Section 5 – 510(k) Summary

Submitter's Details:

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Date of Summary:	March 29th, 2023

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:	BK220752
Device Class:	II
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Clearance Letter	November 1, 2022

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 with software version 1.2.5 (BK220752)	Subject Device Diagnostic Grifols S.A. Erytra Eflexis with new software version 3.0.0
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, 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.	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.
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 - Antibody titration - 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.

Parameter	Predicate Device Diagnostic Grifols S.A. Erytra Eflexis with software version 1.2.5 (BK220752)	Subject Device Diagnostic Grifols S.A. Erytra Eflexis with new software version 3.0.0
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.
Hardware		
Reagent Red Cell suspension	Maintained by Rotation Movement	Maintained by Rotation Movement
Barcode Symbologies	- Interleaved 2 of 5. - Code 3 of 9. - Codabar. - EAN 8 / EAN 13 / JAN 8 / JAN 13. - Codes 128 A, B & C (ISBT 128). - Others under configuration.	- Interleaved 2 of 5. - Code 3 of 9. - Codabar. - EAN 8 / EAN 13 / JAN 8 / JAN 13. - Codes 128 A, B & C (ISBT 128). - Others under configuration.
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.
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

Parameter	Predicate Device Diagnostic Grifols S.A. Erytra Eflexis with software version 1.2.5 (BK220752)	Subject Device Diagnostic Grifols S.A. Erytra Eflexis with new software version 3.0.0
Firmware/Software		
Operating System	Microsoft Windows 10 IoT Enterprise	Microsoft Windows 10 IoT Enterprise
Software version	1.2.5	3.0.0
Software applications	Executor, Manager, Importer, Technical Service, Diagnostic, System Tools and Diana Server.	Eflexis, Importer, Technical Service, Diagnostic, System Tools and Diana Server.
Interfaced with Laboratory Information System (LIS)	Yes - Unidirectional. - Bidirectional.	Yes - Unidirectional. - Bidirectional.
Capability to process STAT samples	Yes	Yes
QC procedures implemented	Yes	Yes
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.
Centrifugation time	9.0 minutes +/- 0.5min (measured from the starting to accelerate moment to the starting to brake moment).	9.0 minutes +/- 0.5min (measured from the starting to accelerate moment to the starting to brake moment).
Automated results reading	Yes. Microtube Digital Image Analysis.	Yes. Microtube Digital Image Analysis.
Automated test interpretation	Yes. According to predefined rules stated in a definition file.	Yes. According to predefined rules stated in a definition file.
Access control	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.	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.
Barcode Reading	Sample Identification Reagent Lot Nº. and Expiration Date	Sample Identification Reagent Lot Nº. and Expiration Date

Main functionalities introduced with software version 3.0.0

The new software version 3.0.0 introduces both new functionalities, major architecture changes and resolution of defects and complaints. The main functionalities are described in Section 16 - Software. A detailed Revision History table including all changes from version 1.2.5 to 3.0.0 is included in Attachment 1.

The main functionalities introduced in software version 3.0.0 are:

- Implement use of Adobe AIR technology
- To create one single application for Manager and Executor applications
- Implement reagents stability on board functionality
- Implement the new planification of techniques in incubators and centrifuges
- Implement the management of reusable cards area
- Modify the decontamination process of the instrument
- Modify Eflexis Diagnostic application
- Improve the communication with LIS
- Implement new Backup and Restore applications

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 the information submitted and discussed in this submission and in this summary that Erytra Eflexis with the new software version 3.0.0, when used for the defined indications for use, performs as well as or better than the legally marketed predicate device Erytra Eflexis (BK220752) running under software 1.2.5.