AlbaQ-Chek® Simulated Whole Blood Controls

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:

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Date:

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Premarket Notification 510(k)
AlbaQ-Chek® Simulated Whole Blood Controls
510(k) Summary (as required by 21 CFR 807.92(a)

B. Name of Device:

AlbaQ-Chek® Simulated Whole Blood Controls

Alba Bioscience Limited Product Code:

Z498

Common Name:

Quality control kit for blood banking reagents

Proprietary Name:

AlbaQ-Chek® Simulated Whole Blood Controls

Device Class:

AlbaQ-Chek® Simulated Whole Blood Controls 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):

AlbaQ-Chek® Simulated Whole Blood Controls (510(k) Number: BK170013, Product Code: KSF).

D. Device Description:

AlbaQ-Chek® Simulated Whole Blood Controls is supplied as a set of 4 x 6 mL simulated whole blood samples (vial 1 to vial 4).

AlbaQ-Chek® is prepared from red blood cells collected from blood donors. Each individual donation expresses the appropriate ABO and RhD blood group antigens and also the appropriate ABO blood group antibodies. ABO and anti-D antibodies are of monoclonal origin and anti-c is of polyclonal origin.

The concentration of red blood cells in each of the controls is 15±2%. The red blood cells are suspended in a preservative solution to retard hemolysis and bacterial contamination.

- Vial 1 - Group A RhD Negative (rr) containing anti-B, anti-D
- Vial 2 - Group O RhD Positive (R_1R_1) containing anti-A, anti-B, anti-c
- Vial 3 - Group B RhD Positive (R_1r) containing anti-A
- Vial 4 - Group A_2B RhD Positive

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

E. Indications for Use:

For *in vitro* diagnostic use only.

AlbaQ-Chek® is intended for use as ABO, RhD and antibody screening controls for automated/semi-automated blood grouping systems using column agglutination techniques.

F. Substantial Equivalence Comparison and Discussion:

Table 1 below presents a direct comparison of the subject device, Alba**Q-C**hek®, and the US legally marketed predicate device, Alba**Q-C**hek®, (510(k) Number: BK170013).

Table 1 – Device Comparison

Characteristic	Predicate Device AlbaQ-Chek® Simulated Whole Blood Controls 510(k) Number: BK170013	Subject Device AlbaQ-Chek® Simulated Whole Blood Controls
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	864.9650	Same as predicate
US FDA Review Panel	Hematology	Same as predicate
Intended Use	Alba**Q-C**hek® is intended for use as ABO, RhD and antibody screening controls for automated/semi- automated blood grouping systems using column agglutination techniques.	Same as predicate
Intended Use Clarification	Alba**Q-C**hek® provides a means of confirming the reactivity of routinely used reagents. Observation of expected test results with Alba**Q-C**hek® will confirm the reactivity of Anti-A, Anti-B, Anti-A,B and Anti-D (Anti-Rho), as well as reverse grouping cells and reagent red blood cells used for antibody detection.	Same as predicate

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Characteristic	Predicate Device AlbaQ-Chek® Simulated Whole Blood Controls 510(k) Number: BK170013	Subject Device AlbaQ-Chek® Simulated Whole Blood Controls
Intended User(s)	*In vitro* diagnostic (IVD) device for professional use only.	Same as predicate
Reagent	Four vial kit; Vial 1: One vial (1 x 6 mL) of Group A RhD Negative (rr) containing Anti-B, Anti-D Vial 2: One vial (1 x 6 mL) of Group O RhD Positive (R_1R_1) containing Anti-A, Anti-B, Anti-c Vial 3: One vial (1 x 6 mL) of Group B RhD Positive (R_1r) containing Anti-A Vial 4: One vial (1 x 6 mL) of Group A_2B RhD Positive	Same as predicate
Antibody Origin	Anti-A and Anti-B: murine monoclonal Anti-D: human monoclonal Anti-c: polyclonal	Same as predicate
Test Methodology	Automated/semi-automated blood grouping systems using column agglutination techniques	Same as predicate
Validated Blood Grouping Systems		
Automated	N/A	ORTHO VISION® Max Analyzer
	ORTHO VISION® Analyzer	Same as predicate
	ORTHO ProVue® Analyzer	Same as predicate
Semi-automated	N/A	ORTHO™ Workstation

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Characteristic	Predicate Device AlbaQ-Chek® Simulated Whole Blood Controls 510(k) Number: BK170013	Subject Device AlbaQ-Chek® Simulated Whole Blood Controls
	MTS™ Work Table/ ID-MTS™ Centrifuge and ID-MTS™ Incubator	Same as predicate
Test Principle	Hemagglutination - presence of antigens and corresponding antibody induces hemagglutination	Same as predicate
Number of Vials	Four	Same as predicate
Trade Dress	Alba Bioscience Limited	Same as predicate

Table 1 demonstrates that the subject device Alba**Q-C**hek®, and the US legally marketed predicate, Alba**Q-C**hek® (BK170013) are substantially equivalent with regards to the following parameters: classification, intended use, reagent design, and mode of action.

