510(k) Summary: BK 160084/0

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Date Prepared:	August 17, 2016
Trade Name:	Neg Control
Classification:	Class II Quality control kit for blood banking reagents 21 CFR 864.9650
Product Code:	KSF
Predicate Device:	The subject device is equivalent to the following device: o Seraclone® Control ABO+Rh (BK080012)
Device Description:	Neg Control is tested in conjunction with the Anti-D monoclonal reagents to distinguish between specific and non-specific agglutination in the standard direct and indirect tube agglutination methods. Neg Control is similar in composition to DIAGAST Anti-D reagents but with the exception that it does not contain the monoclonal antibodies.
Indication for Use:	Neg Control is used as a negative control in conjunction with DIAGAST monoclonal Anti-D reagents (210524-210525-210526).

Substantial Equivalence:

Parameter	Subject Device DIAGAST Neg Control	Predicate Device Bio-Rad Seraclone® Control ABO+Rh
510(k) Number	TBD	BK080012
Classification	Class II	Same
Product Code	KSF	Same
Regulation	21 CFR 864.9650	Same
Indications for Use	Neg Control is used as a negative control in conjunction with DIAGAST monoclonal ANTI-D reagents (210524-210525-210526).	Seraclone® Control ABO+Rh is used for tube test as negative control in ABO and Rh blood grouping with Seraclone® ABO+Rh Blood Grouping Reagents.

Parameter	Subject Device DIAGAST Neg Control	Predicate Device Bio-Rad Seraclone® Control ABO+Rh
Intended Use	To distinguish between specific and non-specific agglutination	Same
Formulation	Formulated in similar manner to DIAGAST Anti-D reagents without the monoclonal antibody	Formulated in similar manner to Bio-Rad Seraclone® ABO- and Rh-reagents without the monoclonal antibodies
Applicable Assays	Used only with Anti-D Blood Grouping Reagents	Used with ABO and Rh reagents
Applicable Method	Standard manual tube method	Same
Packaging	5 x 10 mL vial	1 x 10 mL vial

Functional and Safety Testing:	To verify that device design met its functional and performance requirements, representative sample of the device underwent visual, specificity, bioburden, lot to lot, aging and anticoagulant, interfering substance and clinical testing.
Conclusion:	DIAGAST considers the Neg Control to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in intended use, formulation, applicable assays and methods, and performance.