K983151

BECKMAN COULTER

NOV 5 1998

Summary of Safety & Effectiveness
Beckman Coulter IMMAGE® Immunochemistry System Digoxin (DIG) Reagent

1.0 **Submitted By:**

Richard T. Ross
Staff Regulatory Specialist, Product Submissions
Beckman Coulter, Inc.
200 South Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 961-4912
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2.0 **Date Submitted:**

09 September 1998

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMMAGE® Immunochemistry System Digoxin (DIG) Reagent

3.2 **Classification Name**

Digoxin Test System (21 CFR §862.3320)

4.0 **Predicate Device(s):**

IMMAGE Reagent	Predicate	Manufacturer	Docket Number
IMMAGE System Digoxin (DIG)	TDx®* Digoxin (DIG)	Abbott** Laboratories, Inc	K882233

*Trademark of Abbott Laboratories
**Abbott Laboratories, Abbott Park, IL 60064

5.0 **Description:**

The IMMAGE® Immunochemistry System Digoxin (DIG) Reagent is designed for optimal performance on the IMMAGE® Immunochemistry Systems. It is intended for the quantitative determination of Digoxin in serum and plasma.

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6.0 **Intended Use:**

The IMMAGE® Immunochemistry System Digoxin (DIG) Reagent, when used in conjunction with Beckman Coulter's IMMAGE® Immunochemistry Systems and IMMAGE® Immunochemistry Systems Drug Calibrator 2, is intended for the quantitative determination of digoxin in human serum or plasma by turbidimetric immunoassay.

The IMMAGE® Immunochemistry Systems Drug Calibrator 2, used in conjunction with IMMAGE® Digoxin reagent, is intended for use on Beckman Coulter's IMMAGE® Immunochemistry Systems for the calibration of digoxin test systems.

7.0 **Comparison to Predicate(s):**

The following tables show similarities and differences between the predicate identified in Section 4.0 of this summary.

SIMILARITIES to the PREDICATE

Reagent	Aspect/Characteristic	Comments
IMMAGE System DIG Reagent	Intended use.	Same as Abbott TDx Digoxin II Reagent.
	Reaction temperature of 37° C.	
	Sample types of plasma or serum.	

DIFFERENCES from the PREDICATE

Reagent	Aspect/Characteristic	Comments
IMMAGE System DIG Reagent	IMMAGE DIG uses Near Infrared Particle Immunoassay (NIPIA) rate immunoassay methodology.	Abbott TDx reagents utilize fluorescence polarization immunoassay.
	Antibody source for IMMAGE DIG is mouse monoclonal.	Antiserum source for TDx Digoxin II is rabbit.
	IMMAGE System DIG uses a single point calibration.	TDx System Digoxin II calibration is multipoint.
IMMAGE System DIG Sample	IMMAGE System DIG requires a sample volume of 12 µL.	TDx Digoxin II requires a sample volume of 160µL.
	IMMAGE DIG does not require sample pretreatment.	TDx Digoxin II requires sample pretreatment .

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence to chemistry test systems already in commercial distribution. Equivalence is demonstrated through method comparison and imprecision experiments.

Method Comparison Study Results
IMMAGE® Immunochemistry System Digoxin (DIG) Reagent

Analyte	Sample Type	Slope	Intercept (ng/mL)	r	n	Predicate Method
IMMAGE DIG Reagent	serum	1.051	-0.13	0.993	113	Abbott TDx Digoxin II

Estimated IMMAGE System Digoxin (DIG) Reagent Imprecision

Sample	Mean (ng/mL)	S.D. (ng/mL)	%C.V.	N
Within-Run Imprecision				
Level 1	1.04	0.075	7.2	80
Level 2	2.28	0.060	2.6	80
Level 3	3.76	0.101	2.7	80
Total Imprecision				
Level 1	1.04	0.077	7.4	80
Level 2	2.28	0.064	2.8	80
Level 3	3.76	0.113	3.0	80

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 5 1998

Richard T. Ross
Staff Regulatory Specialist
Beckman Coulter, Inc.
200 South Kraemer Blvd., W-104
Brea, CA 92822-8000

Re: K983151
Trade Name: Immage Immunochemistry System Digoxin (DIG) Reagent
Regulatory Class: II
Product Code: KXT
Dated: September 9, 1998
Received: September 9, 1998

Dear Mr. Ross:

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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

510(k) Number (if known): Not yet assigned

Device Name: **IMMAGE® Immunochemistry System**
Digoxin (DIG) Reagent

Indications for Use:

The IMMAGE® Immunochemistry System Digoxin (DIG) Reagent, when used in conjunction with Beckman IMMAGE® Immunochemistry Systems and Beckman Drug Calibrator 2, is intended for the quantitative determination of digoxin in human serum or plasma by turbidimetric immunoassay.

Clinical Significance:

Digoxin is administered for conditions of heart failure or in the treatment of certain cardiac arrhythmias. Digoxin therapy is monitored for possible toxicity and inadequate therapuetic response.

Digoxin (21 CFR §862.3320)
(b) *Classification.* Class II.

(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 K 98 3157