

Exhibit 1, Summary

PREMARKET NOTIFICATION 510(k) SUMMARY
As required by §807.92

Device Name – as required by 807.92(a)(2):

Trade Name: **Antibody Check©**
Common/Classification Name: **Blood Establishment stand alone software**
Classification Name: **Software, Blood Bank, Stand Alone Products**
Classification Regulation: **No classification regulation**
Device Class: **Unclassified**
Product Code (Procode): **MMH**
Premarket Notification submitter:
Company Name: **Prescott Ideas, LLC**
Company Address: **8960 E. Anna Pl.**
Tucson, AZ 85710
Contact: **David Prescott**
Preparation Date: **March 30, 2007**

A. LEGALLY MARKETED PREDICATE DEVICE – as required by 807.92(a)(3)

Meditech Blood Bank (Magic) (Antibody Identification Functionality only)
Magic Client Server, Version 5.1, BK980046
FDA SE Letter: 2/8/2000
MEDITECH Medical Information Technology, Inc.
MEDITECH Circle
Westwood, MA 02090

B. DEVICE DESCRIPTION – as required by 807.92(a)(4) [Exhibit 5]

The submitted device, **Antibody Check©**, is a computer panel used in the identification of unexpected antibodies. It is intended to aid the technologist in ruling out antibodies by automating the same logic pattern followed when using the printed versions of the panel. It also helps quickly choose selected cells to use for further testing.

Antibody Check© makes no decision about which antibodies are present. It helps the technologist see which antibodies are ruled out, interpret the data, and decide which antibodies are present.

Some of the main functionality available in **Antibody Check©** includes:

Automates the process used with the current manual method (paper and pencil) panels to identify unexpected antibodies.

Creates an archive, unique for each subscriber, of expired reagent cells that can be searched for selected cells.

Automates the process used with the current manual method panels to search for selected cells to aid in identifying unexpected antibodies.

Technologist and reviewers get the same, repeatable results with automated speed.

Helps prevent technologists from reversing or mixing the proper logic while ruling out antibodies.

C. DEVICE CLAIMS - as required by 807.92(a)(4)

Antibody Check© is a computer panel used in the identification of unexpected antibodies.

It is intended to aid the technologist in ruling out antibodies by automating the same logic pattern followed when using the printed versions of the panel.

It also helps quickly choose selected cells to use for further testing.

Antibody Check© makes no decision about which antibodies are present. It helps the technologist see which antibodies are ruled out, interpret the data, and decide which antibodies are present.

D. PRODUCT AND TECHNICAL SPECIFICATIONS - as required by 807.92(a)(4) [Exhibit 9]

Antibody Check© automates the transfusion service's two steps of using reagent red blood cells for antibody identification:

- entry of test results onto a paper copy of the antigen panel and the application of logic patterns to determine identity of antibodies that may be present in the patient's blood,
- choosing of selected cells to complete the identification from an archive specific to each subscriber.

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As with the manual methods, the technologist is the one that makes the decision as to the identity of the specific antibody.

Antibody Check© is stand alone software and does not require networking.

E. INTENDED USE - as required by 807.92(a)(5) [Exhibit 3]

Antibody Check© is an electronic aid to trained blood transfusion service technologists for use in the identification and ruling out of antibodies to human red blood cell antigens from antibody test systems, it is updated with each lot number, and it assists technologists in quickly choosing selected cells to complete the identification.

Antibody Check© duplicates the logic used in existing antibody test systems in an electronic version of the printed panel for each lot of reagent cells: If an antigen is *present* on the cell and the specimen *did not react*, the presence of the corresponding antibody is tentatively excluded.

Antibody Check© tracks individual subscriber's past lot numbers, and as allowed by standard protocols, searches these expired lots for specific cells that have the antigens which will complete the identification.

F. LEVEL OF CONCERN – as requested by recent FDA guidance [Exhibit 4]

The FDA guidance document "*Guidance For The Content of Premarket Submissions For Software Contained In Medical Devices*," May 11, 2005, clearly identifies that all devices with the indications for use like the submitted device are considered by FDA to be a MAJOR Level of Concern.

