K003419

FEB 1 4 2001

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: Lorraine Piestrak
Dade Behring Inc.
P.O. Box 6101
Newark, DE 19714-6101

Date of Preparation: October 31, 2000

Name of Product: High Sensitivity C-Reactive Protein (RCRP) Flex® reagent cartridge

FDA Classification Name: C-Reactive Protein Test System

Predicate Device: N High Sensitivity CRP assay (K991385)

Device Description: The RCRP method is based on a particle enhanced turbidimetric immunoassay (PETIA) technique. Latex particles coated with antibody to C-Reactive Protein aggregate in the presence of C-Reactive Protein in the sample. The increase in turbidity which accompanies aggregation is proportional to the C-Reactive Protein concentration. The concentration is determined by means of a mathematical function.

Intended Use: The High Sensitivity C-Reactive Protein (RCRP) Flex® reagent cartridge used on the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of C-reactive protein in serum and plasma. Measurement of C-Reactive Protein is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

Comparison to Predicate Device:

Item	RCRP Flex® reagent cartridge	N High Sensitivity CRP
Sample Type	serum and plasma	serum and plasma
Technology	particle enhanced turbidimetric immunoassay (PETIA)	particle agglutination immunonephelometry
Antibody	goat polyclonal	mouse monoclonal
Detection	Aggregation (turbidimetric) measurement	Agglutination measurement

Comments on Substantial Equivalence:
Split sample comparison between the RCRP Flex® reagent cartridge on the Dimension® clinical chemistry system and the N High Sensitivity CRP assay gave a correlation coefficient of 0.998, slope of 0.95, and an intercept of –0.13 mg/dL [-1.3mg/L] when tested with 221 clinical patient samples.

Conclusion: The RCRP Flex® reagent cartridge is substantially equivalent in principle and performance to the N High Sensitivity CRP assay based on the split sample comparison discussed above.

Lorraine Piestrak

Lorraine Piestrak
Regulatory Affairs and Compliance Manager
October 31, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 4 2001

Ms. Lorraine Piestrak
Regulatory Affairs and Compliance Manager
Dade Behring Inc.
Glasgow Business Community, Building 500
P.O. Box 6101
Newark, Delaware 19714

Re: K003419
Trade Name: High Sensitivity C-Reactive Protien (RCRP) Flex® reagent cartridge
Regulatory Class: II
Product Code: DCN
Dated: January 9, 2001
Received: January 10, 2001

Dear Ms. Piestrak:

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: High Sensitivity C-Reactive Protein (RCRP) Flex® reagent cartridge

Indications for Use:

The High Sensitivity C-Reactive Protein (RCRP) Flex® reagent cartridge for the Dimension® clinical chemistry system is an *in vitro* diagnostic test intended for the quantitative determination of C-reactive protein in serum and plasma. Measurement of C-reactive protein is useful for the detection and evaluation of infection, tissue injury, inflammatory disorders and associated diseases.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003419

Lorraine Piestrak
Regulatory Affairs and
Compliance Manager

October 31, 2000

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional format 1-2-96)