510(k) Summary For Emit® 2000 Vancomycin Calibrators

1. **Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation**

Manufacturer:
Dade Behring Inc
Syva Company
20400 Mariani Avenue
Cupertino, CA 95014

Contact Information:
Donna A. Wolf
Dade Behring Inc.
P. O. Box 6101
Newark, DE 19714
Phone: 302-631-0384
Fax: 302-631-6299
E-mail: wolfda@dadebehring.com

2. **Device Name / Classification:**
Emit® 2000 Vancomycin Calibrator: Calibrator, drug specific
Classification Number: Class II (862.3200)

3. **Identification of the Legally Marketed Device:**
Emit® Vancomycin Calibrator (K881040)

4. **Device Description:**
Emit® 2000 Vancomycin Calibrators are liquid, six-level calibrators prepared from vancomycin, buffer and preservatives. The calibrators are intended for use with the Emit® 2000 Vancomycin Assay as a reference for use in determining vancomycin levels in human serum or plasma.

5. **Device Intended Use:**
The Emit® 2000 Vancomycin Calibrators are intended for use with the Emit® 2000 Vancomycin Assay as a reference for use in determining vancomycin levels in human serum or plasma.

6. **Medical device to which equivalence is claimed and comparison information:**
The Emit® 2000 Vancomycin Calibrators are substantially equivalent in intended use to the Emit® Vancomycin Calibrators (K881040) currently marketed. The modified Emit® 2000 Vancomycin Calibrators contain the same vancomycin concentrations as the currently marketed device. Both devices are intended for use in the calibration of human serum or plasma in conjunction with a Vancomycin Reagent.

7. **Device Performance Characteristics:**

Stability:
Shelf life stability was evaluated by testing the calibrators at a minimum in duplicate, stored at 9°C, with comparison to calibrator sets stored at -20°C. The assignment of shelf life will be based on real time data from at least 3 lots of calibrators. To date, stability studies support no significant change in recovery for at least 13 months.

Preparation:
Emit® 2000 Vancomycin Calibrators (modified) are prepared by standard gravimetric procedures using a synthetic matrix with buffers and preservative which has been supplemented with commercially available vancomycin.

Each new calibrator lot is tested in bulk and final container stages with 20 replicates at each calibrator level. These values are compared to a Master Lot. Calibrator levels are adjusted as needed to match Emit® 2000 responses of the Master Lot calibrators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 0 8 2002

Ms. Donna A. Wolf
Sr. Regulatory Affairs Specialist
Dade Behring Inc.
514 GBC Drive
Newark, DE 19702

Re: k020845
Trade/Device Name: Emit® 2000 Vancomycin Calibrators
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: Class II
Product Code: DLJ
Dated: March 14, 2002
Received: March 15, 2002

Dear Ms. Wolf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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 Gutman

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

Indications For Use Statement

Device Name: Emit® 2000 Vancomycin Calibrators

Indications for Use:

The Emit® 2000 Vancomycin Calibrators are intended for use with the Emit® 2000 Vancomycin Assay as a reference for use in determining vancomycin levels in human serum or plasma.

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020845

Donna A. Wolf
Sr. Regulatory Affairs Specialist
March 14, 2002

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-counter Use**_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)