

## 510(k) Summary

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<b>Date Prepared:</b>	January 24, 2019
<b>Trade Name:</b>	Control
<b>Classification:</b>	Class II Quality control kit for blood banking reagents 21 CFR 864.9650
<b>Product Code:</b>	KSF
<b>Predicate Device:</b>	The subject device is equivalent to the following device: ○ Beckman Coulter Control (BK060024)

### Device Description:

The Control- Formulated for Automated Systems Beckman Coulter PK7300/PK7400 is identical to the currently marketed Beckman Coulter Control (BK060024). The intended use for the Control is being extended for use on the PK7400 instrument in addition to the PK7300 instrument.

The Control is tested in conjunction with the DIAGAST PK system blood grouping and phenotyping reagents to differentiate between specific and non-specific agglutination on the PK7300 and PK7400 instruments.

The Control does not contain the monoclonal antibodies.

### Indication for Use:

The PK SYSTEM CONTROL is devoid of antibody activity and should be used in parallel testing with the PK SYSTEM BLOOD GROUPING and PHENOTYPING REAGENTS to differentiate between specific and non-specific agglutination.

### Substantial Equivalence:

Parameter	Subject Device Control	Predicate Device Beckman Coulter Control
510(k) Number	TBD	BK060024
Classification	Class II	Same
Product Code	KSF	Same
Regulation	21 CFR 864.9650	Same
Parameter	Subject Device Control	Predicate Device Beckman Coulter Control

Indications for Use	The PK SYSTEM CONTROL is devoid of antibody activity and should be used in parallel testing with the PK SYSTEM BLOOD GROUPING and PHENOTYPING REAGENTS to differentiate between specific and non-specific agglutination.	The BECKMAN COULTER CONTROL is devoid of antibody activity and should be used in parallel testing with the BECKMAN COULTER PK SYSTEM BLOOD GROUPING and PHENOTYPING REAGENTS to differentiate between specific and non-specific agglutination.
Instrument Use	For use on PK7300/PK7400 instruments	For use on Pk7200/PK7300 instruments
Formulation	Tris, EDTA, NaCl, azide-arsenite solution, 30% bovine albumin, demineralized water, blue dye and red dye solutions	Identical
Packaging	60 mL HDPE bottle with 20mL fill	Identical
Shelf Life	36 months	Identical
Storage	2-8 degrees C	Identical

**Functional and Safety Testing:**

To verify that device design met its functional and performance requirements, Control samples underwent clinical testing on the PK7400 instrument compared to the currently marketed PK7300 instrument. Lot to lot and interference testing were also performed. The Control is identical to the Beckman Coulter Control, which was cleared in BK060024.

**Conclusion:**

DIAGAST considers the Control to be equivalent to the predicate device listed above. This conclusion is based upon the acceptable results of Lot to Lot testing, interference testing and clinical testing on the PK7400 instrument compared to the PK7300 instrument.