Prescott Ideas, LLC acknowledges this Guidance, but believes that the submitted product, **Antibody Check**, has, at best, a Level of Concern that is at the lowest level of any MAJOR concern. The product makes no decisions regarding which antibodies are present and only aids the technologist to see which antibodies are ruled out, providing an aid to the interpretation of the data, and an aid to deciding which antibodies are present.

G. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6) [Exhibit 17]

Antibody Check© software has these same technological characteristics as the predicated device, Meditech Blood Bank (Magic) (Antibody Identification Functionality only), Magic Client Server, Version 5.1, BK980046:

- Blood Establishment Software used by transfusion services—an application with a focused functionality intended for blood establishments.
- Uses the following computer hardware and input/output devices:
 - Intel Pentium 4 Processor, CPU 2.4 GHz, 512MB RAM
 - MS Windows XP Home Edition, V2002, Java enableed
- Provides User aids and Labeling for blood establishment technologists, including:
 - Installation materials
 - Training materials
 - Validation protocol
 - Detailed user manual provided
- Previous panel data is available for query in retained files.
- Has functional elements specific to blood establishments and blood transfusion activities.
- Functional elements are a small subset of typical blood establishment operations.

Antibody Check© software has these additional characteristics:

- The software application shows which antibodies are ruled out based on negative test results for homozygous positive antigens on reagent cells.
- The software automates the searching of past panels for reagent cells with specific antigen characteristics to aid in identifying unexpected antibodies.
- The software's results are repeatable so technologists' work and decisions may be checked by a reviewer.
- Panel data is updated by the submitter from data sheets provided with each new lot of reagent cells distributed by the original manufacturers.
- Data in the electronic versions of the printed panels is verified by the submitter to a high degree of accuracy.
- Software has an internal check feature. If any data in the panel is changed or corrupted, the program will not open but displays an error message instead. The technologist then reverts to the current procedure with the paper copies of the panel, and works with Antibody Check© submitter to resolve the problem with new, correct software.

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- If any of the data is changed by the reagent manufacturer, a replacement panel with the changed data is distributed. The new changed panel has a unique lot number, and replaces the panel containing the previous data.

H. PERFORMANCE DATA TESTING AND REVIEW - as required by 807.92(b)(1)

Non-Clinical Testing [Exhibits 12 & 13]

The submitted device has undergone significant verification and validation testing. Alpha validation testing included testing of all executable code and functionality and confirmation that all identified hazards have been adequately addressed by software functionality, the user interface, documentation, or user SOP.

Alpha validation activities included exhaustive validation scripts of all Software Design Specifications (SDS) which was summarized and discussed to provide a preliminary record of performance data. Additionally, the submitter duplicated the operational environment of a sophisticated user and provided the complete record of those executed scripts as operational performance data. The output of these two performance data records documents that **Antibody Check**® met its required requirements and design specifications as intended.

Clinical Data [Exhibit 14]

Finally, the submitter had users establish an operational environment of the submitted device and create their own validation record ("clinical data") of that implemented environment as a third record of performance data. The output of this clinical data confirms that **Antibody Check**® met its required requirements and design specifications as intended.

The submitter believes the predicate device, Meditech Blood Bank (Magic) (Antibody Identification Functionality only), submission did include alpha validation submitted in compliance with 807.92(b)(2). The submitter cannot document any clinical data or beta testing data submitted by the predicate device submitter. The submitter believes **Prescott Ideas** submitted **Antibody Check**'s validation testing/performance data clearly documents the submitter's claim of substantial equivalence.

I. SUBSTANTIAL EQUIVALENCE SUMMARY [Exhibit 17]

The submitted device, **Antibody Check**®, has the same indications for use as the predicate device, Meditech Blood Bank (Magic) (Antibody Identification Functionality only), that is a software application intended to be used by professionals in blood establishments.

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Antibody Check© has the same or very similar technological characteristics as the predicate device. However, while the submitter believes the characteristics are sufficiently precise to assure equivalence, the submitter has carried out validation and performance testing to further document substantial equivalence. The results of this testing substantiates that **Antibody Check©** performs as well as the predicate device.

J. CONCLUSIONS

The performance testing and validation studies document that **Antibody Check©** is substantially equivalent to the predicate software application, Meditech Blood Bank (Magic) (Antibody Identification Functionality only).