

DEC 14 1998

K983340



Summary of Safety & Effectiveness
Beckman Coulter IMAGE® Immunochemistry System Ferritin 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:**

21 September 1998

3.0 **Device Name(s):**

3.1 **Proprietary Names**

IMAGE® Immunochemistry System Ferritin (FER) Reagent
IMAGE® Immunochemistry System Ferritin Calibrator

3.2 **Classification Name**

Ferritin Test System (21 CFR §862.3920)
Calibrator (21 CFR §862.1150)

4.0 **Predicate Device(s):**

IMAGE System	Predicate	Manufacturer	Docket Number
IMAGE System Ferritin (FER) Reagent	IMx®* Ferritin (FER)	Abbott** Laboratories, Inc	K881345 (K882233) (DIGOXAG)
IMAGE System Ferritin Calibrator			

*Trademark of Abbott Laboratories

**Abbott Laboratories, Abbott Park, IL 60064

5.0 **Description:**

The IMAGE® Immunochemistry System Ferritin (FER) Reagent and Ferritin Calibrator are designed for optimal performance on the IMAGE® Immunochemistry Systems. They are intended for the quantitative determination of Ferritin in serum.

6.0 **Intended Use:**

The IMAGE® Immunochemistry System Ferritin (FER) Reagent, when used in conjunction with Beckman Coulter's IMAGE® Immunochemistry Systems and IMAGE® Immunochemistry System Ferritin Calibrator, is intended for the quantitative determination of ferritin in human serum by turbidimetric immunoassay.

Beckman Coulter Ferritin Calibrator, when used in conjunction with Ferritin reagent, is intended for use on IMAGE Immunochemistry Systems for the calibration of ferritin.

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

IMAGE System	Aspect/Characteristic	Comments
IMAGE System FER Reagent	Intended use.	Same as Abbott IMx Ferritin
	Reaction temperature of 37° C	
IMAGE System FER Calibrator	Human Spleen Origin	
	Calibrator linked to a WHO Standard	

DIFFERENCES from the PREDICATE

IMAGE System	Aspect/Characteristic	Comments
IMAGE System FER Reagent	IMAGE FER uses Near Infrared Particle Immunoassay (NIPIA) rate immunoassay methodology	Abbott IMx reagents utilize fluorescence polarization immunoassay
	Antibody source for IMAGE FER is rabbit (polyclonal)	Antiserum sources for IMx Ferritin are rabbit and mouse
IMAGE System FER Calibrator	Calibration	IMAGE FER uses a single point calibration while IMx is multipoint
IMAGE System FER Sample	IMAGE System FER requires a sample volume of 7.5 µL	IMx ferritin requires a sample volume of 150µL

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
IMAGE® Immunochemistry System Ferritin (FER) Reagent

Analyte	Sample Type	Slope	Intercept (ng/mL)	r	n	Predicate Method
IMAGE FER Reagent	serum	1.059	-6.5	0.987	116	IMx Ferritin

Estimated IMAGE System Ferritin (FER) Reagent Imprecision

Sample	Mean (ng/mL)	S.D. (ng/mL)	%C.V.	N
Within-Run Imprecision				
Level 1	53.5	2.4	4.4	80
Level 2	172.0	5.3	3.0	80
Level 3	397.0	10.5	2.6	80
Total Imprecision				
Level 1	53.5	2.9	5.5	80
Level 2	172.0	7.1	4.1	80
Level 3	397.0	12.4	3.1	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

Mr. Richard T. Ross
Staff Regulatory Specialist,
Product Submissions
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Brea, California 92822-8000

DEC 14 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: K983340
Trade Name: IMAGE® Immunochemistry System Ferritin (FER)
Reagent and IMAGE® Immunochemistry System Ferritin
Calibrator
Regulatory Class: II
Product Code: DBF
Dated: September 21, 1998
Received: September 23, 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.

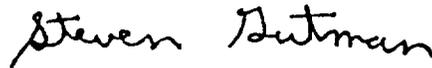
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2

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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K983340

page 1 of 2

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

Device Name: **IMAGE® Immunochemistry System
Ferritin (FER) Reagent**

Indications for Use:

The IMAGE® Immunochemistry System Ferritin (FER) Reagent, when used in conjunction with Beckman Coulter IMAGE® Immunochemistry Systems and Beckman Coulter Ferritin Calibrator, is intended for the quantitative determination of ferritin in human serum by turbidimetric immunoassay.

Clinical Significance:

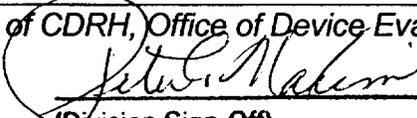
Ferritin is the main iron storage protein in the body. The concentration of ferritin is directly proportional to the iron stores in the body. Measurement of ferritin may aid in the diagnosis of anemia and hemochromatosis (Iron overload).

Ferritin (21 CFR §866.5340)

(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)



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K983340

Prescription Use _____
(per 21 CFR 801.109)

OR

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

K 983340

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

Device Name: **IMAGE® Immunochemistry Systems
Ferritin Calibrator**

Indications for Use:

Beckman Coulter Ferritin Calibrator, when used in conjunction with Ferritin reagent, is intended for use on IMAGE® Immunochemistry Systems for the calibration of ferritin.

Clinical Significance:

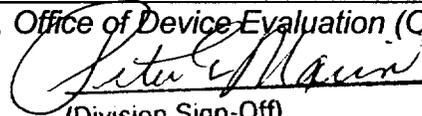
Ferritin is the main iron storage protein in the body. The concentration of ferritin is directly proportional to the iron stores in the body. Measurement of ferritin may aid in the diagnosis of anemia and hemochromatosis (Iron overload).

Calibrator (21 CFR §862.1150)

(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)



(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K983340

Prescription Use _____
(per 21 CFR 801.109)

OR

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