510(k) Summary

Submitter:	Millipore (U.K) Ltd. Fleming Road, Kirkton Campus Livingston, EH54 7BN, United Kingdom
Contact Person:	Mark Thomson Senior Regulatory Expert Telephone: +44 1506 404087 or +44 7831 688893 (Mobile) E-mail: Mark.d.thomson@merckgroup.com
Date Prepared:	31 May 2022
Trade Name:	ORTHO™ Daily QC Simulated Whole Blood Quality Control Kit (ORTHO™ Daily QC Kit)
Classification:	Class II Hematology 21 CFR 864.9650
Product Code:	KSF
Predicate Device:	The subject device is substantially equivalent to the following device: Trade name: AlbaQ-Chek® Simulated Whole Blood Controls (AlbaQ- Chek®) Device Name: Quality Control Kits for Blood Banking Reagents 510(k) Number: BK170086

The ORTHO™ Daily QC Simulated Whole Blood Quality Control Kit (ORTHO™ Daily QC Kit) is intended for use as qualitative controls of ABO and Rh phenotyping and antibody screening using the ID-Micro Typing System™, ORTHO™ Workstation with or without ORTHO Optix™ Reader, ORTHO VISION® Analyzer, and ORTHO VISION® Max Analyzer.

The ORTHO™ Daily QC kit for in vitro diagnostic use only. The product is for use by professional users trained in blood typing techniques

Device Description:

The purpose of daily quality assurance in the blood bank is to confirm the reliability of the test system. The test system includes reagents, test procedures and equipment. Testing known samples is an accepted method of quality control. If expected test results are observed procedures are being performed accurately and reagents and equipment are performing properly. If unexpected results are observed, the problem may be due to improper test performance, faulty equipment or contamination or deterioration of reagents. The source of the problem should be determined and resolved before patient/donor test results are reported.

ORTHO™ Daily QC kit provides a means of confirming the reactivity of routinely used reagents and is to be tested on each day of use. Observation of expected test results with ORTHO™ Daily QC kit will confirm the reactivity of ABO, Rh, and K antibodies, as well as reverse grouping cells and reagent red blood cells used for antibody detection.

The ORTHO™ Daily QC Kit is prepared from red blood cells collected from blood donors. ABO, Anti-D, anti-c and anti-Fy^a antibodies are of monoclonal origin. The Anti-D antibody is prepared to a concentration of approximately 0.1 IU/mL. The concentration of red blood cells in each of the samples is 15% ± 2%. The red cells are suspended in a citrate preservative solution to retard hemolysis and bacterial contamination. The preservative solution has been specially formulated to preserve red cell integrity and antigenicity and includes the following components; Neomycin Sulphate 0.01% & Chloramphenicol 0.03% as antibacterial additives.

- Vial 1 - Group A_1B, DCEce
- Vial 2 - Group O, DCe containing Anti-A, Anti-B and Anti-c
- Vial 3 - Group A, DcE containing Anti-B and Anti-Fy^a
- Vial 4 - Group B, ce containing Anti-A and Anti-D (concentration of approximately 0.1 IU/mL)

Indication for Use:

The ORTHO™ Daily QC Simulated Whole Blood Quality Control Kit (ORTHO™ Daily QC Kit) is intended for use as qualitative controls of ABO and Rh phenotyping and antibody screening using the ID-Micro Typing System™, ORTHO™ Workstation with or without ORTHO Optix™ Reader, ORTHO VISION® Analyzer, and ORTHO VISION® Max Analyzer.

Substantial Equivalence:

Characteristic	**Predicate Device** AlbaQ-Chek® Simulated Whole Blood Controls	**Subject Device** ORTHO™ Daily QC Simulated Whole Blood Quality
Device Classification Name	Quality control kit for blood	Same as predicate
Product Code	KSF	Same as predicate
US FDA Classification	Class II	Same as predicate
US FDA Regulation #	864.9650	Same as predicate
US FDA Review Panel	Hematology	Same as predicate
Intended Use	AlbaQ-Chek® is intended for use as ABO, RhD and antibody screening controls for automated/semi-automated blood grouping systems using column agglutination techniques.	The ORTHO™ Daily QC Simulated Whole Blood Quality Control Kit (ORTHO™ Daily QC Kit) is intended for use as qualitative controls of ABO and Rh phenotyping and antibody screening using the ID-Micro Typing System™, ORTHO™ Workstation with or without ORTHO Optix™ Reader, ORTHO VISION® Analyzer, and ORTHO VISION® Max Analyzer.

Functional and Safety Testing:	To verify that the subject device met its functional and performance requirements, repeatability and reproducibility tests were performed. The ORTHO™ Daily QC Kit is substantially equivalent to the AlbaQ-Chek® Simulated Whole Blood Controls (BK170086). The following false assay conditions were tested and were shown to demonstrate that the matrix effect of the Daily QC Kit does not impact the ability of the QC material to act in the same manner as a natural human blood sample in generating unexpected results to the factors that could affect assay performance • Incorrect diluent • Reagent mix up • Deterioration of reagents • Cards not suitable for use • Incorrect card type used • Incorrect centrifugation • Incorrect incubation conditions • Pipetting errors
Conclusion:	Millipore considers the ORTHO™ Daily QC Kit to be substantially equivalent to the predicate device listed above. This conclusion is based upon the acceptable results of testing and comparisons.