

OCT 27 1997

**510(k) Summary for
OPUS hLH Controls**

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

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

Preparation date: October 6, 1997

2. Device Name/ Classification:

OPUS hLH Controls: Quality Control Material
Classification Number: Class I (862.1660)

3. Identification of the legally marketed device:

OPUS® hCG

4. Proposed Device Description:

OPUS hLH Controls are intended for use as quality control material to monitor the accuracy and precision of the OPUS hLH assay run on the OPUS analyzers.

5. Proposed Device Intended Use:

OPUS hLH controls are intended for use as an assayed quality control material in the clinical laboratory to assess or verify the performance of the OPUS hLH assay.

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

The OPUS hLH Controls are substantially equivalent in intended use to the OPUS hCG Controls. Both products are *in vitro* diagnostic reagents intended for use as a quality control material to monitor specific laboratory procedures. The OPUS hLH Controls, like the OPUS hCG Controls, are a tri-level serum-based matrix controls for specific OPUS assays only. Both controls are provided with lot specific values for the Behring OPUS Immunoassay System.

The OPUS hLH Controls differ from the OPUS hCG Controls in that the OPUS hLH Controls are for use with the OPUS hLH assay and contain known levels of LH, while the OPUS hCG Controls are for use with the the OPUS hCG assay and contain known levels of hCG.

510(k) Notification
Dade-Behring Inc.
OPUS hLH Controls

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 4.51% to 6.48%.

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 2.48% to 6.41%.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

OCT 27 1997

Re: K973832
OPUS hLH Controls
Regulatory Class: I
Product Code: JJX
Dated: October 6, 1997
Received: October 7, 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 (Pre-market 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.

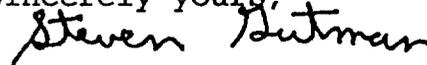
Page 2

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

510(k) Notification
Dade-Behring Inc.
OPUS hLH Controls

Page ___ of ___

510(k) Number (if known): _____

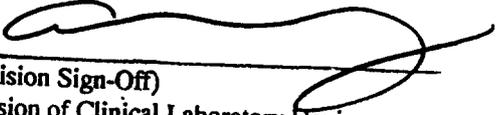
Device Name: _____
OPUS hLH Controls

Indications For Use:

OPUS hLH Controls are quality control materials intended for use in the clinical laboratory to assess or verify the performance of the OPUS hLH assay, run on 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 K 97 38 32

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

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