K991385

OCT 25 1999

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

Dade Behring N High Sensitivity CRP

Summary of Safety and Effectiveness

N High Sensitivity CRP is a nephelometric assay for the quantitative measurement of C-reactive protein in human serum, or heparinized or EDTA plasma. FDA has previously cleared this assay via the 510(k) process for the intended use for "the detection and evaluation of inflammatory disorders, tissue injury and infection".

The proposed revision is limited to modifications in the intended use. The intended use will be "for the detection and evaluation of tissue injury, inflammatory disorders, and associated diseases."

There are no other changes to the assay reagents or test system.

This labeling change is supported by a large, published literature base that uses both the Dade Behring methodology as well as other high sensitivity CRP methods.

Rebecca S. Ayash

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Manager, Regulatory Affairs

9/28/99

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 25 1999

Ms. Rebecca S. Ayash
Manager, Regulatory Affairs
Dade Behring Inc.
Glasgow Building 500, Mailbox 514
P.O. Box 6101
Newark, Delaware 19714

Re: K991385
Trade Name: Dade Behring N High Sensitivity CRP Assay
Regulatory Class: II
Product Code: DCK
Dated: September 28, 1999
Received: September 29, 1999

Dear Ms. Ayash:

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,

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 Statement

Device Name: Dade Behring N High Sensitivity CRP assay

Indications for Use: The Dade Behring N High Sensitivity CRP assay is an *in vitro* diagnostic test for the quantitative determination of C-reactive protein in human serum as well as heparin- and EDTA-plasma by means of particle-enhanced immunonephelometry using Dade Behring Nephelometer Systems. In acute phase response, increased levels of a number of plasma proteins, including C-reactive protein, are observed. Measurement of CRP 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 K991385

Rebecca S. Ayash
Manager, Regulatory Affairs

9/28/99
Date

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K991385
510(k) Number

Division Sign-Off
Office of Device Evaluation

✓ prescription use