

Section 4 – 510(k) Summary

Submitter's Details

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Name of Device:

Trade Name: DG Reader
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
Classification Name: Automated Blood Grouping and Antibody Test System
510(k) Number: BK140101
Device Class: II
Product Code: KSZ
Regulation Number: 21 CFR 864.9175
Clearance Letter: May 21, 2014

Device Description:

The DG Reader reads processed DG Gel® 8 cards by using an internal camera to photograph DG Gel® 8 cards. This photograph is transmitted to the computer, where it is digitized by the image processing card. The digitized image is then processed by the software, which provides the reaction strength according to the grading scales as defined in the Package Insert of the DG Gel® 8 cards and interprets the results. The instrument identifies DG Gel® 8 cards by reading their barcodes.

Indications for Use:

The DG Reader is a device designed to read, interpret, and generate reports of the results of processed DG Gel® 8 cards. The instrument also identifies DG Gel® 8 cards by reading their barcodes. As a stand-alone instrument or interfaced to the customer's Laboratory Information System (LIS), the DG Reader 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 (BK140101)	Subject Device Diagnostic Grifols S.A. DG Reader
Indications for Use Statement	The DG Reader is a device designed to read, interpret, and generate reports of the results of processed DG Gel® 8 cards. The instrument also identifies DG Gel® 8 cards by reading their barcodes. As a stand-alone instrument or interfaced to the customer’s Laboratory Information System (LIS), the DG Reader automates data management requirements using DG Gel® 8 cards and digital image processing.	Same
Reagents	DG Reader is used with Diagnostic Grifols DG Gel 8 cards.	Same
Barcode reading	DG Gel® 8 card Lot No. and Expiration Date	Same
DG Gel 8 card loading capacity	1 DG Gel 8 card	Same
DG Gel 8 card loading system	Manual	Same
Number of different DG Gel 8 card types	Unlimited	Same
Test interpretation	Yes. According to pre-defined rules stated in a definition file that is part of the software	Same
Reading system	CCD camera and an image acquisition card located inside the PC	Same
Results reading	Yes. Microtube Digital Image Analysis. (Reactions graded according to the definitions provided in the DG Gel® 8 cards Package Inserts)	Same
Useful life	5 years (based on an average use of 8 hours a day and 200 days a year)	Same

Performance:

All required performance tests have been conducted with acceptable results. All performance studies have demonstrated that DG Reader 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 when used for the defined indications for use performs as well as or better than the legally marketed predicate device DG Reader (BK140101).