

Section 5 – 510(k) Summary

Submitter's Details

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Name of Device:

Trade Name: Blood Typing Manager
Regulation Number: 21 CFR 864.9165
Regulation Name: Blood establishment computer software and accessories
Regulatory Class: Class II
Product Code: MMH

Identification of the Legally Marketed Device (Predicated Device):

Trade Name: ImmuLINK
510(k) Number: BK150333
Regulation Number: 21 CFR 864.9165
Regulation Name: Blood establishment computer software and accessories
Regulatory Class: Class II
Product Code: MMH
Clearance Letter: November 19, 2015

Device Description:

Blood Typing Manager is a stand-alone software specifically designed to aid in interfacing and managing data among immunohematology instruments, Blood Establishment Computer Software and Laboratory Information System as part of the DG Gel System.

Blood Typing Manager can only be used with:

- Grifols Erytra[®] instruments,
- Grifols Erytra Eflexis[®] instruments,
- Grifols DG Reader Net instruments.

The main functions of the Blood Typing Manager software are:

- Connectivity with immunohematology instruments and Laboratory Information System
- Data results management
- Quality Control (QC) Management
- Results validation management
- Create and print reports

Blood Typing Manager can only work with tests validated by Grifols.

Blood Typing Manager is limited to skilled personnel who have received specific training on the use of this software. The Operator must also have Laboratory Technician-level training and knowledge of immunohematology. Blood Typing Manager is regarded as a “Rx only” product.

Indications for Use:

Blood Typing Manager is a transfusion data manager software that aids in interfacing and managing data between immunohematology instruments, Blood Establishment Computer Software and Laboratory Information System.

Comparison to Predicative device:

	Predicate Device ImmuLINK BK150333	Subject Device Blood Typing Manager
Indications for Use Statement	<p>ImmuLINK is software for use in a blood banking environment as an aid in interfacing and managing data between blood bank instruments, Blood Establishment Computer Software and Laboratory Information System. ImmuLINK includes the following features and/or functions:</p> <ul style="list-style-type: none"> • It provides the ability to create and print reports of tests and results. • It supports the ability to compare current results with previous results. • It supports the automatic ordering of reflex tests. • It provides a tool so that test results produced by a testing platform can be remotely validated prior to delivery to a LIS. Results 	<p>Blood Typing Manager is a transfusion data manager software that aids in interfacing and managing data between immunohematology instruments, Blood Establishment Computer Software and Laboratory Information System. Blood Typing Manager includes the following features:</p> <ul style="list-style-type: none"> • Bidirectional connectivity with one or more LIS. • Provides the ability to centralize the management of Quality Control. • Allows user to view and validate results remotely prior to export to LIS. • Allows to create and print reports.

	can also be viewed remotely and edited prior to delivery to a LIS. <ul style="list-style-type: none"> • It provides bi-directional communication with LIS and instrument platform(s) 	
Classification	II	II
Regulation number	21 CFR 864.9165	21 CFR 864.9165
Regulation Name	Blood establishment computer software and accessories	Blood establishment computer software and accessories
Product Code	MMH	MMH
LISS Connectivity	Bidirectional	Bidirectional
Connectivity with multiple instruments	Yes	Yes
Management with multiple instruments	Yes	Yes
Accessibility	Web-based interface	Web-based interface
Secure Web access	HTTPS	HTTPS
Reports	Create and print reports	Create and print reports
Database results	Yes	Yes
Results management	View, edit and validate	View and Validate
Automatic ordering of reflex tests	Yes.	No
QC Management	No	Yes

Performance:

All risk and hazard analysis have been performed and documented per ISO 14971 guidelines.

All required software and system verification procedures have been executed and analyzed with acceptable results.

The results of the validation supported the conclusion that Blood Typing Manager software v.2.0.0 meets the stated intended use, when it is used in combination with Grifols immunohematology analyzers (Erytra, Erytra Eflexis and Reader Net) and connected to LIS.

Conclusions:

Diagnostic Grifols S.A. concludes, based on all information submitted and discussed in this submission and in this summary, Blood Typing Manager is substantially equivalent to the predicate device ImmuLINK and has been demonstrated to meet all requirements for a product to be marketed in the United States.