Section 4 – 510(k) Summary

Submitter's Details

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Date of Summary:	October 6th, 2017

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:	BK130067
Device Class:	II
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Clearance Letter	January 17, 2014

Device Description:

The 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.

The Erytra® automates the following gel immunohematology tests:
   o   ABO Red Cell and Serum Grouping

- o   Rh(D) Typing
- o   Antigen Typing (C, E, c, e, K)
- o   Antibody Detection
- o   Antibody Identification
- o   Direct Antiglobulin Test
- o   Compatibility Tests (Crossmatching)

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

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® with software version 1.0 (BK130067)	Subject Device Diagnostic Grifols S.A. Erytra® with new software version 4.0.0
General		
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

Parameter	Predicate Device Diagnostic Grifols S.A. Erytra® with software version 1.0 (BK130067)	Subject Device Diagnostic Grifols S.A. Erytra® with new software version 4.0.0
Tests Performed	o ABO Red Cell and Serum Grouping o Rh(D) Typing o Antigen Typing (C, E, c, e, K) o Antibody Detection o Antibody Identification o Direct Antiglobulin Test o Compatibility Tests (Crossmatching) (using gel card technology)	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.	Same
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
Hardware		
Computer	Erytra® contains an industrial embedded computer based on Kontron 986LCD-M/mITX.	Erytra® contains an industrial embedded computer based on ASRock IMB-150.
Barcode Symbologies	Code 2 of 5 interleaved Code 3 of 9 Code-128 (A, B & C) ISBT 128	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

Parameter	Predicate Device Diagnostic Grifols S.A. Erytra® with software version 1.0 (BK130067)	Subject Device Diagnostic Grifols S.A. Erytra® with new software version 4.0.0
Sample/Reagent Dispensing (pipetting) Unit	Two probes to dispense samples and reagents.	Same
Card loading capacity	400 cards.	Same
Barcode reading	The barcode readings are performed by means of a laser barcode reader (Symbol SE-955).	Same
Incubator	Four independent incubators for 12 cards each.	Same
Centrifuge	2 Centrifuges for 12 cards each.	Same
Reader	Color camera (Guppy F-033-C) connected to the computer through IEEE1394.	Same
Firmware/Software		
Operating System	Windows XP	Windows Embedded Standard 7
Software version	1.0	4.0
Interfaced with Laboratory Information System (LIS)	Yes. Bidirectional.	Same.
Capability to process STAT samples	Yes	Same
QC procedures implemented	Yes	Same
Manual Entry of Sample IDs	Requires Double Blind Entry	Same
Dispense Verification	Yes. After card processing, by image analysis.	Same
Automated results reading	Yes. Microtube Digital Image Analysis.	Same
Automated test interpretation	Yes. According to predefined rules stated in a definition file.	Same
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. User's passwords are encrypted. Complies with 21CFR11.

Parameter	Predicate Device Diagnostic Grifols S.A. Erytra® with software version 1.0 (BK130067)	Subject Device Diagnostic Grifols S.A. Erytra® with new software version 4.0.0
Barcode Reading	Sample Identification Reagent Lot No. and Expiration Date	Same.

Main functionalities introduced with software version 4.0.0

The new software version 4.0.0 introduces new functionalities, several minor changes and error corrections derived from complaints. The main functionalities are described in Section 8 – Software. A detailed Revision History table including all changes from version 1.0 to 4.0 is included in Attachment 1.

The main functionalities introduced in software version 4.0.0 are:

- Auto-query
- Autovalidate and autoexport results
- Incubation process optimization
- Centrifugation start optimization
- Location to perform the final washing changed to the dilution cup.
- Reagent and sample volume calculation enhancements
- Sample barcode reading process improvements
- Configuration of rinse after inactivity periods
- Addition of a button to manually Prime
- Improve management of sample drawer lights
- Implement a warning message when new lots of reagents or cards are detected.
- Implement Technical Service remote access
- Implement user management passwords encryption
- Implement ISBT128 barcode management
- Reporting improvements
- Manage patient ID information

Performance:

Verification and Validation activities were conducted following the instruction DI.INS.301_ING "Life and Cycle and Software Validation". Regression analysis and Verification testing data showed no impact on the instrument's performance characteristics by the changes 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® with the new software version 4.0.0 when used for the defined indications for use performs as well as or better than the legally marketed predicate device Erytra® (BK130067) running under software version 1.0.