

7.0 510(k) Summary

Date Prepared

June 4, 2021

510(k) Owner/Manufacturer

Immucor, Inc.
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Norcross, Georgia 30071
Establishment Registration Number: 1034569

Contact Information

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Device Name

Trade/Device Name:	Complement Control Cells
Common Name:	Complement-Coated Control Cells
Classification Name:	Quality control kits for blood banking reagents
Unique Device Identifier (UDI):	10888234000914

Device Class

Regulatory Class:	II
Product Code:	KSF
Regulation Number:	21CFR§864.9650
Classification Advisory Committee:	Hematology
Review Advisory Committee:	Hematology

Predicate Device Information

Trade/Device Name:	Complement Control Cells
Clearance:	Pre-Amendment Device Component of Gamma Biologicals, Inc.'s RQC Kit; reagent quality control for blood banking reagents

Device Description

Complement Control Cells is a blood bank quality control reagent used to verify the anti-C3 reactivity of Anti-Human Globulin reagents. Red blood cells are coated with the C3b (C3c/C3d) component of human complement in plasma using a cold-low-ionic-strength procedure (Fruitstone method). The C3b-coated red blood cells are suspended to a concentration of 2-4% in a buffered preservative solution containing adenosine and adenine to retard hemolysis and/or loss of reactivity during the dating period. Chloramphenicol (0.25 mg/mL), neomycin sulfate (0.1 mg/mL), and gentamycin sulfate (0.05 mg/mL) are added as preservatives. The reagent is filled into a glass vial with attached dropper assembly. For *in vitro* diagnostic use only.



Intended Use

Complement Control Cells are intended for use in confirming reactivity of the anti-C3 component of Anti-Human Globulin.

Technological Comparison to Predicate Device

Below is a comparison of the technological characteristics of modified Complement Control Cells compared to the predicate Complement Control Cells.

Characteristic	Predicate	Modified Device
Trade/Device Name	Complement Control Cells (Pre-Amendment Device)	Identical
Product Code	KSF	Identical
Regulation Number	21CFR§864.9650	Identical
Intended Use Statement	Complement Control Cells are intended for use in confirming reactivity of the anti-C3 component of Anti-Human Globulin.	Identical
Method of Manufacturing	Prepared from whole blood using a cold low-ionic-strength procedure (Fruitstone method)	Identical
Red Blood Cell Concentration	2-4%	Identical
Suspending Solution	Buffered preservative solution containing adenosine and adenine to retard hemolysis and/or loss of reactivity during the dating period. Chloramphenicol (0.25 mg/ml), neomycin sulfate (0.1 mg/ml), and gentamycin sulfate (0.05 mg/ml) are added as preservatives	Identical
Fill Volume	3 mL	Identical
Shelf Life	67 days, stored at 1-10 °C	Identical
Container Closure	20x60 mm glass vial with dropper assembly	Identical
Test Method(s)	Manual	Manual Adding use in automated assays to indications for use

Non-clinical Performance

Complement Control Cells were used as the positive run control for verification performance studies of the Automated C3d Plate in C3d DAT assays on the Galileo NEO (v2.0)/NEO Iris and Galileo Echo (v.20)/ECHO Lumena. 418 test runs were performed on the NEO's and 366 test runs were performed on the ECHO's. No test runs failed related to performance of the Complement Control Cells.

Basis for Claim of Substantial Equivalence

The successful performance testing demonstrates the safety and efficacy of the modified Complement Control Cells when used for the defined indications for use.