K994293

MAR - 1 2000

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: Richard M. Vaught
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: February 17, 2000

Name of Product: C4 Flex® Reagent Cartridge

FDA Classification Name: Complement C4, Antigen, Antiserum, Control; 82CZW

Predicate Device: Beckman Array® Complement C4 Assay (K780913; K922273)

Device Description: The C4 Flex® reagent cartridge for the Dimension® clinical chemistry system is a quantitative, turbidimetric assay using endpoint detection, based on the precipitation of complement component C4 by its polyclonal antibody.

Intended Use: The C4 Flex® reagent cartridge for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure complement C4 (C4) in serum as an aid in the diagnosis of immunologic disorders associated with complement C4 protein.

Comparison to Predicate Device:

Item	Dimension® C4 Flex® Reagent Cartridge	Beckman Complement C4
Sample Type	Serum	Serum
Methodology	Immunoprecipitation	Immunoprecipitation
Antibody	Rabbit polyclonal	Goat polyclonal
Detection	Bichromatic endpoint (340 and 700 nm) (turbidimetry)	Nephelometry (405 nm)

Comments on Substantial Equivalence: Split sample comparison between the Dimension® C4 Flex® reagent cartridge method and the Beckman Array® Complement C4 method gave a correlation coefficient of 0.980, slope of 1.01, and an intercept of 6.7 mg/dL when tested with 94 clinical patient samples.

Conclusion: The C4 Flex® reagent cartridge method is substantially equivalent in principle and performance to the Beckman Array® Complement C4 method based on the split sample comparison discussed above.

R.M. Vaught

Richard M. Vaught
Regulatory Affairs and Compliance Manager
Date: February 17, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR - 1 2000

Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
P.O. Box 6101
Newark, Delaware 19714-6101

Re: K994293
Trade Name: C4 Flex® Reagent Cartridge
Regulatory Class: II
Product Code: DBI
Dated: December 20, 1999
Received: December 21, 1999

Dear Mr. Vaught:

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.

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" (21CFR 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,

Steven Gutman

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:

Dimension® C4 Flex® Reagent Cartridge

Indications for Use:

The C4 Flex® reagent cartridge for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended to quantitatively measure complement C4 (C4) in serum as an aid in the diagnosis of immunologic disorders associated with complement C4 protein.

Richard M. Vaught
Regulatory Affairs and Compliance Manager

February 28, 2000

(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 K994293

Prescription Use ✓ **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)