Section 5 – 510(k) Summary

Submitter's Details:

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Date of Summary:	August 3rd, 2022

Name of Device:

Trade Name:	DG Reader Net
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:	DG Reader Net
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) Number:	BK190379
Device Class:	II
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Clearance Letter	October 11th, 2019

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

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:

Parameter	Predicate Device Diagnostic Grifols S.A. DG Reader Net (BK190379)	Subject Device Diagnostic Grifols S.A. DG Reader Net
General		
Indications for Use Statement	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.	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.
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. - 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).

Parameter	Predicate Device Diagnostic Grifols S.A. DG Reader Net (BK190379)	Subject Device Diagnostic Grifols S.A. DG Reader Net
Useful life	7 years considering 8 hours a day of continuous operation at maximum throughput (read 12 cards/hour), 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.
Hardward		
Grifols gel card loading capacity	1 card	1 card
Reading system	High-resolution color reading using a color CCD camera.	High-resolution color reading using a color CCD camera.
Software		
Barcode Reading	Sample Identification Reagent Nº and Expiration Date	Sample Identification Reagent Nº and Expiration Date
Automated test interpretation	Yes. According to predefined rules stated in a definition file.	Yes. According to predefined rules stated in a definition file.

Performance:

All new risks and hazard analysis related to the addition of the antibody titration technique into the DG Gel System have been performed and documented per ISO 14971 guidelines.

A total of 172 plasma or serum samples containing a known ABO or non-ABO antibody but with unknown titer, were tested with three (3) DG Reader Net and FDA-licensed reagents. DG Gel 8 Anti-IgG (rabbit) and DG Gel 8 Neutral cards were read in parallel, in DG Reader Net (method under validation) and visually by the operator. Afterwards, the obtained titers were compared. The selected plasma or serum samples covered the common blood group antigens (ABO, Rh, K, Kidd, Duffy, MNS, etc.).

The results obtained in the Method Comparison studies supported the conclusion that the semi-automated antibody titration using the DG Reader Net was equivalent to the manual DG Gel 8 titration technique, up to a titer of 64 (higher titers are considered not reached in DG Reader Net).

Conclusions:

Diagnostic Grifols S.A. concludes, based on all the information submitted and discussed in this submission and in this summary that DG Reader Net, when used for the defined indications for use, performs as well as or better than the legally marketed predicate device DG Reader Net (BK190379). In addition, all the requirements for a product to be marketed in the United Stated has been demonstrated.