510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K032573

B. Analyte:
Procainamine

C. Type of Test:
Quantitative

D. Applicant:
Dade Behring, Inc.

E. Proprietary and Established Names:
Dimension Procainamide (PROC) Flex reagent cartridge method

F. Regulatory Information:
1. Regulation section:
   862.3320
2. Classification:
   II
3. Product Code:
   LAR
4. Panel:
   Toxicology (91)

G. Intended Use:
1. Intended use(s):
   Refer to Indications for use.

2. Indication(s) for use:
   The method is used on the Dade Behring Dimension clinical chemistry system for the quantitative determination of procainamide in serum or plasma. Measurements may be used in the diagnosis and treatment of procainamide overdose, and in therapeutic drug monitoring.

   The device is for in vitro diagnostic use.
   It is intended for prescription use.

3. Special condition for use statement(s):
   None applicable.

4. Special instrument Requirements:
   The device is for use on Dimension clinical chemistry systems.

Performance was demonstrated in this submission on the Dimension RxL analyzer.

H. Device Description:
The Flex® reagent cartridge method consists of prepackaged ready-to-use reagents in a flexible plastic cartridge for use only on the Dimension® clinical chemistry system.

I. Substantial Equivalence Information:
1. Predicate device name(s):
    Dade Behring aca procainamide test pack
2. Predicate K number(s):
    K833384
3. Comparison with predicate:

    Both devices are for measurement of the same analyte(s) in the same matrix, and are run on automated analyzers.

    The reagent formulations vary between the two devices.

Similarities		
Item	**Device**	**Predicate**
Manufacturer	Dade Behring	Dade Behring
Differences		
Item	**Device**	**Predicate**
Instrument	Dimension analyzer	aca analyzer
Technology	Petina, turbidometric	EMIT, colorimetric

J. Standard/Guidance Document Referenced (if applicable):
Refer to individual sections.

K. Test Principle:

The methodology is based on a homogenous particle enhanced turbidimetric inhibition immunoassay (PETINIA) technique which uses a latex particle procainamide conjugate (PR) and monoclonal procainamide specific antibody (Ab). Procainamide present in the sample competes with procainamide on the particles for available antibody, thereby decreasing the rate of aggregation. The rate of aggregation is inversely proportional to the concentration of procainamide in the sample. The rate of aggregation measured using bichromatic turbidimetric readings at 340 nm and 700 nm. The concentration is determined by means of a mathematical extrapolation through the use of calibrators run with the assay.

L. Performance Characteristics (if/when applicable):
1. Analytical performance:

a. *Precision/Reproducibility:*
(All performance was established on the Dimension RxL analyzer.

The number of lots of product used was not specified in the studies.

Typical precision observed for the Dimension® Procainamide (PROC) Flex® reagent cartridge method is summarized in the table below:

Sample	Mean		Standard Deviation (%CV)					
	µg/mL	[µmol/L]	Within Run			*Total*		
BioRad Liquichek® TDM Control Level 1	2.7	11.4	0.11	0.47	(4.3)	0.13	0.55	(4.9)
BioRad Liquichek® TDM Control Level 2	5.8	24.7	0.08	0.34	(1.4)	0.15	0.63	(2.6)
BioRad Liquichek® TDM Control Level 3	10.4	44.1	0.09	0.38	(0.9)	0.31	1.31	(3.0)
Low Pool (4 µg/mL)	3.76	15.98	0.16	0.68	(4.2)	0.16	0.68	(4.2)
Mid Pool (12 µg/mL)	11.64	49.47	0.17	0.72	(1.5)	0.28	1.19	(2.4)
High Pool (18 µg/mL)	17.61	74.84	0.21	0.89	(1.2)	0.43	1.83	(2.5)

Sample pools were analyzed in duplicate for 20 days. The within-run and total coefficients of variation (%CV) were calculated by the analysis of variance method according to the National Committee of Clinical Laboratory Standards (NCCLS) Guideline EP5-A (February 1999). Liquichek® is a registered trademark of BioRad, Bio-Rad Laboratories, Irvine, California 92618.

b. *Linearity/assay reportable range:*

Support for linearity is provided through visual examination of graph contrasting expected versus observed results. Expected results were established through spiking of serum samples. Samples in the study ranged from 0.29 to 20.23 micrograms per mL.

Linearity claims are also supported by visual examination of replicate measurements of the calibrators plotted against expected results.

c. *Traceability (controls, calibrators, or method):*

Calibrators are specified in the labeling but are not supplied in the kit. Calibrators were cleared under 510K number k032574.

Five levels of calibrator material, ranging in concentration from 0-20 microgram per mL are intended for use with the assay.

Traceability of the assay is not discussed by the sponsor.

d. *Detection limit:*

Sensitivity of the assay is 0.5 micrograms/mL.

To determine analytical sensitivity, the sponsor assayed the negative 0 calibrator 20 times. The mean concentration and standard deviation was calculated. The analytical sensitivity was estimated by adding 2 standard deviations to the average of the readings.

e. *Analytical specificity:*

Cross-reactivity of Desethylprocainamine is estimated to be 12%. The method used to establish this estimate is not described.

The sponsor evaluated over 50 endogenous and exogenous compounds and determined that their systemic bias was less than 10%. The compounds are listed in the package insert.

f. *Assay cut-off:*
Not applicable. This is a quantitative assay for a therapeutic drug.

2. Comparison studies:
   a. *Method comparison with predicate device:*

A total of 89 serum samples were evaluated by the candidate device and by the predicate device. The range of sample concentrations is 1.0 – 16.0 ug/mL and are adequately distributed across the reportable range of the assay.

Sample selection: The method used to select samples for inclusion in the study was not specified.
Number of study sites: not specified
Description of the site(s): not specified
Type of study site: not specified.
Operator description: not specified
Number of instruments used: not specified

Regression analysis results of the method comparison are:
Slope = 1.03
Intercept =   -0.02 ug/mL
Correlation Coefficient = 0.997

    b. *Matrix comparison:*
In order to evaluate for potential bias between the claimed matrices, the sponsor analyzed 20 replicate split samples of serum, sodium heparin, lithium heparin, and EDTA specimens. Each set of plasma results was compared to serum results. The sample concentrations spanned the reportable range of the assay. There is no apparent bias between the claimed plasma types and serum.

3. Clinical studies:
    a. *Clinical sensitivity:*
Not applicable. Clinical studies are not necessary for this device type.
    b. *Clinical specificity:*
Not applicable. Clinical studies are not necessary for this device type.
    c. *Other clinical supportive data (when a and b are not applicable):*

4. Clinical cut-off:
Not applicable.
5. Expected values/Reference range:
The therapeutic range for this assay is 4-12 micrograms/mL of procainamide.

M. Conclusion:
I recommend that this device be found substantially equivalent to the predicate device.