

## **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](mailto:joaquin.alberto@grifols.com)  
Phone: (34) 670-924-632  
Date of Summary: February 8<sup>th</sup>, 2019

### **Name of Device:**

Trade Name: WADiana® Compact  
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: WADiana® Compact  
Classification Name: Automated Blood Grouping and Antibody Test System  
510(k) Number: BK130025  
Device Class: II  
Product Code: KSZ  
Regulation Number: 21 CFR 864.9175  
Clearance Letter: August 30, 2013

### **Device Description:**

The WADiana Compact Analyzer is designed to carry out immunohematological tests, automating all operations to:

- Increase process safety and traceability by reducing possible errors in identification and transcription.
- Increase analytical reliability by standardizing the steps to reduce possible handling errors and perform results interpretation with objective criteria.
- Reduce the danger of operator contamination by reducing operator interaction with samples and reagents during the analytical process.

The WADiana® Compact Analyzer is designed to be used with DG Gel® 8 cards and Grifols Diluent, Grifols Medion Red Blood Cells and Validated Antisera Reagents.

### **Indications for Use:**

The WADiana® Compact Analyzer is a fully automated analyzer designed to automate in vitro

immuno-hematological testing of human blood utilizing the DG Gel® 8 cards technology. As a standalone or interfaced to the customer's Laboratory Information System (LIS), the WADiana® Compact Analyzer automates test processing functions and data management requirements using DG Gel® 8 cards and digital image processing.

**Comparison to Predicate Device:**

<b>Parameter</b>	<b>Predicate Device Diagnostic Grifols S.A. WADiana® Compact (BK130025)</b>	<b>Subject Device Diagnostic Grifols S.A. WADiana® Compact</b>
Indications for Use Statement	The WADiana® Compact Analyzer is a fully automated analyzer designed to automate in vitro immuno-hematological testing of human blood utilizing the DG Gel® 8 cards technology. As a standalone or interfaced to the customer's Laboratory Information System (LIS), the WADiana® Compact Analyzer automates test processing functions and data management requirements using DG Gel® 8 cards and digital image processing.	Same
Primary components	Analyzer Computer Software Optional hand-held bar code scanner Optional printer	Same
Specimen Types	Plasma, Serum and Red Blood Cells.	Same
Reagents	WADiana Compact is used with Diagnostic Grifols DG Gel 8 cards and Medion Grifols Diagnostics Reagent Red Blood Cells.	WADiana Compact is used with Diagnostic Grifols DG Gel 8 cards, Medion Grifols Diagnostics Reagent Red Blood Cells and Validated Antisera Reagents.
Positive identification of samples and reagents	Yes	Same
Useful life	5 years (based on an average use of 160 DG Gel 8 cards/day and 250 days/year)	Same
Sample loading capacity	48 tubes simultaneously; 1 carousel	Same
Reagent positions	18 positions (16 of them agitated), 1 carousel.	Same

<b>Parameter</b>	<b>Predicate Device Diagnostic Grifols S.A. WADiana® Compact (BK130025)</b>	<b>Subject Device Diagnostic Grifols S.A. WADiana® Compact</b>
Sample/Reagent Dispensing (pipetting) Unit	Single probe to dispense samples and reagents.	Same
Card loading capacity	24 cards.	Same
Incubator	2 independent incubators	Same
Centrifuge	1 Centrifuges for 12 cards each.	Same
System solution and waste containers	Wash Solution A Wash Solution B Waste solutions Processed cards disposal	Same

**Performance:**

All required performance tests have been conducted with acceptable results. All performance studies have demonstrated that WADiana Compact 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 WADiana® Compact when used for the defined indications for use performs as well as or better than the legally marketed predicate device WADiana® Compact (BK130025).