510(K) SUMMARY

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21CFR 807.92.

1.0 SUBMITTER:

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2.0 DEVICE:

Trade Name:	Procleix HIV-1/HCV/HBV Quality Control
Common Name:	Quality Control material
Classification Name:	Assayed quality control material for clinical microbiology assays
Regulation Name:	21 CFR 866.3920
Classification:	Class II
Product Code:	QTM

3.0 PREDICATE DEVICE:

Trade Name:	Amplichek I
Classification Name:	Assayed quality control material for clinical microbiology assays
Regulation Name:	21 CFR 866.3920
Classification:	Class II
Product Code:	PMN

4.0 Device Description

Procleix HIV-1/HCV/HBV Quality Control is a set of external assayed quality controls that consists of one (1) negative and three (3) positive controls. Each of the components is filled individual vials with volume of 1.3 ml of material, packaged and sold separately.

5.0 Intended Use

Procleix HIV-1/HCV/HBV Quality Control, a set of quality controls, is intended for use as an external assayed quality control material to monitor the performance of the qualitative detection of Hepatitis B Virus (HBV) DNA, Hepatitis C Virus (HCV) RNA, and Human Immunodeficiency Virus Type 1 (HIV-1) RNA with the Procleix Ultrio Elite Assay performed on the Procleix Panther System. This product is intended to be used solely with the Procleix Ultrio Elite Assay, a licensed donor screening assay, performed on the Procleix Panther System. This product is not intended to replace manufacturer controls provided with the device. This product is for in vitro diagnostic use only.

6.0 Comparison of Technological Characteristics with the Predicate Device

Grifols Diagnostic Solutions is claiming substantial equivalence to Amplichek I. The tables below compare the similarities and differences between the new and predicate devices.

Table 1. Similarities between the Subject Device and Predicate Device.

Description	**Subject Device**	**Predicate Device**
Trade Name	**Procleix HIV-1/HCV/HBV Quality Control**	**Amplichek I**
Intended Use	Procleix HIV-1/HCV/HBV Quality Control, a set of quality controls, is intended for use as an external assayed quality control material to monitor the performance of the qualitative detection of Hepatitis B Virus (HBV) DNA, Hepatitis C Virus (HCV) RNA, and Human Immunodeficiency Virus Type 1 (HIV-1) RNA with the Procleix Ultrio Elite Assay performed on the Procleix Panther System. This product is intended to be used solely with the Procleix Ultrio Elite Assay, a licensed donor screening assay, performed on the Procleix Panther System. This product is not intended to replace manufacturer controls provided with the device. This product is for in vitro diagnostic use only.	Amplichek I is intended for use as an external assayed quality control material to monitor the performance of in vitro laboratory nucleic acid testing procedures for the quantitative detection of Human Immunodeficiency Virus Type 1 (HIV-1), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV) for molecular diagnostic platforms listed in the package insert. This product is not intended to replace manufacturer controls provided with the device. This product is not intended for use with blood donor screening assays in U.S. or Canada.
Analytes	HIV-1, HBV, HCV	HIV-1, HBV, HCV
Form	Liquid	Liquid
Preservatives	Contain Preservatives	Contain Preservatives
Matrix	Human Plasma based	Human Plasma based
Storage (unopened)	Frozen (-35ºC to -15ºC)	Frozen (-70ºC to -20ºC)
Bench Tests Performed	Value Assignment, Reproducibility/Precision	Value Assignment, Reproducibility/Precision

Table 2. Differences between the Subject Device and Predicate Device.

Description	**Subject Device**	**Predicate Device**
Trade Name	**Procleix HIV-1/HCV/HBV Quality Control**	**Amplichek I**
Levels	2 Levels (Negative and Positive)	4 Levels (Negative and Positive L1, L2, L3)
Expected Results	For use with qualitative assays (Representative results provided)	For use with quantitative assays (Lot specific results provided)
Open Vial Claim	None (single use reagent)	7 days at 2 to 8°C or 3 vial entries whichever comes first
Package Presentation	Positive control of each analyte is packaged and sold separately (i.e. HIV-1 positive control, HCV positive control, HBV positive control)	HIV-1, HCV and HBV are packaged together in the positive control (i.e. HIV-1/HCV/HBV Positive Control)

7.0 Conclusions

The Procleix HIV-1/HCV/HBV Control are human plasma-based quality controls intended to be used to monitor the performance of nucleic acid testing in vitro diagnostic assays for the detection of HIV-1, HCV, and HBV. It is comprised of single use vials that have an expiration date of 34 months when stored at -35ºC to -15ºC.

The Procleix HIV-1/HCV/HBV Quality Control has similar technology, intended use and the data presented demonstrate the claimed equivalence to the predicate device, Amplichek I.