510(k) SUMMARY

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

Submitter's Name: Verax Biomedical Incorporated
Submitter's Address: 377 Plantation Street, 4 Biotech
Worcester, MA 01605

Submitter's Telephone: 508-755-7029

Submitter's Contact: Nancy Hornbaker, VP Regulatory Affairs

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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: Bacterial Detection System

Classification Name: Bacterial Detection System for platelet transfusion products

Classification Code: Unclassified

Predicate Device: 5% sheep blood agar plates (pre-amendment)

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 for the detection of aerobic and anaerobic Gram-positive (GP) and Gram-negative (GN) bacteria in leukocyte reduced apheresis platelet (LRAP) units as an adjunct quality control test following testing with a bacterial detection device cleared by FDA for quality control testing of LRAP and pools of up to 6 leukocyte reduced and non-leukocyte reduced whole blood derived platelets (LRWBDPp and nLRWBDPp) pooled within 4 hours of transfusion as a quality control test. 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 for the detection of aerobic and anaerobic Gram-positive and Gram-negative bacteria in

- leukocyte reduced apheresis platelets (LRAP) as an adjunct quality control test following testing with a bacterial detection device cleared by the FDA for quality control testing of LRAP and
- pools of up to six (6) units of leukocyte reduced and non-leukocyte reduced whole blood derived platelets that are pooled within (4) hours of transfusion as a quality control test.

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

The Platelet PGD Test System is substantially equivalent to 5% sheep blood agar plates. Table 1 summarizes the technological characteristics of the Platelet PGD vs. the predicate device.

Table 1: Comparison of Platelet PGD and 5% Sheep Blood Agar Culture Plates

Features	Platelet PGD Test System	5% Sheep Blood Agar Culture Plates (Pre-amendment Device)
Similarities		
Intended Use	Bacterial (qualitative) detection for (adjunct) quality control testing of leukocyte-reduced apheresis platelets (LRAP) and quality control testing of pools of up to 6 leukocyte reduced and non-leukocyte reduced whole blood derived platelets (LRWBDPp and nLRWBDPp) that are pooled within 4 hours of transfusion.	Multi-purpose media for growth of micro-organisms in human specimens, including platelets.
Device	In-vitro use	In-vitro use
Category	Pre-market Notification 510(k)	Exempt (pre-amendment device)
Sample Source	LRAP, pools of whole blood derived platelets (WBDP) (LRWBDPp and nLRWBDPp)	LRAP, whole blood derived platelets (WBDP)
Bacteria detected	Aerobic and anaerobic Gram-positive and Gram-negative bacteria	Aerobic and anaerobic Gram-positive and Gram-negative bacteria
Differences		
Technology	Manual, rapid immunoassay detecting bacterial antigens	Growth of organisms on culture medium using conventional manual method
Detection Used	Development of visible pinkish-red lines in the presence of bacterial contamination.	Visual examination for presence of colonies.
Assay Controls	Positive and Negative Controls	Prepared by user as required

Summary of Performance Testing:

Testing confirmed performance characteristics of the Platelet PGD Test system and 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 $\leq$ 10 CFU/mL in a single unit.

Because of the bacterial 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 samples and 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 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 LRWBDP pools prepared by spiking a single unit with bacteria before pooling 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 Platelet PGD Test system to 5% Sheep Blood Agar Culture plates based on the results of a timed sampling growth model study of 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. Testing using BA culture plates confirmed that the Platelet PGD Test appropriately detected bacteria.