

**510(k) Summary for
OPUS Ferritin**

1. Manufactures Name, Address, Telephone, and contact person, date of preparation:

Manufacturer: Behring Diagnostics Inc.
151 University Avenue
Westwood, MA 02090
617-320-3117
Attn: Ruth Forstadt

Preparation date: July 7, 1997

2. Device Name/ Classification:

OPUS Ferritin: Ferritin Test System
Classification Number: Class II (866.5340).

3. Identification of the legally marketed device:

IMX® Ferritin

4. Proposed Device Description:

OPUS Ferritin is a set of reagents intended to be used together with the OPUS immunoassay analyzers for the quantitative measurement of ferritin in human serum.

5. Proposed Device Intended Use:

OPUS Ferritin is an *in vitro* fluorogenic enzyme immunoassay (ELISA) for the quantitative measurement of ferritin in human serum, as an aid in the diagnosis of hemochromatosis (iron overload) and iron deficiency anemia. OPUS Serum Ferritin is intended for use with the OPUS analyzers.

6. Medical device to which equivalence is claimed and comparison information:

The OPUS Serum Ferritin assay is substantially equivalent in intended use to results obtained using the Abbott IMX Ferritin. The Abbott IMX Ferritin, like the proposed product, employs the principle of two site or sandwich immunoassay. Both methods use a labeled antibody for the quantitative measurement of ferritin in human serum. The OPUS Serum Ferritin and Abbott IMX Ferritin are both based on a six level calibrator system. Also, both the Abbott IMX Ferritin and the OPUS Serum Ferritin assay include a tri-level control.

The OPUS Serum Ferritin differs from the Abbott IMX Ferritin in that human serum and plasma samples may be used in the Abbott IMX Ferritin and only human serum in the OPUS Serum Ferritin assay.

7. Device Performance Characteristics:

Precision

Intra-assay precision was determined by the evaluation of three levels of control material in replicates of twenty (20) each. %CV ranged from 5.5% to 7.00%.

Inter-assay precision was determined by the evaluation of three levels of control material in duplicate, assayed over a five day period to total 20 replicates. %CV ranged from 4.60% to 9.00%.

Accuracy by Recovery

Recovery was determined by spiking previously assayed and pooled human serum matrix with different levels of ferritin. The samples were assayed using OPUS Ferritin in triplicate. Percent recovery ranged from 89 to 101%.

Accuracy by Correlation

OPUS Ferritin was compared to a commercially available Ferritin assay by evaluation of 70 serum samples ranging from 2.31 to 807.00 ng/ml. A correlation coefficient of 0.98 was obtained, with a y-intercept value of 11.95 and a slope of 0.92.

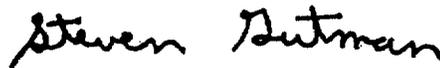
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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 at (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): K973202

Device Name: _____

OPUS Ferritin Test System

Indications For Use:

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

Concurrence of CDRE, Office of Device Evaluation (ODE)

[Handwritten Signature]

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

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)