

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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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
510(k) number:	-
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 infinity
Common Name:	Automated Blood Grouping and Antibody Test System
Classification Name:	Automated Blood Grouping and Antibody Test System
510(k) number:	BK190312
Device Class:	II
Product Code:	KSZ
Regulation number:	21 CFR 864.9175
Clearance Letter:	April 10, 2019

DESCRIPTION OF THE DEVICE

TANGO infinity is an automated instrument intended for the *in vitro* serological analysis of human blood specimens utilizing hemagglutination and solid phase methodology.

The analyzer is capable of automating the testing process from pipetting sequences of liquids (including diluting samples) through automated and standardized analysis of the end reaction. Process control features on the TANGO infinity include positive sample identification, automated recording of reagents (lot number, expiration date, onboard storage time tracking, sample dilutions, reagent addition and mixing, incubation (room temperature and 37°C), washing, centrifugation, re-suspension, and image analysis. Orders can be generated manually at the TANGO infinity or can be imported by a Laboratory Information System (LIS) interface.

This 510(k) summary applies to the modification of TANGO infinity associated with the instrument's software version (SW) update to SW 1.6.

DEVICE COMPARISON TABLE

The predicate device identified for this submission is TANGO infinity, FDA cleared under BK190312. The device comparison of the subject and predicate device is presented in Table 1 below.

Table 1: Substantial Equivalence Comparison

Parameter	Predicate Device Bio-Rad, TANGO infinity BK190312	Subject Device Bio-Rad, TANGO infinity -
Indications for Use Statement	The TANGO infinity automated blood grouping and antibody test system is an automated instrument intended for the <i>in vitro</i> 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	The TANGO infinity automated blood grouping and antibody test system is an automated instrument intended for the <i>in vitro</i> serological analysis of human blood specimens. In the USA, TANGO infinity is "Rx only" and operates with TANGO infinity Software Version 1.6. 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

Parameter	Predicate Device Bio-Rad, TANGO infinity BK190312	Subject Device Bio-Rad, TANGO infinity -
	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 cell alloantibodies, crossmatch, 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. The 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.	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 cell alloantibodies, crossmatch, 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. The 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	BK190312	-
Product Code	KSZ	Same
Regulation No.	21 CFR 864.9175	Same
Common name	Automated Blood Grouping and Antibody Test System	Same
Software version	SW 1.5	SW 1.6
Tests Performed	<ul style="list-style-type: none"> • Blood Group and Rh(D) • Antigen typing • Antibody Screening • Antibody Identification • Direct Antiglobulin Test • AHG crossmatch • Auto control 	Same

Parameter	Predicate Device Bio-Rad, TANGO infinity BK190312	Subject Device Bio-Rad, TANGO infinity -
Primary components	<ul style="list-style-type: none"> Analyzer Computer Software Printer 	Same
Specimen Types	Plasma, Serum and Red Blood Cells	Same
Capability to process STAT samples	Yes	Same
QC procedures implemented	Yes	Same
Barcode Reading	Sample Identification, Reagent Lot No. and Expiration Date	Same
Sample loading capacity	120 tubes simultaneously, 10 racks with 12 samples each	Same
Sample Barcode Type	<ul style="list-style-type: none"> Coda-bar Code 39 Interleaved 2/5 EAN (isbt) Code 128 (Subset C) 	Same
Reagent loading capacity	27 positions <ul style="list-style-type: none"> 3 racks with 5 positions for Reagent Red Blood Cells 3 Racks with 4 positions for Diluents 	27 positions <ul style="list-style-type: none"> 3 racks with 5 positions for Reagent Red Blood Cells 3 Racks with 4 positions for Diluents (Rinsing Solution will occupy Position 1 in Rack 1 if Solidscreen II tests are scheduled)
Reagent Barcode type	Code 128 (Subset C)	Same
Plate loading capacity	10 Plates with 12 strips each	Same
Plate and Strip Transport System	Yes	Same
Pipettor	1 pipettor arm	Same
Aspirate Verification	After each aspirate step	Same
Strip linear shaking system	Yes	Same

Parameter	Predicate Device Bio-Rad, TANGO infinity BK190312	Subject Device Bio-Rad, TANGO infinity -
Incubator	Two independent temperature areas 37°C and room temperature	Same
Incubator Temperature Tolerance	Incubator temperature specification at 37 °C is $\pm 2^{\circ}\text{C}$	Same
Incubator capacity	16 positions <ul style="list-style-type: none"> • 5 position for RT • 10 positions for 37 °C • 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 frequency	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	<ul style="list-style-type: none"> • System liquid: isotonic saline • Wash buffer • Liquid waste container • Strip waste using conveyer belt 	<ul style="list-style-type: none"> • System liquid: DI water • Rinsing Solution (0.5 N NaOH) • Wash buffer • Liquid waste container • Strip waste using conveyer belt
Interfaces	Bidirectional with Laboratory Information System	Same
Computer	TANGO infinity is supplied with a general purpose computer meeting the required specifications can be used	Same
Operating system	Windows 7	Same
IH-Com Connectivity	Yes	Same

CONCLUSION

The verification and validation activities for TANGO infinity (SW 1.6) have been completed and the results have been found satisfactory to confirm the system is meeting the software requirements. Additional in-house performance studies were done to confirm safety and effectiveness of the device.

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