510(k) SUMMARY

Submitter's Name, address, telephone number, a contact person and date the summary was prepared:

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Name of the device, including the trade or proprietary name if applicable, the common or usual name and the classification name, if known:

Proprietary Name: **Platelet PGD® Test System**

Common or Usual Name: System, Detection, Bacterial, For Platelet Transfusion Products

Classification Name: Microbial growth monitor

Classification Code: Class I (Exempt)

Predicate Device: **Platelet PGD Test System (BK140201)**

Description of the Device

The Platelet PGD Test system comprises the Platelet PGD Test and Platelet PGD Controls. The Platelet PGD Test is a rapid, qualitative immunoassay that detects the presence of bacteria in platelets for transfusion. The Platelet PGD is indicated for the detection of aerobic and anaerobic Gram-positive (GP) and Gram-negative (GN) bacteria in leukocyte reduced apheresis platelets (LRAP) suspended in plasma, LRAP suspended in Platelet Additive Solution C (PAS-C) and plasma, and pre-storage pools of up to six (6) leukocyte reduced whole blood derived platelets suspended in plasma, within 24 hours prior to platelet transfusion as a safety measure following testing with a growth-based quality control test cleared by FDA for platelet components; post-storage pools (pooled within four (4) hours of transfusion) of up to six (6) units of leukocyte reduced (LR) and non-leukocyte reduced (nLR) whole blood derived platelets (WBDP) suspended in plasma and single units of LR and nLR WBDP suspended in plasma and tested within four (4)

hours prior to transfusion as individual platelet units or as components of a post-storage pool. The Platelet PGD Test consists of single-use PGD Test Devices, Reagents and Disposable Pipettes and Microfuge Tubes. There are two Platelet PGD Controls: the Platelet PGD Positive and Negative Controls. The PGD Controls are to be used only with the Platelet PGD Test as assay Quality Control Samples to verify the performance of the Platelet PGD Test. Platelet PGD Controls are provided with the Platelet PGD Test and are also available separately.

When processed platelet sample containing bacteria is added to the sample well of the Test Device, it flows into the sample pad and then enters the GP and GN conjugate pads. Here it re-solubilizes GP and GN conjugate/detector antibodies, which bind to bacterial antigens in the sample. The processed sample then carries the conjugate-labeled antigen through the nitrocellulose of the test strips to the capture lines (GP and GN antibodies). Any antigen present binds to the immobilized antibodies on the capture lines of the GP or GN test strip forming a visible pink / red line(s) if it is present in the sample above the assay's detection limit. This line is visible in the Gram-Positive (GP) and/or Gram-Negative (GN) Test Result Window. The processed sample continues to flow into the terminal wicks of both strips. As the terminal wicks are wetted by the processed sample, dye coated on their surfaces changes color from yellow to blue/purple (visible through the Procedural Control (PC) Windows). When both PC Windows have changed color to a blue/purple, the test has run to completion and is ready to be interpreted.

Statement of the Intended Use:

The Verax Platelet PGD Test is a rapid, qualitative immunoassay that detects the presence of bacteria in platelets for transfusion.

Indications for Use:

The Platelet PGD Test is a rapid, qualitative immunoassay for the detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria in
• leukocyte reduced apheresis platelets (LRAP) suspended in plasma, LRAP suspended in Platelet Additive Solution C (PAS-C) and plasma, and pre-storage pools of up to six (6) leukocyte reduced whole blood derived platelets suspended in plasma, within 24 hours prior to platelet transfusion as a safety measure following testing with a growth-based quality control test cleared by FDA for platelet components
• post-storage pools (pooled within four (4) hours of transfusion) of up to six (6) units of leukocyte reduced (LR) and non-leukocyte reduced (nLR) whole blood derived platelets (WBDP) suspended in plasma and
• single units of LR and nLR WBDP suspended in plasma and tested within four (4) hours prior to platelet transfusion as individual platelet units or as components of a post-storage pool.

Summary of the technological characteristics of the device compared to the predicate device

The Platelet PGD Test System is the same physical product as was cleared for marketing under 510(k) BK140201 (and, previously, BK110014, BK090028 and BK070044). Only the modified product's Indications for Use statement differs.

Table 1: Comparison of "Modified" Platelet PGD and Predicate Platelet PGD

Features	Platelet PGD Test System	Platelet PGD Test System BK140201
Similarities		
Intended Use	Detects the presence of bacteria in platelets for transfusion	Detects the presence of bacteria in platelets for transfusion
Device	In-vitro use	In-vitro use
Category	Class I (Exempt)	Class I (Exempt)
Sample Source	LRAP in plasma and PAS-C/plasma and whole blood derived platelets (WBDP) in plasma	LRAP in plasma and PAS-C/plasma and pools of whole blood derived platelets (WBDP) in plasma
Bacteria detected	Aerobic and anaerobic Gram-positive and Gram-negative bacteria	Aerobic and anaerobic Gram-positive and Gram-negative bacteria
Technology	Manual, rapid immunoassay detecting bacterial antigens	Manual, rapid immunoassay detecting bacterial antigens
Detection Used	Development of visible pinkish-red lines in the presence of bacterial contamination	Development of visible pinkish-red lines in the presence of bacterial contamination
Assay Controls	Positive and Negative Controls	Positive and Negative Controls

Table 1: Comparison of "Modified" Platelet PGD and Predicate Platelet PGD (continued)

