Section 4 – 510(k) Summary

Submitter's Details

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Date of Summary:	June 20th, 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 11, 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.
- 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 DG Reader Net BK190379	Subject Device 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.	Same
Classification	II	Same
Regulation number	21 CFR 864.9175	Same
Regulation Name:	Automated blood grouping and antibody test system	Same
Product Code	KSZ	Same
Useful life	7 years considering 8 hours a day of continuous operation at maximum throughput (read 12 cards/hour), 250 days a year.	Same
Grifols gel card loading capacity	1 card	Same
Reading system	High-resolution color reading using a color CCD camera.	Same
Software applications	Executor, Manager, Importer, Technical Service, End-of-Line, System Tools and Diana Server	Same

Barcode Reading	Sample Identification Reagent Nº and Expiration Date	Same
Automated results reading	Yes. Microtube Digital Image Analysis. (Reactions graded according to the definitions given in the DG Gel 8 Package Insert).	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.	Same

Performance:

All required performance tests have been conducted with acceptable results. All performance studies have demonstrated that DG Reader Net 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 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).