user is unique and has a user identifier and specific password. Complies with 21CFR11.

Performance:
All required software and system verification procedures have been executed and analyzed with acceptable results.

All risk and hazard analysis have been performed and documented per ISO 14971 guidelines. All electrical safety testing has been performed by a NRTL according to the applicable safety standards.

Erytra Eflexis® was tested in parallel at three (3) clinical sites with FDA-licensed reagents and FDA-cleared instruments including nine (9) Blood Grouping Reagents, one (1) Anti Human Globulin and three 0.8 % Reagent Red Blood Cells products. The data obtained in the Method Comparison studies included 37,302 comparison tests.

More than 9,000 individual unique specimens representing diverse population groups in broad geographic areas and composed of approximately 55.61% hospital patients and 44.39% 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 Medion Grifols Diagnostics Reagent Red Blood Cells yielded equivalent results to FDA licensed reagents and Erytra® instruments.

	Positive		Negative		Total	
	Nº of samples	**Percent Agreement (Lower 95% CI)**	**Nº of samples**	**Percent Agreement (Lower 95% CI)**	**Nº of samples**	**Percent Agreement (Lower 95% CI)**
Concordances obtained for Blood Grouping Reagents						
Anti-A	1183	100.00% (99.75%)	1886	100.00% (99.84%)	3069	100.00% (99.90%)
Anti-B	497	100.00% (99.40%)	2572	100.00% (99.88%)	3069	100.00% (99.90%)
Anti-AB	1563	100.00% (99.81%)	1506	100.00% (99.80%)	3069	100.00% (99.90%)
Anti-D	2623	100.00% (99.89%)	446	100.00% (99.33%)	3069	100.00% (99.90%)
Anti-C	1438	100.00% (99.79%)	833	100.00% (99.64%)	2271	100.00% (99.87%)
Anti-E	735	99.86% (99.36%)	1536	100.00% (99.81%)	2271	99.96% (99.79%)
Anti-c	1914	100.00% (99.84%)	357	100.00% (99.16%)	2271	100.00% (99.87%)
Anti-e	2203	100.00% (99.86%)	68	100.00% (95.69%)	2271	100.00% (99.87%)
Anti-K	315	97.78% (95.87%)	4325	99.98% (99.89%)	4640	99.83% (99.69%)
Concordances obtained for Anti-Human Globulin						
Ab. Screening	338	96.75% (94.67%)	1714	99.77% (99.47%)	2052	99.27% (98.88%)
Ab. Identification	578	99.31% (98.42%)	654	97.71% (96.49%)	1232	98.46% (97.75%)
IgG Crossmatch*	332	99.70% (98.58%)	332	99.70% (98.58%)	664	99.70% (99.05%)
DAT	138	97.83% (94.48%)	331	99.70% (98.57%)	469	99.15% (98.06%)
Concordances Obtained for Neutral Gel						
ABO Compatibility*	374	99.73% (98.74%)	374	99.73% (98.74%)	748	99.73% (99.16%)
Reverse ABO Group A	1885	99.89% (99.67%)	1184	99.75% (99.35%)	3069	99.84% (99.66%)
Reverse ABO Group B	2556	99.84% (99.64%)	512	99.80% (99.08%)	3068	99.84% (99.66%)

Notes: * These tests were complemented with an internal study with well characterized samples to replace disqualified testing samples.

Percent of Agreement only indicates agreement between the Diagnostic Grifols instrument and the FDA-cleared instrument and does not indicate which device gave the correct result(s).

The discrepancies found caused the anti-K to not meet the PPA acceptance criteria. However, 7 of the 8 discrepancies were resolved in favor of the Erytra Eflexis. The discrepancies were all from transfused patient samples that would not normally be used for K typings.

For Anti-Human Globulin testing, all discrepancies obtained were associated with very weak positive reactions ("w+" or "1+") and most of them were associated with flagged results that required the operator review. These results show that the discrepancies obtained in anti-IgG testing were associated with samples containing weak antibodies that were at the limit of detection or may indicate potential quality issues of samples (as hemolysis, fibrin, etc.).

In addition, each of the three (3) Clinical Study Sites was assigned to perform reproducibility studies.

The study was done using the same Reproducibility Panel shipped to the three (3) 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 demonstrates that Erytra Eflexis® consistently obtained the expected results in all the repetitions.

In summary the results of this clinical evaluation support a conclusion that the Erytra Eflexis® with its DG Gel 8 cards and Medion Grifols Diagnostics Reagent Red Blood Cells, 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, the Erytra Eflexis® is substantially equivalent to the predicate device and has been demonstrated to meet all requirements for a product to be marketed in the United States.