

3/22/99

K9290553

DADE BEHRING

DADE BEHRING INC.
P.O. Box 6101
Newark, DE 19714

Summary of Safety and Effectiveness Information

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.

Submitter's Name: Cathy P. Craft
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: February 16, 1999

Name of Product: IGM Flex™ Reagent Cartridge

FDA Classification Name: Immunoglobulin M Test System

Predicate Device: Beckman Array® Immunoglobulin M Method (K922273)

Description: The IGM Flex™ reagent cartridge for the Dimension® clinical chemistry system is a quantitative, turbidimetric assay based on the precipitation of IgM by its polyclonal antibodies.^a

IgM from serum or plasma reacts with its polyclonal antibodies to form an immunoprecipitate. Addition of polyethylene glycol accelerates the formation of the precipitate. Turbidity created by immunoprecipitation is measured as bichromatic endpoint measurements at 340 and 700 nm. The increase in turbidity is proportional to the concentration of IgM and it is calculated from a five point calibration curve.

PEG

IgM + Antibody -----> IgM-Antibody Complex

^a The antibody is manufactured by Dade Behring, Marburg, Germany

Intended Use: The IgM Method is used in the Dimension® clinical chemistry system to quantitatively measure immunoglobulin M (IgM) in human serum.

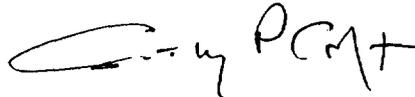
Comparison to Predicate Device:

<u>Item</u>	<u>IGM Flex™ Reagent Cartridge</u>	<u>Beckman Array® IgM</u>
Sample Type	Serum and plasma	Serum
Methodology	Immunoprecipitation	Immunoprecipitation
Detection	Bichromatic endpoint (340 and 700 nm) (turbidimetry)	Nephelometry (405 nm)

Comments on Substantial Equivalence:

Split sample comparison between the IGM Flex™ reagent cartridge and the Beckman Immunoglobulin M assay gave a correlation coefficient of 0.943, slope of 0.88, and an intercept of 4.92 mg/dL when tested with 94 clinical patient samples.

Conclusion: The IGM Flex™ reagent cartridge is substantially equivalent in principle and performance to the Beckman Immunoglobulin M Assay based on the split sample comparison discussed above.



Cathy P. Craft
Regulatory Affairs and Compliance Manager
Date: February 16, 1999



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Cathy P. Craft
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Re: K990553
Trade Name: IgM™ Flex Reagent Cartridge
Regulatory Class: II
Product Code: CFQ
Dated: February 16, 1999
Received: February 22, 1999

Dear Ms. Craft:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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.

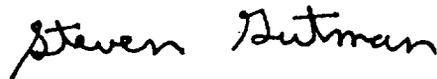
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use Statement

Device Name: IGM Flex™ Reagent Cartridge

Indications for Use:

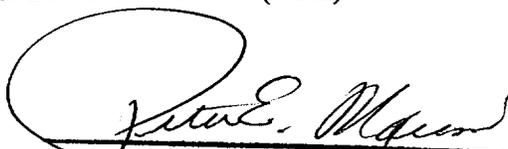
The IGM Flex™ reagent cartridge for the Dimension® Clinical Chemistry System is an *in vitro* diagnostic test intended to quantitatively measure immunoglobulin M (IgM) in serum and plasma.

Cathy P. Craft
Regulatory Affairs and
Compliance Manager

February 16, 1999

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990553

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-counter Use

(Optional format 1-2-96)