Features	Platelet PGD Test System	Platelet PGD Test System BK140201
Differences		
Indications for Use	Detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria in • leukocyte-reduced apheresis platelets (LRAP) suspended in plasma, LRAP suspended in Platelet Additive Solution C (PAS-C) and plasma, and pre-storage pools of up to six (6) leukocyte reduced whole blood derived platelets suspended in plasma, within 24 hours prior to platelet transfusion as a safety measure following testing with a growth-based quality control test cleared by FDA for platelet components • post-storage pools (pooled within four (4) hours of transfusion) of up to six (6) units of leukocyte reduced (LR) and non-leukocyte reduced (nLR) whole blood derived platelets (WBDP) suspended in plasma and • single units of LR and nLR WBDP suspended in plasma and tested within four (4) hours prior to platelet transfusion as individual platelet units or as components of a post-storage pool.	Detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria in • leukocyte-reduced apheresis platelets (LRAP) suspended in plasma, LRAP suspended in Platelet Additive Solution C (PAS-C) and plasma, and pre-storage pools of up to six (6) leukocyte reduced whole blood derived platelets suspended in plasma, within 24 hours prior to platelet transfusion as a safety measure following testing with a growth-based quality control test cleared by FDA for platelet components and • pools of up to six (6) units of leukocyte reduced and non-leukocyte reduced whole blood derived (WBD) platelets suspended in plasma that are pooled within four (4) hours of transfusion.

Summary of Performance Testing:

Results of studies conducted to support Premarket Notifications leading to clearance of the predicate PGD Test, BK140201, were reviewed for their abilities to demonstrate that performance of the Platelet PGD would not be negatively impacted if single WBD platelet units were tested. Studies reviewed included a timed sampling growth model study.

Bacteria were grown on blood agar (BA) and then used to prepare bacterial stocks. Verax made serial dilutions of the stocks using phosphate buffered saline (PBS) to reach the target inoculation dose of ≤ 10 CFU/mL in a single unit.

Because of the antibacterial properties of fresh platelet-rich plasma, Verax used outdated platelet-derived plasma (OP) as inoculation media. The plasma (OP) was recovered by low-speed centrifugation, pooled and placed into empty platelet bags, one of which was used for bacteria inoculation (Test unit) and one for PBS inoculation for use as negative control (Control unit).

Following inoculation, each bag was mixed to disperse the bacteria and then sampled for testing by semi-quantitative agar plate culture to confirm the target inoculation. Approximately 18 hours post-inoculation, BA plate culture (APC) was performed to 1) confirm growth in the Test unit and 2) confirm no growth (i.e. no contamination during inoculation) in the Control unit. Test units were monitored until growth was observed; Control units were monitored for at least 5 days. For the 9 aerobic bacteria, if bacteria were not detected on the 18 hour BA plates, the cycle ended for that inoculation. Although 18 hour BA plates for the 20 *Clostridium perfringens* Test units did not detect viable bacteria, the cycles continued to 96 hours post-inoculation.

Approximately 36 hours post-inoculation, units were sampled and samples were pooled at a 1:5 ratio of inoculated Test or Control: PGD Non-reactive, in-date platelets [equal volumes from 5 different platelet units] to prepare mini-pool samples for PGD testing. Six test samples and 3 Control samples were aliquoted and coded for testing. Each of 3 Platelet PGD lots was used to test 2 replicates of Test samples and 1 replicate of Control sample. If all 9 PGD results were correct, the cycle ended. If less than 9 PGD results were correct, sampling and PGD testing was performed approximately every 12 hours until all PGD results were correct or until 96 hours post-inoculation.

All testing cycles ended with performance of BA culture testing either at the time of 100% PGD detection (the 9 aerobic bacteria) or at 96 hours post-inoculation (*Clostridium perfringens*). If bacteria were detected, identification testing was performed to confirm that the inoculated bacterial species was the species detected by both the Platelet PGD Test and APC.

The Platelet PGD Test detected 8 of the 9 aerobic bacteria at 36-48 hours post-inoculation. *Staphylococcus epidermidis* was detected at 60 and 72 hours post-inoculation.

APC testing and subsequent bacteria identification confirmed that Platelet PGD results agreed with APC results when bacteria grew (the 9 aerobic bacteria). The methods also agreed in the case of *Clostridium perfringens*; neither the Platelet PGD Test nor APC detected bacteria at 96 hours post-inoculation. Additional studies demonstrated that *Clostridium perfringens* was detected in 6-member LR WBDP mini-pools prepared by spiking a single unit with bacteria before pooling samples and testing with the PGD test.

Additional studies demonstrated that bacterial growth was comparable in fresh and outdated plasma.

Conclusions

Study data support the determination of substantial equivalence of the modified Platelet PGD Test system to the current Platelet PGD Test system based on the results of a timed sampling growth model study conducted using mini-pools. In this study 10 bacteria inoculated at low levels into single units, samples of which were subsequently pooled with 5 samples from 5 other units at the time of Platelet PGD testing. For each bacteria species, had a sample from the one bacteria-inoculated unit been tested, the time to detection could not possibly have been later (worse) than what was observed when testing the mini-pools containing a sample from the inoculated unit plus equal volumes of samples from 5 uncontaminated units. Testing using BA culture plates confirmed that the Platelet PGD Test appropriately detected bacteria.