

BECKMAN

DEC 24 1997

Summary of Safety & Effectiveness
IMMAGE™ Immunochemistry System Antithrombin III (AT3) Reagent

1.0 Submitted By:

Annette Hellie
 Sr. Regulatory Specialist, Product Submissions
 Beckman Instruments, Inc.
 200 S. Kraemer Blvd., W-337
 Brea, California 92822-8000
 Telephone: (714) 993-8767
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2.0 Date Submitted:

October 30, 1997

3.0 Device Name(s):**3.1 Proprietary Names**

IMMAGE™ Immunochemistry System Antithrombin III (AT3) Reagent

3.2 Classification Name

Antithrombin III assay (21 CFR § 864.7060)

4.0 Predicate Device(s):

IMMAGE System Reagent	Predicate	Manufacturer	Docket Number
IMMAGE System Antithrombin III (AT3)	Array Systems Antithrombin III(AT3)	Beckman Instruments, Inc.	K901977

5.0 Description:

The IMMAGE Immunochemistry System AT3 Reagent, in conjunction with Beckman Calibrator 2, is intended for use in the quantitative determination of Antithrombin III concentrations on Beckman's IMMAGE Immunochemistry System.

6.0 Intended Use:

The IMMAGE Immunochemistry System Antithrombin III (AT3) Reagent, when used in conjunction with Beckman IMMAGE™ Immunochemistry Systems and Beckman Calibrator 2, is intended for the quantitative determination of human Antithrombin III by rate nephelometry.

7.0 Comparison to Predicate(s):

The following table shows similarities and differences between the predicates identified in Section 4.0 of this summary.

Reagent	Aspect/Characteristic	Comments
SIMILARITIES		
IMMAGE System AT3 Reagent	Analytic Range	Same as Beckman Antithrombin III reagent
	Nephelometric methodology	
	Antibody source (goat)	
DIFFERENCES		
IMMAGE System AT3 Reagent	Buffer/Reagent volumes	IMMAGE System uses half of the volumes than are utilized by the Array System for AT3.
	Antibody concentration	IMMAGE AT3 has a higher antibody concentration than the Beckman Antithrombin III reagent

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, stability, and imprecision experiments that relate results obtained from the Beckman Reagent on the Array® 360 System to the IMMAGE System Reagent.

Method Comparison Study Results
 IMMAGE Antithrombin III (AT3) Reagent

Analyte	Sample Type	Slope	Intercept	r	n	Predicate Method
IMMAGE AT3 Reagent	plasma	1.088	-0.10	0.996	136	Array 360 System AT3 Reagent

Stability Study Results

Reagent	Product Claim
IMMAGE AT3	24 month shelf-life 14 day open container stability 14 day calibration stability

Estimated Imprecision

Sample	Mean (mg/dL)	S.D. (mg/dL)	%C.V.	N
Within-Run Imprecision				
Level 1	5.75	0.176	3.1	80
Level 2	29.8	0.58	2.0	80
Level 3	43.4	0.88	2.0	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.

510(k) Number (if known):

Device Name: **IMAGE™ Immunochemistry System
Antithrombin III (AT3) Reagent**

Indications for Use:

The IMAGE Immunochemistry System Antithrombin III (AT3) Reagent, when used in conjunction with Beckman IMAGE™ Immunochemistry Systems and Beckman Calibrator 2, is intended for the quantitative determination of human Antithrombin III by rate nephelometry.

21 CFR 864.7060 Antithrombin III assay

(a) Identification. An antithrombin III assay is a device that is used to determine the plasma level of antithrombin III (a substance which acts with the anticoagulant heparin to prevent coagulation). This determination is used to monitor the administration of heparin in the treatment of thrombosis. The determination may also be used in the diagnosis of thrombophilia (a congenital deficiency of antithrombin III).

(b) Classification. Class II (performance standards).

[Handwritten Signature]
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K974110

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(per 21 CFR 801.109)

OR

Over-the-Counter Use _____
Optional Format 1-2-96



DEC 24 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Annette Hellie
• Senior Regulatory Specialist
Beckman Instruments, Inc.
200 S. Kraemer Boulevard, W-104
P.O. Box 8000
Brea, California 92822-8000

Re: K974110
IMAGE™ System Antithrombin III (AT3) Reagent
Regulatory Class: II
Product Code: DDQ, JBQ
Dated: December 11, 1997
Received: December 12, 1997

Dear Ms. Hellie:

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 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.

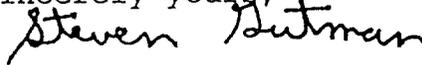
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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/dsmamain.html>".

Sincerely yours,



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): K 974110

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(Division Sign-Off)

Division of Clinical Laboratory Devices

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(per 21 CFR 801.109)

OR

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