510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance to requirements of SMDA 1990 and 21 CFR §807.92.

Submitter´s Details

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Device Information

Device Name:	IH-Card Control
Common Name:	IH-Card Control
Classification Name:	Quality control kit for blood banking reagents
510(k) number:	BK140139
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9650

Identification of the Legally Marketed Device (Predicated Device)

Trade Name:	ORTHO ProVue® Analyzer
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) number:	BK110029
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9175
Clearance Letter:	July 14, 2011

Device Description

The IH-Card Control is a plastic card with six microtubes containing control gel. The control gel is designed as negative control for Blood Grouping Reagents.

Intended use

The IH-Card Control is intended for use with Bio-Rad's IH-1000 Analyzer as a supplemental control for IH-Cards with monoclonal Blood Grouping Reagents without a control well included.

Comparison to Predicate Device

The following table identifies the predicate device that was used to show equivalence of the IH-Card Control with the already FDA approved MTS™ monoclonal Control Card.

Parameter	**Predicate Device** **Micro Typing Systems Inc.** **MTS™ Monoclonal Control Card**	**Subject Device** **Bio-Rad** **IH-Card Control**
Indications for Use Statement	For use with MTS™ Monoclonal Blood Grouping Cards	Supplement Control for IH-Cards with monoclonal Blood Grouping Reagents
Composition	Formulation of the diluent and gel used is identical to manufactured MTS™ monoclonal Blood Grouping Cards. Monoclonal Control is contained in six microtubes per card.	IH-Card Control consists of six microtubes with buffered control gel and preservative.
Storage Condition	2 to 25°C	18 to 25°C
Reagent Preparation	Ready to use	Ready to use
Preservative	0.1% Sodium Azide	0.1% Sodium Azide

Clinical Performance Characteristics

Bio-Rad conducted a multicenter clinical trial in the US testing different monoclonal Blood Grouping Reagents on IH-Cards with the IH-1000 Analyzer. The study was conducted with six representative IH-Cards containing all monoclonal Blood Grouping Reagents. 4,186 patient and donor samples have been tested with this negative control formulation in comparison to FDA cleared negative control reagents.
All performance tests have been conducted with acceptable results.

Conclusion

Bio-Rad concludes, based on all information submitted and discussed in this submission and in this summary that IH-Card Control is safe, effective and substantially equivalent to the predicate device and has been demonstrated to meet all requirements for a product to be marketed in the U.S.A.