

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: Blood Typing Manager
510(k) Number: BK220744
Regulation Number: 21 CFR 864.9165
Regulation Name: Blood establishment computer software and accessories
Regulatory Class: Class II
Product Code: MMH
Clearance Letter October 4th, 2022

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, and to aid users in Antibody Identification procedure 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
- Load of Grifols RRBCs antigenic table and aid users in antibody identification results
- 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, and aids users in Antibody Identification procedure.

Blood Typing Manager includes the following features:

- Bidirectional connectivity with one or more LIS.
- Provides the ability to centralize the management of Quality Control.
- Allows user to load Grifols RRBCs antigenic tables and aids user in antibody identification results.
- Allows user to view and validate results remotely prior to export to LIS.
- Allows to create and print reports.

Comparison to Predicative device:

	Predicate Device Blood Typing Manager (BK220744)	Subject Device Blood Typing Manager
Intended Use	<p>Blood Typing Manager is a transfusion data manager software that aids in interfacing and managing data between immunoematology 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. 	<p>Blood Typing Manager is a transfusion data manager software that aids in interfacing and managing data between immunoematology instruments, Blood Establishment Computer Software and Laboratory Information System, and aids users in Antibody Identification procedure. 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 load Grifols RRBCs antigenic tables and aids user in antibody identification results. • Allows user to view and validate results remotely prior to export to LIS. • Allows to create and print reports.
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

	Predicate Device Blood Typing Manager (BK220744)	Subject Device Blood Typing Manager
Database results	Yes	Yes
Results management	View and Validate	View, edit and validate
Automatic ordering of reflex and rerun tests	No	Yes
QC Management	Yes	Yes
Software version	2.0.0	3.0.0

Main functionalities introduced with software version 3.0.0

The new software version 3.0.0 introduces new functionalities, several minor changes and resolution of defects derived from complaints. The main functionalities are described in [Section 16 – Software](#). A detailed Revision History table including all changes from version 2.0.0 to 3.0.0 is included in [Attachment 1](#).

The main functionalities introduced in software version 3.0.0 are:

- Multisite management. Allow the possibility to assign access to a role in more than one laboratory.
- Creation of manual orders by authorized users.
- Authorized users will be able to request to execute again a profile (rerun) test.
- Automatic rules to generate new orders (reflex) or repeat orders (rerun).
- Allow the user to manage samples through Sample detail view.
- Modify the interpretation results of non-validated orders.
- Implementation of modular licensing system.
- Load of Grifols RRBCs antigenic table and aid users in antibody identification results.
- Cybersecurity improvements

Performance:

All new risk and hazard analysis related to the new software version 3.0.0 have been performed and documented per ISO 14971 guidelines.

Verification and Validation activities were conducted following the instruction DI.INS.301_ING “Life and Cycle and Software Validation”. Regression analysis and Verification testing data showed no impact on the instrument’s performance characteristics by the changes described in this submission.

Moreover, additional performance studies of some new functionalities were performed. A comparison study was performed to evaluate the performance of the Ab ID module of Blood Typing Manager compared with the antibody identification obtained manually, using AABB standard procedures.

Likewise, an internal study was performed to validate the correct performance of the automatic ordering of reflex tests of Blood Typing Manager. Six different reflex rules were created to cover different configurations before order creation and/or after receiving the results leading to a result action: creation of a new profile, creation of a rerun order or conversion of the trigger profile to another.

To finalize, an internal study was carried out to validate the modular licensing of Blood Typing Manager. Different licensing modules were tested to assess each feature under each license complied with the expected result.

In summary, the results of the validation and performance studies supported the conclusion that Blood Typing Manager software 3.0.0 with new main functionalities and improvements, meets the defined user needs and intended use when it is used in combination with Grifols immunochemistry 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, that Blood Typing Manager with the new software version 3.0.0 and when used for the defined indications for use, performs as well as or better than the legally marketed predicate device Blood Typing Manager (BK220744) running under software version 2.0.0.