



**December 13, 2019**

Bio-Rad Medical Diagnostics GmbH  
Attention: Mr. David Bhend  
Bio-Rad Laboratories  
6565 185<sup>th</sup> Avenue NE  
Redmond, WA 98052

Re: BK190388  
Device Name: TANGO infinity  
Regulation Number: 21 CFR 864.9175  
Regulation Name: Automated blood grouping and antibody test system  
Regulatory Class: Class II  
Product Code: KSZ  
Dated: November 13, 2019  
Received: November 13, 2019

Dear Mr. Bhend:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email ([DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Orieji Illoh, MD  
Director  
Division of Blood Components and Devices  
Office of Blood Research and Review  
Center for Biologics Evaluation and Research

Enclosure  
Indications for Use

### Indications for Use

**510(K) Number:** BK190388

**Device Name:** TANGO infinity

#### Indications for Use:

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 1.6. 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 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.

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.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CBER, Office of Blood Research and Review

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Division Sign-Off, Office of Blood Research and Review