ALBAcyte® IgG Sensitized Red Blood Cells II

510(k) Summary (as required by 21 CFR 807.92(a))

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. Submitter:

Alba Bioscience Limited

Manufacturer and Manufacturing Site:

Alba Bioscience Limited

James Hamilton Way

Penicuik

EH26 0BF

Scotland

United Kingdom

Tel. +44 (0)131 357 3333

Fax. +44 (0)131 445 7125

Contact Person:

Vittorio Borromeo, Senior Manager, Regulatory Affairs

Date:

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Premarket Notification 510(k)
ALBAcyte® IgG Sensitized Red Blood Cells II
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B. Name of Device:

ALBAcyte® IgG Sensitized Red Blood Cells II

Alba Bioscience Limited Product Code:

Z443U

Common Name:

Quality control kit for blood banking reagents

Proprietary Name:

ALBAcyte® IgG Sensitized Red Blood Cells II

Device Class:

ALBAcyte® IgG Sensitized Red Blood Cells II is a class II IVD medical device according to the stipulations of 21 CFR 864.9650.

Regulation Number and Product Code:

Regulation Number: 864.9650

US FDA Product Code: KSF

Classification Panel:

Hematology

C. Predicate(s):

ALBAcyte® IgG Sensitized Red Blood Cells (510(k) Number: BK100005, Product Code: KSF).

D. Device Description:

ALBAcyte® IgG Sensitized Red Blood Cells II (Product Code Z443U) consists of one component: one vial of ALBAcyte® IgG Sensitized Red Blood Cells II. The vial contains 10 mL washed red blood cells (3-5% suspension) in a preservative solution (Modified Alsever's Solution). The red blood cells are prepared from at least four group O R_r1 blood donors and are sensitized using a human monoclonal IgG antibody of Anti-D specificity.

ALBAcyte® IgG Sensitized Red Blood Cells II is presented in a 10 mL capacity vial fitted with a dropper. The volume delivered by the dropper is approximately 40 µL.

The preservative solution, Modified Alsever's Solution, has been specially formulated to preserve red cell integrity and contains the following components - trisodium citrate, citric acid, dextrose, inosine, neomycin sulfate (0.103 g/L) and chloramphenicol (0.349 g/L).

ALBAcyte® IgG Sensitized Red Blood Cells II, is a modified version of the legally marketed predicate device, ALBAcyte® IgG Sensitized Red Blood Cells. ALBAcyte® IgG Sensitized Red Blood Cells II has been developed to show an increased reaction strength, when used in confirmation of the validity of a negative indirect antiglobulin test (IAT), when compared to the US legally marketed predicate device, ALBAcyte® IgG Sensitized Red Blood Cells (BK100005).

There are no additional components or accessories provided, or required for use, with ALBAcyte® IgG Sensitized Red Blood Cells II.

E. Indications for Use:

These IgG Sensitized Red Blood Cells are for the control of the Indirect Antiglobulin Test (IAT) and Direct Antiglobulin Test (DAT).

F. Substantial Equivalence Comparison and Discussion:

Table 1 below presents a direct comparison of the subject device, ALBAcyte® IgG Sensitized Red Blood Cells II, and the US legally marketed predicate device, ALBAcyte® IgG Sensitized Red Blood Cells (BK100005).

Table 1 – Device Comparison

Characteristic	**Predicate Device** ALBAcyte® IgG Sensitized Red Blood Cells (BK100005)	**Subject Device** ALBAcyte® IgG Sensitized Red Blood Cells II
Device Classification Name	Quality control kit for blood banking reagents	Same as predicate
Product Code	KSF	Same as predicate
US FDA Classification	Class II	Same as predicate
US FDA Regulation Number	21 CFR 864.9650	Same as predicate
US FDA Review Panel	Hematology	Same as predicate
Intended Use	These IgG Sensitized Red Blood Cells are for the control of the Indirect Antiglobulin Test (IAT) and Direct Antiglobulin Test (DAT).	Same as predicate

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Characteristic	**Predicate Device** ALBAcyte® IgG Sensitized Red Blood Cells (BK100005)	**Subject Device** ALBAcyte® IgG Sensitized Red Blood Cells II
Explanation of Intended Use (summarized from Instructions for Use)	ALBAcyte® IgG Sensitized Red Blood Cells are used to confirm the validity of negative antiglobulin tests by demonstrating the Anti-IgG activity of the anti-human globulin (AHG) reagent used in the test. When ALBAcyte® IgG Sensitized Red Blood Cells are added to a negative antiglobulin test the resultant agglutination indicates both the presence and the activity of the anti-human globulin.	Same as predicate (with exception of revision to product name)
Intended User(s)	*In vitro* diagnostic (IVD) device for professional use only.	Same as predicate
Reagent	One vial containing 10 mL, 3-5% (v/v) suspension of red blood cells in Modified Alsever's Solution. Red blood cells prepared from at least four group O R_1r blood donors, sensitized using a human monoclonal IgG antibody of Anti-D specificity	Same as predicate
Antibody Component – Cell Line	(b) (4) manufactured by Alba Bioscience Limited	Same as predicate
Anti-D Sensitization Ratio/Time/Temperature	(b) (4)	(b) (4)
Mode of Action	Hemagglutination by manual tube methods	Same as predicate

