510(k) Summary of Safety and Effectiveness for the Dimension® Ethyl Alcohol (ETOH) Flex® Reagent Cartridge (DF22)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: K071811

AUG 24 2007

B. Date of Preparation: June 29, 2007

C. Proprietary and Established Names:

Dimension® Ethyl Alcohol (ETOH) Flex® Reagent Cartridge (DF22)

D. Applicant:

Dade Behring Inc., P.O. Box 6101, Newark, DE 19714-6101
Victor M. Carrio, Regulatory Affairs and Compliance Manager
Office: (302) 631-0376 Fax: (302) 631-6299

F. Regulatory Information:

1. Regulation section: 21 CFR § 862.3040 Clinical toxicology test system
2. Classification: Class II
3. Product Code: DIC – Alcohol Dehydrogenase, Specific Reagent for Ethanol Enzyme Method
4. Panel: Toxicology

G. Predicate Device:

The Dimension® ETOH Flex® reagent cartridge is substantially equivalent to the Dimension® ALC Flex® reagent cartridge (K904302) and to the Syva® Emit® II Plus Ethyl Alcohol Assay (K010960).

H. Device Description:

The Dimension® ETOH Flex® reagent cartridge is a prepackaged *in-vitro* diagnostic test method that is specifically designed to be used on the Dade Behring Dimension® Clinical Chemistry System. The reagents contained in the Dimension® ETOH Flex® reagent cartridge are: Reagent 1 which contains the buffering system and; Reagent 2 which contains alcohol dehydrogenase (ADH), the coenzyme nicotinamide adenine dinucleotide (NAD), buffer, preservatives, and stabilizers.

G. Intended Use: The ETOH method is an *in-vitro* diagnostic test for the quantitative measurement of ethyl alcohol (ethanol) in human serum, plasma and urine on the Dimension® System.
Ethyl alcohol test results may be used in the diagnosis and treatment of alcohol intoxication and poisoning.

I. Substantial Equivalence Information:

The Dimension Vista® ETOH Flex® reagent cartridge and the predicates, Dimension® ALC Flex® reagent cartridge and Syva® Emit® II Plus Ethyl Alcohol Assay, were compared. A comparison of the important similarities and differences between the device and the predicates is provided in the following table:

Feature	Dimension® ETOH Flex® reagent cartridge	Dimension® ALC Flex® reagent cartridge (K904302)	Syva® Emit® II Plus Ethyl Alcohol Assay (K010960)*
Intended Use	The Dimension® ETOH Flex® reagent cartridge is an *in-vitro* diagnostic test for the quantitative measurement of ethyl alcohol (ethanol) in human serum, plasma, and urine in the Dimension® System. Ethyl alcohol test results may be used in the diagnosis and treatment of alcohol intoxication and poisoning.	The ALC method used in the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to measure ethyl alcohol in human serum and supernatants from precipitated whole blood and to qualitatively detect ethyl alcohol in urine. Ethyl alcohol test results may be used in the diagnosis and treatment of alcohol intoxication and poisoning.	The EMIT® II Plus Ethyl Alcohol Assay is intended for use in the quantitative analysis of ethyl alcohol (ethanol) in human urine, serum, or plasma.
Sample Type	Plasma, serum, and urine.	Serum, supernatants from precipitated whole blood and urine.	Plasma, serum, and urine.
Measuring Range	3 -300 mg/dL	0 – 300 mg/dL	10 – 600 mg/dL
Sample Size	9 µL	3 µL	4 µL
Measurement	Bichromatic rate	Bichromatic endpoint	Bichromatic rate
Principle	The ETOH method is based on an enzymatic reaction.	The ethyl alcohol (ALC) method is a modification of the alcohol dehydrogenase (ADH) enzymatic procedure.	The Emit® II Plus Ethyl Alcohol Assay is based on an enzymatic reaction.

*Tested on the SYVA30R Analyzer.

J. Conclusion:

The Dimension® ETOH Flex® reagent cartridge is substantially equivalent to the Dimension® ALC Flex® reagent cartridge (K904302) and to the Syva® Emit® II Plus Ethyl Alcohol Assay (K010960). Comparative testing described in the protocol included in this submission demonstrates substantial equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Dade Behring, Inc.
Glasgow Business Community
c/o Mr. Victor Carrio
RA/QS Compliance Manager
P.O. Box 6101, M/S 514
Newark, DE 19714-6101

AUG 24 2007

Re: k071811
Trade/Device Name: Dimension Ethyl Alcohol (ETOH) Flex Reagent Cartridge (DF22)
Regulation Number: 21 CFR 862.3040
Regulation Name: Alcohol test system
Regulatory Class: Class II
Product Code: DIC
Dated: July 2, 2007
Received: July 11, 2007

Dear Mr. Carrio:

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 (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. 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 such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Carol Benson for

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications For Use Statement

510(k) Number (if known): K071811

Device Name:

Dimension® ETOH Flex® Reagent Cartridge (DF22)

Indications for Use:

The ETOH method is an *in-vitro* diagnostic test for the quantitative measurement of ethyl alcohol in human serum, plasma and urine. Ethyl alcohol test results may be used in the diagnosis and treatment of alcohol intoxication and poisoning.

Prescription Use __X__ **AND/OR** **Over-the-counter Use** _____
(Per 21 CFR 801 Subpart D) **(21 CFR 801 Subpart C)**

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

Concurrence of CDRH, Office of -In Vitro Diagnostic Devices (OIVD)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K071811