Appendix 3

510(k) SUMMARY

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

Alba Bioscience, 21 Ellen's Glen Road, Edinburgh EH17 7QT, Scotland, United Kingdom.
Tel. +44 (0)131 536 5907
Contact : Ian Carmichael, Quality Assurance and Regulatory Affairs Manager
Date: May 17, 2007

Name of Device: AlbaQ-Chek® Simulated Whole Blood Controls
The assigned 510(k) number is:

AlbaQ-Chek® Simulated Whole Blood Controls is classified as a Quality Control Kit for Blood Banking Reagents under the classification number: 864.9650 as Product Code: KSF.

AlbaQ-Chek® Simulated Whole Blood Controls is intended for use as ABO, RhD and antibody screening controls for automated/semi-automated blood grouping systems using column agglutination techniques to determine the suitability of the intended blood grouping reagents to be used.

AlbaQ-Chek® Simulated Whole Blood Controls comprises of a set of 4 x 6mL whole blood samples. Sample A is a pool of Group A Rh D Negative (rr) and contains Anti-B and Anti-D. Sample B is a pool of Group O Rh D Positive (R_1R_1) and contains Anti-A, Anti-B and Anti-c. Sample C is a pool of Group B Rh D Positive (R_1r) and contains Anti-A. Sample D is a pool of Group A_2B Rh D Positive and contains no other antibodies.

AlbaQ-Chek® Simulated Whole Blood Controls is substantially equivalent to another currently marketed predicate, the Ortho Confidence System. The intended use of these two devices is the same although the methodologies are different. AlbaQ-Chek® is designed for the control of reagents used in Column Agglutination Technology (CAT) whereas the Ortho Confidence System is designed for use in tube testing. The technological characteristics are similar, except that the Ortho Confidence System contains cells and sera in separate tubes and AlbaQ-Chek® Simulated Whole Blood Controls have cells and sera in a single tube (x 4).

Conclusions

From clinical, non-clinical tests and available data sources and comparison of the results presented at 4.1, it is possible to conclude substantial equivalence between the AlbaQ-Chek® Simulated Whole Blood Controls and the Ortho Confidence System.

AlbaQ-Chek® Simulated Whole Blood Controls is as safe, as effective and is substantially equivalent to the legally marketed predicate device the Ortho Confidence System.