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

OCT 16 2002

DADE BEHRING

K023065

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: April 10, 2001

Name of Product: Cyclosporine (CSA) Flex® reagent cartridge

FDA Classification Name: Cyclosporine Test System

Predicate Device: Abbott TDx® Cyclosporine Monoclonal Whole Blood Assay (P890025)

Device Description: The automated Dimension® CSA method uses an immunoassay technique in which free and CSA-bound antibody-enzyme species are separated using magnetic particles. Following separation, the CSA-antibody-enzyme complex is mixed with the substrate. ß-galactosidase catalyzes the hydrolysis of CPRG (chlorophenol red ß-d- galactopyranoside) to produce CPR (chlorophenol red) that absorbs light maximally at 577 nm. The change in absorbance at 577 nm due to the formation of CPR is directly proportional to the amount of CSA in the patient's sample and is measured using a bichromatic (577, 700 nm) rate technique.

Intended Use: The CSA Flex® reagent cartridge is an *in vitro* diagnostic test intended to quantitatively measure cyclosporine A (CSA) in human whole blood for the Dimension® clinical chemistry system. Measurements of CSA are used as an aid in the management of heart, liver, and kidney transplant patients.

Comparison to Predicate Device:

Item	CSA Flex® reagent cartridge	TDx® CSA
Sample Type	Whole blood	Whole blood
Technology	Affinity Particle Mediated Immunoassay	Fluorescence Polarization Immunoassay
Antibody	Mouse monoclonal	Mouse monoclonal
Detection	Bichromatic (577,700 nm) rate measurement	Fluorometric endpoint measurement
Assay sensitivity	25.00 ng/mL	25.00 ng/mL

Comments on Substantial Equivalence:
Split sample comparison between the CSA Flex® reagent cartridge on the Dimension® clinical chemistry system and the Abbott TDx® CSA assay gave a correlation coefficient of 0.957, slope of 0.83, and an intercept of - 20.7 ng/mL [-18.6 nmol/L] when tested with 667 clinical patient samples. Comparative method slope results were expected due to metabolite cross-reactivity differences.

Conclusion: The Cyclosporine(CSA) Flex® reagent cartridge is substantially equivalent in principle and performance to the Abbott TDx® Cyclosporine Monoclonal Whole Blood assay.

Lorraine Piestrak
Regulatory Affairs and Compliance Manager
April 10, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Lorraine Piestrak
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
Chemistry/Immunochemistry
Glasglow Business Community
P.O. Box 6101 – Building 500
Newark, DE 19714

OCT 16 2002

Re: k023065
Trade/Device Name: Cyclosporine (CSA) Flex® reagent cartridge
Regulation Number: 21 CFR 862.1235
Regulation Name: Cyclosporine test system
Regulatory Class: Class II
Product Code: MKW
Dated: September 13, 2002
Received: September 16, 2002

Dear Ms. Piestrak:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

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

K023065

Device Name: Cyclosporine (CSA) Flex® reagent cartridge

Indications for Use:

The CSA Flex® reagent cartridge is an *in vitro* diagnostic test intended to quantitatively measure cyclosporine A (CSA) in human whole blood for the Dimension ® clinical chemistry system. Measurements of CSA are used as an aid in the management of heart, liver and kidney transplant patients.

Lorraine Piestrak
Regulatory Affairs and
Compliance Manager

April 10, 2001

(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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023065