Section 4 – 510(k) Summary

Submitter's Details

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Date of Summary:	February 8th, 2019

Name of Device:

Trade Name:	Erytra®
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:	BK170130
Device Class:	II
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Clearance Letter	October 30, 2017

Device Description:

Erytra® 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.

Erytra® is designed to be used with DG Gel 8 cards, Grifols Diluent, Grifols Medion Red Blood Cells and Validated Antisera Reagents.

Indications for Use:

The Erytra® is a fully-automated high-throughput analyzer designed to automate in vitro immunohematological testing of human blood utilizing 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.

Comparison to Predicate Device:

Parameter	**Predicate Device** **Diagnostic Grifols S.A.** **Erytra® (BK170130)**	**Subject Device** **Diagnostic Grifols S.A.** **Erytra®**
Indications for Use Statement	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.	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 is used with Diagnostic Grifols DG Gel 8 cards and Medion Grifols Diagnostics Reagent Red Blood Cells.	Erytra 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® (BK170130)	Subject Device Diagnostic Grifols S.A. Erytra®
Positive identification of samples and reagents	Yes	Same
Throughput	67 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	96 tubes distributed in four drawers.	Same
Reagent loading capacity	54 vials (36 of them agitated) distributed in two drawers.	Same
Sample/Reagent Dispensing (pipetting) Unit	Two probes to dispense samples and reagents.	Same
Card loading capacity	400 cards.	Same
Incubator	Four independent incubators for 12 cards each.	Same
Centrifuge	2 Centrifuges for 12 cards each.	Same
System solution and waste containers	Wash Solution A Wash Solution B Waste solutions Processed cards disposal	Same

Performance:
All required performance tests have been conducted with acceptable results. All performance studies have demonstrated that Erytra performance was not negatively impacted by the change described in this submission.

Conclusions:
Diagnostic Grifols S.A. concludes, based on all information submitted and discussed in this submission and in this summary that Erytra® when used for the defined indications for use performs as well as or better than the legally marketed predicate device Erytra® (BK170130).