

K971725

Behring Diagnostics Inc.  
OPUS® Progesterone  
510(k) Notification

JUN 18 1997

## 510(k) Summary for OPUS Progesterone

**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: May 8, 1997

**2. Device Name/ Classification:**

OPUS Progesterone: Progesterone Test System  
Classification Number: Class I (862.1620)

**3. Identification of the legally marketed device:**

DPC Coat-a-Count® Progesterone

**4. Proposed Device Description:**

OPUS Progesterone is a set of reagents intended to be used together with the OPUS immunoassay analyzers for the quantitative measurement of progesterone in human serum or heparanized plasma.

**5. Proposed Device Intended Use:**

OPUS Progesterone is an *in vitro* fluorogenic enzyme immunoassay (ELISA) for the quantitative measurement of progesterone in human serum or heparanized plasma. OPUS Progesterone is intended for use with the OPUS analyzers.

000016

**CONFIDENTIAL**

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

The OPUS Progesterone assay is substantially equivalent in intended use to the DPC Coat-a-Count® Progesterone. The DPC Coat-a-Count® Progesterone, like the proposed product, use a labeled antibody for the quantitative measurement of progesterone in human serum or heparanized plasma.

The OPUS Progesterone differs from the DPC Coat-a-Count® Progesterone in the technique employed for the quantitative measurement of progesterone. While the DPC Coat-a-Count® Progesterone employs competitive immunassay, the OPUS Progesterone test system is one of sequential binding. Progesterone is labeled with I<sup>125</sup> in the DPC Coat-a-Count® Progesterone, while in the OPUS Progesterone test the antibody is an enzyme labeled mouse monoclonal. Also, the OPUS Progesterone includes a six-point calibrator sytem, whereas the DPC Coat-a-Count® Progesterone includes a seven-point calibrator system. Additionally, the OPUS Progesterone is used with a fully automated fluorometric instrument system, while the DPC Coat-a-Count® Progesterone uses a gamma counter.

**7. Proposed 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 8.2% to 14.4%.

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 9.7% to 14.4%.

**Accuracy by Recovery**

Recovery was determined by spiking previously assayed and pooled human serum matrix with five different levels of Progesterone. The samples were assayed using OPUS Progesterone in duplicate. Percent recovery ranged from 80 to 111%.

**Accuracy by Correlation**

OPUS Progesterone was compared to a commercially available Progesterone assay by evaluation of 83 serum samples ranging from 0.44 to 37.92 ng/ml. A correlation coefficient of 0.97 was obtained, with a y-intercept value of -0.19 and a slope of 0.99.

000017



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

JUN 18 1997

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

Re: K971725  
OPUS® Progesterone Test System  
Regulatory Class: I  
Product Code: JLS  
Dated: May 8, 1997  
Received: May 9, 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

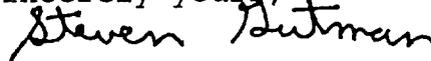
Page 2

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

510(k) Number (if known): K971725

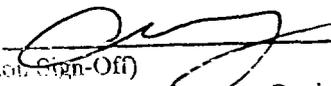
Device Name: OPUS Progesterone Test System

**Indications For Use:**

OPUS Progesterone is an *in vitro* fluorogenic enzyme immunoassay (ELISA) for the quantitative measurement of progesterone in serum or heparanized plasma, used in the diagnosis and treatment of disorders of the ovaries or placenta. OPUS Progesterone 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 K971725

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

000000