3/31/99

K990251

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: 1/22/99

Name of Product: DGTX Flex™ reagent cartridge

FDA Classification Name: Digitoxin Test System

Predicate Device: aca® Digitoxin Method (K891094)

Device Description: The digitoxin assay uses an immunoassay technique in which free and digitoxin-bound antibody-enzyme species are separated using magnetic particles. Digitoxin in the sample is bound by the F(ab')2-β-galactosidase in the Antibody Conjugate reagent. Magnetic particles coated with the digitoxin analog ouabain are added to bind free (unbound) antibody-enzyme conjugate. The reaction mixture is then separated magnetically. Following separation, the supernatant containing the digitoxin-antibody-enzyme complex is transferred and mixed with a substrate. The β-galactosidase (β-gal) portion of the Digoxin-F(ab')2-β-galactosidase complex catalyzes the hydrolysis of chlorophenol red-β-D galactopyranoside (CPRG) to chlorophenol red (CPR). The change in absorbance at 577 nm due to the formation of CPR is directly proportional to -β-galactosidase activity. Since β-galactosidase is not present in serum, its activity is directly proportional to digitoxin in the patient's sample and is measured using a bichromatic (577, 700 nm) rate technique.

Intended Use: The DGTX Flex™ reagent cartridge is used in the Dimension® clinical chemistry system to quantitatively measure digitoxin (DGTX) in human serum and plasma.

Comparison to Predicate Device:

Item	Dimension® DGTX	aca® DGTX
Sample Type	serum and plasma	serum
Antibody	monoclonal	polyclonal
Methodology	Affinity particle mediated immunoassay	Affinity column mediated immunoassay
Detection	Bichromatic rate (577 and 700 nm)	Monochromatic rate (405 nm)

Comments on Substantial Equivalence:
Split sample comparison between the DGTX Flex™ reagent cartridge on the Dimension® clinical chemistry system and the aca® DGTX assay gave a correlation coefficient of 0.952, slope of 1.06, and an intercept of –0.6 when tested with 93 clinical patient samples.

Conclusion: The DGTX Flex™ reagent cartridge is substantially equivalent in principle and performance to the aca® DGTX assay based on the split sample comparison discussed above.

Cathy P. Craft
Regulatory Affairs and Compliance Manager
Date:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 31 1999

Ms. Cathy P. Craft
Regulatory Affairs and Compliance Manager
DADE BEHRING, INC.
P.O. Box 6101
Newark, Delaware 19714

Re: K990251
Trade Name: Digitoxin (DGTX) Flex™ Reagent Cartridge
Regulatory Class: II
Product Code: LFM
Dated: January 22, 1999
Received: January 27, 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,

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: DGTX Flex™ reagent cartridge

Indications for Use:

The DGTX Flex™ reagent cartridge for the Dimension® clinical chemistry system is an *in vitro* diagnostic device intended to quantitatively measure digitoxin in human serum and plasma. Measurements of digitoxin are used in the diagnosis and treatment of digitoxin overdose and in monitoring levels of digitoxin to ensure appropriate therapy.

Sean Boyle

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990251

Cathy P. Craft
Regulatory Affairs and
Compliance Manager

January 22, 1999

(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)