The composition of the subject device, Alba**Q-C**hek®, is identical to that of the US legally marketed predicate, Alba**Q-C**hek® (BK170013). The subject device differs from the predicate device as follows:

- The subject device extends the indications for use of Alba**Q-C**hek® to include suitability for use on an additional automated blood grouping system, the ORTHO VISION® Max Analyzer.
- The subject device extends the indications for use of Alba**Q-C**hek® to include suitability for use on an additional semi-automated blood grouping system, ORTHO™ Workstation.

Automated Blood Grouping Systems

To demonstrate suitability for use on an additional automated blood grouping system, the ORTHO VISION® Max Analyzer, comparator testing was performed at one external

test site. Comparator testing was performed using Alba**Q-C**hek® as ABO, RhD and antibody screening controls on both the ORTHO VISION® Max Analyzer and the ORTHO VISION® Analyzer, to demonstrate substantial equivalence, with respect to safety and effectiveness, between the subject device, Alba**Q-C**hek®, and the US legally marketed predicate, Alba**Q-C**hek®, (BK170013).

Comparator testing was conducted according to the instructions for use. Results from all tests performed on the ORTHO VISION® Max Analyzer were compared to those performed on the ORTHO VISION® Analyzer. No discrepant results were reported and all results met the expected results stated in the Instructions for Use.

The results produced from this comparator study confirmed that Alba**Q-C**hek® is suitable for use on the ORTHO VISION® Max Analyzer, and use of Alba**Q-C**hek® on the ORTHO VISION® Max Analyzer is comparable to use of Alba**Q-C**hek on the ORTHO VISION® Analyzer with regards to safety and effectiveness for the intended use as ABO, RhD and antibody screening controls.

Semi-Automated Blood Grouping Systems

To demonstrate suitability for use on an additional semi-automated blood grouping system, ORTHO™ Workstation, comparator testing was performed internally, at Alba Bioscience Limited. Comparator testing was performed using Alba**Q-C**hek® as ABO, RhD and antibody screening controls manually on ORTHO™ Workstation and separate ID-MTS™ Centrifuge and ID-MTS™ Incubator, to demonstrate substantial equivalence, with respect to safety and effectiveness, between the subject device, Alba**Q-C**hek®, and the US legally marketed predicate, Alba**Q-C**hek® (BK170013).

Comparator testing was conducted according to the instructions for use. Results from all tests performed on ORTHO™ Workstation were compared to those performed on separate ID-MTS™ Centrifuge and ID-MTS™ Incubator. No discrepant results were reported and all results met the expected results stated in the Instructions for Use.

The results produced from this comparator study confirmed that Alba**Q-C**hek® is suitable for use on ORTHO™ Workstation, and use of Alba**Q-C**hek® on ORTHO™

Workstation is comparable to use of Alba**Q-C**hek on separate ID-MTS™ Centrifuge and ID-MTS™ Incubator with regards to safety and effectiveness for the intended use as ABO, RhD and antibody screening controls.

G. Performance Testing:

Automated Blood Grouping Systems

To demonstrate suitability for use on an additional automated blood grouping system, the ORTHO VISION® Max Analyzer, performance evaluation testing was performed at one external test site.

Performance evaluation testing comprised precision/reproducibility testing to demonstrate that, when used in accordance with the Instructions for Use, Alba**Q-C**hek® performs reliably and is not influenced by variables including different ORTHO VISION® Max Analyzers, the same ORTHO VISION® Max Analyzer used on different test days, and different test lots of Alba**Q-C**hek®. No discrepant results were reported and all results met the expected results stated in the Instructions for Use.

Results of comparator testing and performance evaluation testing demonstrated that Alba**Q-C**hek® performs consistently when tested on different ORTHO VISION® Max Analyzers, on the same ORTHO VISION® Max Analyzer on different test days, and between different test lots of Alba**Q-C**hek® used on the same ORTHO VISION® Max Analyzer.

Semi-Automated Blood Grouping Systems

To demonstrate suitability for use on an additional semi-automated blood grouping system, ORTHO™ Workstation, performance evaluation testing was performed internally at Alba Bioscience Limited.

Performance evaluation testing comprised precision/reproducibility testing to demonstrate that, when used in accordance with the Instructions for Use, Alba**Q-C**hek® performs reliably and is not influenced by variables including different operators, different test days, and different test lots of Alba**Q-C**hek®. No discrepant

results were reported and all results met the expected results stated in the Instructions for Use.

Results of comparator testing and performance evaluation testing demonstrated that Alba**Q-C**hek® performs consistently when tested by different operators, by the same operator on different test days, and between different test lots of Alba**Q-C**hek® used on the same ORTHO™ Workstation.

Alba**Q-C**hek® is therefore suitable for its intended use as ABO, RhD and antibody screening controls for automated/semi-automated blood grouping systems using column agglutination techniques, including extension of the Alba**Q-C**hek® indications for use to include suitability for use on the ORTHO VISION® Max Analyzer and ORTHO™ Workstation.

H. Summary of Software:

Alba**Q-C**hek® 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 Alba**Q-C**hek® 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:

Alba**Q-C**hek® has not been designed or manufactured in conjunction with any US FDA consensus standards.

J. Conclusion:

Alba**Q-C**hek® 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, Alba**Q-C**hek® (510(k) Number: BK170013).

Substantial equivalence has been demonstrated via comparator studies using both automated and semi-automated blood grouping systems, and subsequent analysis of results obtained.

Performance Evaluation testing has confirmed that Alba**Q-C**hek® 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.