510(k) Summary of Safety and Effectiveness

Submitted By (21 CFR 807.92 (a)(1)):

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Date Submitted (21 CFR 807.92 (a)(1)):

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Device Name (21 CFR 807.92(a)(2)):

Name/Proprietary Trade Name:

Procleix® Optiva™ RAS (Reagent Addition Station)

Common/Usual Name:

Procleix® Optiva™ RAS

Classification Name:

Product Code: JQW

Device Classification:

Class II (Traditionally a Class I product, the RAS will be used in Blood Banking and has been deemed a Class II instrument by CBER)

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

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Predicate Device (21 CFR 807.92(a)(3)):

TECAN GENESIS Series RSP Model 150/8, currently marketed by TECAN Schweiz AG.

The instrument is classified under 21 CFR 862.2750 – Class I exempt, Product Code JQW. It received 510(k) clearance in 1995 (K953345) and is now 510(k) exempt.

Product Description (21 CFR 807.92(a)(4)):

The Procleix® Optiva™ RAS is a bench-top system that automates the reagent dispensing steps in the licensed/registered Procleix® Assays. Operation of the RAS is controlled by an operator via the built-in LCD panel, which provides a user interface with the instrument firmware. RAS firmware provides automated prompts to guide operators through dispensing procedures. The RAS also features a heating element, which may be used to regulate the temperature of pipetted liquids.

RAS instruments are configured to dispense reagents from one of the following two categories:

- **Pre-Amplification**: If configured for pre-Amplification, the RAS dispenses Amplification Reagent, Oil, and Enzyme Reagent in the Amplification step of the licensed/registered Procleix Assays. The Procleix Optiva RAS is equipped with a heating block that maintains the required temperature for Enzyme Reagent addition.

- **Post-Amplification**: If configured for post-Amplification, the RAS dispenses Probe Reagent and Selection Reagent in the Hybridization Protection Assay (HPA) step of the licensed/registered Procleix Assays.

Intended Use and Indications for Use (21 CFR 807.92(a)(5):

Intended Use

The Procleix® Optiva™ Reagent Addition Station (RAS) is a bench top, firmware-controlled liquid pipettor intended for use in the licensed/registered Procleix® Assays. The RAS also features a heating element, which may be used to regulate the temperature of pipetted liquids.

Indications for Use

The Procleix Optiva RAS automates the reagent dispensing steps in the licensed/registered Procleix Assays. RAS instruments are configured to dispense reagents from one of the following two categories.

- **Pre-Amplification**: If configured for pre-Amplification, the RAS dispenses Amplification Reagent, Oil, and Enzyme Reagent in the Amplification step of the licensed/registered Procleix Assays. The Procleix Optiva RAS is equipped with a heating block that maintains the required temperature for Enzyme Reagent addition.

- **Post-Amplification**: If configured for post-Amplification, the RAS dispenses Probe Reagent and Selection Reagent in the Hybridization Protection Assay (HPA) step of the licensed/registered Procleix Assays.