

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

K060489

B. Purpose for Submission:

To obtain a change in indications for the Dade[®] PFA-100[®] Platelet Function Analyzer and Dade[®] PFA-100[®] Reagents.

C. Measurand:

Platelet function

D. Type of Test:

Aggregation

E. Applicant:

Dade Behring Inc.

F. Proprietary and Established Names:

Dade[®] PFA-100[®] Platelet Function Analyzer and Dade[®] PFA-100[®] Reagents

G. Regulatory Information:

1. Regulation section:

21 CFR 864.5700

2. Classification:

Class II

3. Product code:

JOZ

4. Panel:

H. Intended Use:

1. Intended use(s):

The Dade[®] PFA-100[®] Platelet Function Analyzer and Dade[®] PFA-100[®] Reagents are in vitro diagnostic devices intended to aid in the detection of platelet dysfunction in citrated human whole blood.

2. Indication(s) for use:

To aid in the detection of platelet dysfunction in citrated human whole blood.

3. Special conditions for use statement(s):

4. Special instrument requirements:

I. Device Description:

The PFA-100[®] system provides a tool for clinicians to use in the detection of platelet dysfunction induced by intrinsic platelet defects, von Willebrand factor (vWF) functional deficiencies, or exposure to platelet inhibiting agents. The PFA-100[®] system simulates, under high shear stress, the interaction of platelets with an injured blood vessel. These conditions allow the PFA-100[®] system to measure in vitro platelet function as related to primary hemostasis. The PFA-100[®] instrument determines the time from the start of the test until the platelet plug occludes the aperture, and reports the time interval as the Closure Time (CT).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Dade[®] PFA-100[®] Platelet Function Analyzer and Dade[®] PFA-100[®] Reagents

2. Predicate 510(k) number(s):

K970505 & K002885

3. Comparison with predicate:

The PFA-100[®] system was described in detail and cleared under 510(k) Premarket Notification Document Control No. K970505. Subsequently, the system was cleared for a new indication, testing pediatric populations, under 510(k) Premarket Control No. K002885.

Similarities		
Item	Device	Predicate
	PFA-100[®]	PFA-100[®] (K970505 & K002885)
Intended Use	Same	To aid in the detection of platelet dysfunction in citrated human whole blood
Indications	Same	<ul style="list-style-type: none"> ▪ Normal population ▪ ASA-induced platelet dysfunction ▪ vWD patients ▪ Glanzmann's thrombasthenia ▪ Adult & pediatric populations
Principle	Same	Measures time required for platelets to adhere and aggregate resulting in occlusion of an aperture under high shear
Reagents	Same	A test cartridge unit containing a membrane coated with collagen and epinephrine or ADP
Specimens	Same	Whole blood with sodium citrate anticoagulant
Test Results	Same	Closure time in seconds; aperture occlusion

Differences		
Item	Device	Predicate
	PFA-100[®]	PFA-100[®] (K970505 & K002885)
Indications	Bleeding management	(listed above)

K. Standard/Guidance Document Referenced (if applicable):

L. Test Principle:

The Dade[®] PFA-100[®] system measures the time required for platelets to adhere and aggregate resulting in occlusion of an aperture under high shear conditions.

M. Performance Characteristics (if/when applicable):

* **Note:** Dade Behring, Inc. proposed modifications to the PFA-100[®] system based on literature references published by independent organizations. The performance characteristics of the instrument and reagents were not modified. The Clinical Performance section of the Dade[®] PFA-100[®] Reagent package insert has been modified as follows:

- The existing pediatric indication was modified to include more information regarding the use of the device as a screening assay and to add information for reference intervals for pediatric populations.
- A new indication is added for using the PFA-100[®] system as a testing aid in the management of desmopressin acetate (DDAVP) therapy.

The modifications of the proposed PFA-100[®] system are limited to labeling modification to the package insert which has been revised to include the new device indications. No modifications have been made to the device intended use or PFA-100[®] instrument Operator's Manual.

1. Analytical performance:

Refer to previously cleared 510(k) submissions – K970505 & K 002885

a. Precision/Reproducibility:

b. Linearity/assay reportable range:

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

d. Detection limit:

e. Analytical specificity:

f. Assay cut-off:

2. Comparison studies:

Refer to previously cleared 510(k) submissions – K970505 & K 002885

a. Method comparison with predicate device:

b. Matrix comparison:

3. Clinical studies:

Refer to previously cleared 510(k) submissions – K970505 & K 002885

a. Clinical Sensitivity:

b. Clinical specificity:

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off:

5. Expected values/Reference range:

N. Instrument Name:

Dade[®] PFA-100[®] Platelet Function Analyzer and Dade[®] PFA-100[®] Reagents

O. System Descriptions:

Refer to previously cleared 510(k) submissions – K970505 & K 002885

1. Modes of Operation:

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes _____ or No _____

3. Specimen Identification:

4. Specimen Sampling and Handling:

5. Calibration:

6. Quality Control:

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.