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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Date of Summary:	January 31, 2018

Name of Device

Trade or Proprietary Name:	TANGO infinity
Common Name:	Automated Blood Grouping and Antibody Test System
Classification Name:	Automated Blood Grouping and Antibody Test System
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9175

Identification of the Legally Marketed Device (Predicated Device)

Trade or Proprietary Name:	TANGO optimo
Common Name:	Automated Blood Bank System
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) number:	BK080013
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9175
Clearance Letter:	July 23, 2008

DESCRIPTION OF THE DEVICE

TANGO infinity Automated Blood Bank Analyzer utilizes hemagglutination and solid phase methodology in ABO, Rh(D) (including weak D testing) and Rh Phenotyping and Kell blood grouping for patient and donor testing. It also includes on receipt, independent confirmation of donor unit labeling as well as antibody, detection, identification of unexpected antibodies. The TANGO infinity instrument is an automated blood bank analyzer for Erytype S and Solidscreen II microplate strips.

DEVICE COMPARISON TABLE

Table 1: Substantial Equivalence Comparison

Parameter	Predicate Device TANGO optimo *Automated Blood Bank Analyzer System*	Subject Device TANGO infinity *Automated Blood Grouping and Antibody Test System*
Indications for Use Statement	Intended for use in ABO, Rh(D) (including weak D testing) and Rh Phenotype and Kell blood grouping for patient and donor testing, including on receipt, independent confirmation of donor unit labeling. The TANGO optimo Automated Blood Bank Analyzer System uses Anti-Human Globulin Anti-IgG Solidscreen II to detect human red blood cells sensitized with IgG alloantibodies and/or autoantibodies to include tests for antibody screening, antibody identification and the Direct Antiglobulin Test. Also, Blood Grouping Reagent Solidscreen II Anti-D is used to detect weak D and partial D (DVI and DVII) antigens.

The TANGO optimo automated system utilizes Blood Grouping Reagents and Anti-Human Globulin Reagents specifically formulated and manufactured by or for Bio-Rad Medical | The TANGO infinity automated blood grouping and antibody test system is an automated instrument intended for the in vitro serological analysis of human blood specimens. In the USA, TANGO infinity is "Rx only" and operates with TANGO infinity Software Version 1.5. It generates results from individual images that must be verified by visual inspection by a qualified person called a validator. In rare cases, where the software is unable to decide, manual editing may be necessary.

TANGO infinity utilizes Erytype S agglutination methodology for ABO (forward and reverse blood grouping), Rh(D), Rh Phenotype and Kell blood grouping.

TANGO infinity utilizes Solidscreen II solidphase methodology for weak D and partial D testing, antibody screening and identification of red |

Parameter	Predicate Device **TANGO optimo** *Automated Blood Bank Analyzer System*	Subject Device **TANGO infinity** *Automated Blood Grouping and Antibody Test System*
	Diagnostics GmbH, and licensed and cleared exclusively for this system.	cell alloantibodies, auto control and direct antiglobulin testing. The TANGO infinity uses reagents and microwell strips approved for the TANGO infinity. Operators of TANGO infinity must be trained by authorized personnel and must be familiar with the content of this TANGO infinity User Manual. This TANGO infinity User Manual is designed to serve as a reference manual for operations and troubleshooting, to assist writing institutional SOPs and to assist training.
Classification	II	Same
510(k) Number	BK080013	-
Product Code	KSZ	Same
Regulation Number	21 CFR 864.9175	Same
Common name	Automated Blood Grouping and Antibody Test System	Same
Tests Performed	• Blood Group and Rh(D) • Antigen typing • Antibody Screening • Antibody Identification • Direct Antiglobulin Test • AHG crossmatch	Same • Auto control
Primary components	• Analyzer • Computer • Software • Printer	Same
Specimen Types	Plasma, Serum and Red Blood Cells	Same
Capability to process STAT samples	Yes	Same

Parameter	Predicate Device TANGO optimo *Automated Blood Bank Analyzer System*	Subject Device TANGO infinity *Automated Blood Grouping and Antibody Test System*
QC procedures implemented	Yes	Same
Barcode Reading	Sample Identification, Reagent Lot No. and Expiration Date	Same
Manual Entry of Sample IDs or Reagent Data	Yes	Same
Sample Loading Random Access	Yes	Same
Sample loading capacity	144 tubes simultaneously, 12 racks with 12 samples each	120 tubes simultaneously, 10 racks with 12 samples each
Sample Barcode Type	• Coda-bar • Code 39 • Interleaved 2/5 • EAN • (isbt) Code 128 (Subset C)	Same
Reagent loading capacity	18 positions • 3 racks with 4 positions for Reagent Red Blood Cells • 2 Racks with 3 positions for Diluents)	27 positions • 3 racks with 5 positions for Reagent Red Blood Cells • 3 Racks with 4 positions for Diluents
Reagent Barcode type	Code 128 (Subset C)	Same
Reagent Red Cell Suspension	Yes	Same
Plate loading capacity	10 Plates with 12 strips each	Same
Plate and Strip Transport System	Yes	Same
Pipettor	2 independent pipettor arms	1 pipettor arm
Aspirate Verification	For the whole strip before centrifuge step	After each aspirate step
Strip linear shaking system	Yes	Same
Incubator	Two independent temperature areas 37ºC and room temperature	Same
Incubator Temperature Tolerance	Incubator temperature specification at 37 ºC is ±2ºC	Same

Parameter	Predicate Device **TANGO optimo** *Automated Blood Bank Analyzer System*	Subject Device **TANGO infinity** *Automated Blood Grouping and Antibody Test System*
Incubator capacity	16 positions • 5 position for RT • 10 postions for 37 ℃ • 1 position for balance strip	Same
Centrifuge	1 Centrifuge; 4 strips capacity	Same
Centrifuge speed	The centrifuge speed is 30 to 900 g depending on the requirements of the test assay	Same
Centrifugation time	The centrifugation time depends on the requirements of the test assay	Same
Orbital shaker	4 strip capacity	Same
Orbital shaking frequence	The orbital shaking frequency is depending on the requirements of the test assay	Same
Results reading	Yes. CCD camera and Digital Image Analysis.	Same
Test interpretation	Yes. According to predefined rules stated in a definition file.	Same
System solutions and waste containers	• System liqiud: DI water • Wash buffer • Liquid waste container • Strip waste using conveyer belt	• System liqiud: DI water • Wash buffer • Liquid waste container • Strip waste using a bin
Total speed	12 samples (ABO/ABS 3) per hour, including forward & reverse group	Same
Interfaces	Bidirectional with Laboratory Information System	Same
Useful life	5 years minimum considering a normal function of 230 tests/day and 300 days/year	Same
Computer	TANGO optimo is supplied with a general purpose computer meeting the required specifications can be used	TANGO infinity is supplied with a general purpose computer meeting the required specifications can be used
Operating system	Window XP, Service Pack 3	Windows 7
IH-Com Connectivity	No	Yes

CONCLUSION

The verification and validation activities for TANGO infinity have been completed and the results have been found satisfactory to confirm the system is meeting the software requirements.

Bio-Rad concludes, based on all information submitted and described in this submission and this summary that TANGO infinity is safe, effective and substantially equivalent to the predicate device.