

SEP 9 1997

**510(k) Summary for
OPUS D-Dimer**

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: June 19, 1997

2. Device Name/ Classification:

OPUS D-Dimer: Fibrinogen/fibrin degradation products assay
Classification Number: Class II (864.7320)

3. Identification of the legally marketed device:

ASSERACHROM® D-Di

4. Device Description:

OPUS D-Dimer is a set of reagents intended to be used together with the OPUS immunoassay analyzers for the quantitative measurement of cross-linked fibrin degradation products containing D-Dimer in human plasma.

5. Device Intended Use:

OPUS D-Dimer is an *in vitro* fluorogenic enzyme immunoassay (ELISA) for the quantitative measurement of cross-linked fibrin degradation products containing D-Dimer in human plasma. OPUS D-Dimer is intended for use with the OPUS analyzers.

000023

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

The OPUS D-Dimer assay is substantially equivalent in intended use to the ASSERACHROM® D-Di. The ASSERACHROM® D-Di, like the proposed product, employs the principle of two site or sandwich immunoassay. The OPUS D-Dimer and ASSERACHROM D-Di both quantitatively measure cross-linked fibrin degradation products that contain D-Dimer in human plasma.

The OPUS D-Dimer differs from the ASSERACHROM® D-Di in that the enzyme labeled antibody is a rabbit polyclonal in the ASSERACHROM® D-Di while the enzyme labeled antibody is a mouse monoclonal in the OPUS test. Also, the OPUS D-Dimer includes a bi-level control, where as the ASSERACHROM® D-Di test does not include a control. Additionally, the OPUS D-Dimer is used with a fully automated fluorometric instrument system which includes a stored calibration curve while the ASSERACHROM® D-Di is a manual assay and uses a calibration curve with each run. Also, the OPUS D-Dimer does not require sample pretreatment for plasma samples while the ASSERACHROM® D-Di requires a predilution of the plasma samples. EDTA, heparinized and citrated plasma samples may be used with the OPUS D-Dimer, but only citrated plasma samples with the ASSERACHROM® D-Di.

7. Device Performance Characteristics:

Precision

Intra-assay precision was determined by the evaluation of two levels of control material in replicates of twenty (20) each. %CV ranged from 7.3% to 8.9%.

Inter-assay precision was determined by the evaluation of two levels of control material in duplicate, assayed over a five day period to total 20 replicates. %CV ranged from 8.6% to 10.3%.

Accuracy by Recovery

Recovery was determined by spiking previously assayed and pooled human serum matrix with five different levels of D-Dimer. The samples were assayed using OPUS D-Dimer in duplicate. Percent recovery ranged from 85 to 95%.

Accuracy by Correlation

OPUS D-Dimer was compared to a commercially available D-Dimer assay by evaluation of 321 human plasma samples ranging from 37 to 8480 ng/ml. A correlation coefficient of 0.93 was obtained, with a y-intercept value of 0.34 and a slope of 0.89.

000024



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 9 1997

Ruth Forstadt
Regulatory Affairs Associate
Behring Diagnostics Inc.
151 University Avenue
Westwood, Massachusetts 02090

Re: K972316
OPUS® D-Dimer Test System
Regulatory Class: II
Product Code: GHH
Dated: June 19, 1997
Received: June 20, 1997

Dear Ms. Forstadt:

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.

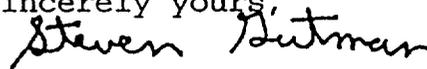
Page 2

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

Behring Diagnostics Inc.
OPUS® D-Dimer
510(k) Notification

Page ___ of ___

510(k) Number (if known): K972316

Device Name: OPUS D-Dimer Test System

Indications For Use:

OPUS D-Dimer is an *in vitro* fluorogenic enzyme immunoassay (ELISA) for the quantitative measurement of cross-linked fibrin degradation products (XL-FDP) containing D-Dimer in human plasma, used in the diagnosis of thromboembolic events. OPUS D-Dimer is intended for use with the OPUS analyzers

(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 K972316

Prescription Use ___
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

000026

CONFIDENTIAL