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Characteristic	Predicate Device ALBAcyte® IgG Sensitized Red Blood Cells (BK100005)	Subject Device ALBAcyte® IgG Sensitized Red Blood Cells II
Test Principle	The principle of the test is hemagglutination. AHG reacts with IgG coated red blood cells, leading to agglutination and verifies the negative result of the IAT and DAT.	The principle of the test is hemagglutination. The Anti-IgG component of AHG reacts with IgG coated red blood cells, leading to agglutination which: 1. Verifies the presence of active Anti-IgG in the antiglobulin test, thereby acting as a positive control, and a negative control for AHG reagents lacking Anti-IgG. 2. Confirms that neutralization of the Anti-IgG has not occurred.
Pack Size	One, three or ten vial pack options (1 x 10 mL, 3 x 10 mL or 10 x 10 mL)	One, three or ten vial pack (1 x 10 mL, 3 x 10 mL or 10 x 10 mL)
Trade Dress	Quotient	Same as predicate

Table 1 shows that the subject device, ALBAcyte® IgG Sensitized Red Blood Cells II, and the US legally marketed predicate, ALBAcyte® IgG Sensitized Red Blood Cells (BK100005), are substantially equivalent with regards to the following parameters: classification, intended use, reagent design, and mode of action.

Comparator testing of ALBAcyte® IgG Sensitized Red Blood Cells II, and the US legally marketed predicate ALBAcyte® IgG Sensitized Red Blood Cells, (BK100005), has been performed as part of the performance evaluation study. The objective of comparator testing was to demonstrate substantial equivalence between the two products, with respect to safety and effectiveness, for their intended use. A more detailed description of the performance evaluation studies is provided in section G.

The results produced from the comparator testing confirmed that the performance of the two products is substantially equivalent when used as controls of the Indirect Antiglobulin Test (IAT) and Direct Antiglobulin Test (DAT).

G. Performance Testing:

Performance evaluation studies have been conducted to demonstrate that the performance of ALBAcyte® IgG Sensitized Red Blood Cells II is substantially equivalent to that of ALBAcyte® IgG Sensitized Red Blood Cells (the US legally marketed predicate), and that the product is safe and effective for its intended use.

Performance evaluation incorporated comparator testing, to demonstrate substantial equivalence between the two reagents with regards to safety and effectiveness, and precision/robustness testing, to demonstrate consistency of results.

The following performance evaluation studies were performed:

1. Comparator Testing: Three lots of Z443U ALBAcyte® IgG Sensitized Red Blood Cells II were tested in parallel with two lots of the US legally marketed, ALBAcyte® IgG Sensitized Red Blood Cells (Z441U), and results were compared for concordance. Comparator testing was performed by trained personnel at one internal site: Alba Bioscience Limited.

2. Precision/Robustness Testing: Three lots of ALBAcyte® IgG Sensitized Red Blood Cells II were tested against a panel of four anti-human globulin reagents, to confirm appropriate reactivity. Precision testing was performed by trained personnel at one internal site (Alba Bioscience Limited), on different days, by different operators, to demonstrate consistency of results, and included a lot to lot comparison.

No discrepancies were reported between ALBAcyte® IgG Sensitized Red Blood Cells II and the legally marketed predicate across the comparator study. Robustness testing demonstrated consistent product performance.

The results of the performance evaluation studies demonstrate that the performance of ALBAcyte® IgG Sensitized Red Blood Cells II is substantially equivalent to that of US legally marketed predicate, ALBAcyte® IgG Sensitized Red Blood Cells (BK100005), and that ALBAcyte® IgG Sensitized Red Blood Cells II is safe and effective for routine use a control of the Indirect Antiglobulin Test (IAT) and Direct Antiglobulin Test (DAT).

H. Summary of Software:

ALBAcyte® IgG Sensitized Red Blood Cells II has not been designed with any software device components or accessories, nor is it intended to be used in combination with any software device. Consequently, this section is not applicable to ALBAcyte® IgG Sensitized Red Blood Cells II as this device does not require software to fulfil its intended use (as stipulated in the Instructions for Use for this device).

I. Compliance with FDA Guidance and Consensus Standards:

ALBAcyte® IgG Sensitized Red Blood Cells II has not been designed or manufactured in conjunction with any US FDA consensus standards.

J. Conclusion:

ALBAcyte® IgG Sensitized Red Blood Cells II is a Class II IVD medical device according to the stipulations of 21 CFR 864.9650. This product is substantially equivalent to the US legally marketed predicate, ALBAcyte® IgG Sensitized Red Blood Cells (510(k) Number: BK100005).

Substantial equivalence has been demonstrated via a comparator study, and subsequent analysis of results obtained.

Performance Evaluation testing has confirmed that ALBAcyte® IgG Sensitized Red Blood Cells II is ‘fit for purpose’, i.e. is suitable for its intended use, as stated in the Instructions for Use for this device. No issues with safety or effectiveness are anticipated for this device.