

Section 5 – 510(k) Summary

Submitter's Details

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Name of Device:

Trade Name: DG Reader Net
Regulation Number: 21 CFR 864.9175
Regulation Name: Automated blood grouping and antibody test system
Regulatory Class: Class II
Product Code: KSZ

Identification of the Legally Marketed Device (Predicated Device):

Trade Name: Erytra Eflexis
510(k) Number: BK180260
Regulation Number: 21 CFR 864.9175
Regulation Name: Automated blood grouping and antibody test system
Regulatory Class: Class II
Product Code: KSZ
Clearance Letter: December 20, 2018

Device Description:

The DG Reader Net is a workstation especially designed to read the reactions and give the results according to the grading scales as defined in the Instructions for Use of the DG Gel 8 cards, allowing laboratories to:

- Increase process safety and traceability by reducing possible identification and eliminating transcription errors.
- Increase analytical reliability interpreting results with objective criteria.

The DG Reader Net reads and interprets the following gel immunohematology tests:

- ABO Red Cell and Serum Grouping.
- Rh(D) Typing.
- Antigen Typing.
- Antibody detection.

- Antibody identification.
- Direct Antiglobulin test.
- Compatibility Tests (Crossmatching).

These tests are used at blood banks to assess compatibility between donors and recipients for blood transfusions, and to diagnose mother-fetus blood type incompatibilities.

Indications for Use:

The DG Reader Net is a device designed to read, interpret, and report the results of the processed DG Gel 8 cards. The instrument also identifies DG Gel 8 cards by reading their barcodes.

As a stand-alone or interfaced to the customer’s Laboratory Information System (LIS), the instrument automates data management requirements using DG Gel 8 cards and digital image processing.

Comparison to Predicate device:

	Predicate Device Erytra Eflexis® BK180260	Subject Device DG Reader Net
General		
Indications for Use Statement	<p>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.</p> <p>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.</p>	<p>The DG Reader Net is a device designed to read, interpret, and report the results of the processed DG Gel 8 cards. The instrument also identifies DG Gel 8 cards by reading their barcodes.</p> <p>As a stand-alone or interfaced to the customer’s Laboratory Information System (LIS), the instrument automates data management requirements using DG Gel 8 cards and digital image processing.</p>
Classification	II	II
Regulation number	21 CFR 864.9175	21 CFR 864.9175
Regulation Name:	Automated blood grouping and antibody test system	Automated blood grouping and antibody test system
Product Code	KSZ	KSZ
Useful life	7 years, considering 8 hours a day of continuous operation at maximum throughput (using DG Gel 8 ABO/Rh cards), 250 days a year.	7 years considering 8 hours a day of continuous operation at maximum throughput (read 12 cards/hour), 250 days a year.

Hardware		
Barcode symbologies	- Codabar. - Code 3 of 9. - Code 2 of 5 interleaved. - Code 128 A, B & C (ISBT 128). - EAN8/EAN13/JAN8/JAN13	- Codabar. - Code 3 of 9. - Code 2 of 5 interleaved. - Code 128 A, B & C (ISBT 128). - EAN8/EAN13/JAN8/JAN13
Grifols gel card loading capacity	200 cards	1 card
Reading system	High-resolution color reading using a color CCD camera.	High-resolution color reading using a color CCD camera.
Software		
Software applications	Executor, Manager, Importer, Technical Service, Diagnostic, System tools and Diana Server.	Executor, Manager, Importer, Technical Service, End-of-Line, System Tools and Diana Server
LIS Connectivity	Yes. Bidirectional.	Yes. Unidirectional
QC procedures implemented	Yes	Yes
Barcode Reading	Sample Identification Reagent N° and Expiration Date	Sample Identification Reagent N° and Expiration Date
Manual Entry of Sample IDs	Requires Double Blind Entry	Requires Double Blind Entry
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.
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.

A total of 2,345 donor and patient samples were tested in parallel with three (3) DG Reader Net and 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 results obtained in the Method Comparison studies supported the conclusion that the DG Reader Net with its DG Gel® 8 cards and Medion Grifols Diagnostics Reagent Red Blood Cells is equivalent to Erytra Eflexis® using the same reagents for the determination of ABO grouping and Rh (D) typing, Rh phenotyping, detection and identification of unexpected IgG antibodies and Compatibility testing.

Conclusions:

Diagnostic Grifols S.A. concludes, based on all information submitted and discussed in this submission and in this summary, DG Reader Net is substantially equivalent to the reader module included in the predicate device Erytra Eflexis and has been demonstrated to meet all requirements for a product to be marketed in the United States.