Section 4 – 510(k) Summary

Submitter's Details

Name	Diagnostic Grifols S.A.
Address	Passeig Fluvial, 24, Parets del Valles Barcelona, 08150, Spain
Establishment Registration Number:	3002772505
Contact Person:	Joaquín Alberto Tamparillas Technical Director at Diagnostic Industrial Group of Grifols, S.A. joaquin.alberto@grifols.com Phone: (34) 670-924-632
Date of Summary:	September 5th, 2018

Name of Device:

Trade Name:	Erytra®
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 Gel 8 Neutral
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) Number:	BK160100
Device Class:	II
Product Code:	KSZ
Regulation Number:	21 CFR 864.9175
Clearance Letter	November 9, 2016

Device Description:

DG Gel 8 Neutral card consists of a plastic support with eight microtubes containing gel in a buffered medium. The microtubes, without antibodies, are used in techniques where antibodies react directly with the red blood cells.

Indications for Use:

The DG Gel 8 Neutral card is for the detection of antibodies to red blood cell antigens of human blood samples and for its use as a control microtube.
For use with the DG Gel System.
For in vitro diagnostic use.

Comparison to Predicate Device:

Parameter	Predicate Device DG Gel 8 Neutral (BK160100)	Subject Device DG Gel 8 Neutral
Intended Use	The DG Gel 8 Neutral card is for the detection of antibodies to red blood cell antigens of human blood samples and for its use as a control microtube. For use with the DG Gel System. For in vitro diagnostic use.	The DG Gel 8 Neutral card is for the detection of antibodies to red blood cell antigens of human blood samples and for its use as a control microtube. For use with the DG Gel System. For in vitro diagnostic use.
Regulatory Class	II	II
Product Code	KSZ	KSZ
Regulation number	21 CFR 864.9175	21 CFR 864.9175
Common Name	Automated Blood Grouping and Antibody Test Systems	Automated Blood Grouping and Antibody Test Systems
Principle of the test	Immunohematology gel technique	Immunohematology gel technique
Techniques	Saline techniques: - Determination of the ABO reverse group - ABO compatibility test (immediate spin crossmatch test) - Antibody detection (at cold, room temperature and 37ºC) - Use as a Control microtube Enzymatic techniques: - Screening and/or identification of unexpected antibodies.	Saline techniques: - Determination of the ABO reverse group - ABO compatibility test (immediate spin crossmatch test) - Antibody detection (at cold, room temperature and 37ºC) - Use as a Control microtube Enzymatic techniques: - Screening and/or identification of unexpected antibodies.
Results	Report results as an agglutination grade, absence of agglutination or hemolysis.	Report results as an agglutination grade, absence of agglutination or hemolysis.
Storage conditions	2-25ºC	2-25ºC
Reagent preparation	Ready to use.	Ready to use.
Number of microtubes	8	8
Instruments for automated method	Erytra or WADiana Compact.	Erytra Eflexis, Erytra or WADiana Compact.

Performance:

All required performance tests have been conducted with acceptable results. All performance studies have demonstrated the device is safe and effective when used with Erytra Eflexis.

Conclusions:

Diagnostic Grifols S.A. concludes, based on all information submitted and discussed in this submission and in this summary, DG Gel 8 Neutral when used with Erytra Eflexis for the defined indications for use performs as well as or better than the legally marketed predicate device DG Gel 8 Neutral (BK160100) when used with Erytra.