

K 972,879

AUG 13 1997

Summary of Safety & Effectiveness  
Beckman VIGIL™ TDM Controls

1.0 **Submitted By:**

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2.0 **Date Submitted:**

28 July 1997

3.0 **Device Name(s):**

3.1 **Proprietary Names**

VIGIL™ TDM Control

3.2 **Classification Name**

Clinical Toxicology Control Material (21 CFR § 862.3280)

4.0 **Predicate Device(s):**

BECKMAN Reagent	Predicate	Predicate Company	Docket Number
VIGIL™ TDM Controls	VIGIL PR <sub>x</sub> Controls	Beckman Instruments, Inc.	K936184

**5.0 Description:**

The VIGIL™ TDM Controls are tri-level ready-to-use human serum-based liquid controls manufactured by Beckman Instruments, Inc. Each kit contains 3 X 3 mL bottles of a specific level of control. The levels are identified as Vigil TDM Control Level 1, Vigil TDM Control Level 2, and Vigil TDM Control Level 3. The products require no preparation prior to use and must be stored at +2° C to +8°C when not in use.

**6.0 Intended Use:**

The Beckman Vigil Therapeutic Drug Monitoring (TDM) Controls are designed for monitoring the reliability and overall performance of Beckman Therapeutic drug test systems in the clinical laboratory. The use of three levels of control allows the laboratorian to monitor change in calibration along with analytical error and imprecision.

**7.0 Comparison to Predicate(s):**

The following tables show similarities and differences between the predicate identified in Section 4.0 of this summary.

**SIMILARITIES to the PREDICATE**

Reagent	Aspect/Characteristic	Comments
Vigil TDM Control	Intended use	Same as the predicate
	Value Assignment	Same process as the predicate

**DIFFERENCES from the PREDICATE**

Reagent	Aspect/Characteristic	Comments
Vigil TDM Control	Formulation	<b>Vigil TDM:</b> delipidized human serum  <b>Vigil PR<sub>x</sub>:</b> fresh frozen human plasma defibrinated and stabilized with ethylene glycol
	Kit Configuration	<b>Vigil TDM:</b> 3 X 3 mL bottles  <b>Vigil PR<sub>x</sub>:</b> 4 X 5 mL bottles
	Storage Temperature	<b>Vigil TDM:</b> +2°C to +8°C  <b>Vigil PR<sub>x</sub>:</b> -15°C to -20°C
	Analytes	<b>Vigil TDM:</b> Contains Digoxin.  <b>Vigil PR<sub>x</sub>:</b> Does not contain Digoxin.

8.0 **Summary of Performance Data:**

The data in the Premarket Notification on safety and effectiveness supports a finding of substantial equivalence of the Vigil TDM Controls to the Vigil PR<sub>x</sub>. Stress stability studies of the Vigil TDM Controls support the Beckman stability claim of 24 months.

**Vigil TDM Controls  
Stability Study Summary**

Stress Temperature	Duration of Incubation	Beckman Stability Claim*
25°C	35 Days	24 months
32°C	30 Days	24 months
37°C	18 Days	24 months
41°C	11 Days	24 months

\*Expiration dating placed on the package based on date of manufacture

This summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Lucina Stockert  
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Brea, CA 92822-8000

AUG 13 1997

Re: K972819  
VIGIL™ TDM Controls  
Regulatory Class: I  
Product Code: DIF  
Dated: July 28, 1997  
Received: July 29, 1997

Dear Ms. Stockert:

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 requirement, 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 pre-market 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.

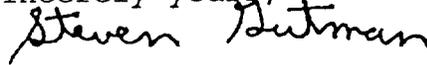
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (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): Not yet assigned

Device Name: **VIGIL™ TDM Control**

Indications for Use:

The Beckman Vigil Therapeutic Drug Monitoring (TDM) Controls are designed for monitoring the reliability and overall performance of Beckman Therapeutic Drug test systems in the clinical laboratory. The use of three levels of control allows the laboratorian to monitor change in calibration along with analytical error and imprecision.

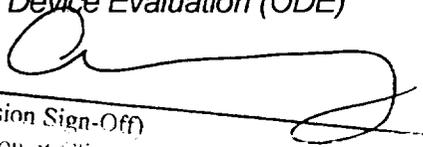
**21 CFR 862.3280 Clinical Toxicology Control Material**

(a) *Identification.* A clinical toxicology control material is a device intended to provide an estimation of the precision of a device test system and to detect and monitor systematic deviations from accuracy resulting from reagent or instrument defects. This generic type of device includes various single, and multi-analyte control materials.

(b) *Classification.* Class I.

(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 K912819

Prescription Use  (per 21 CFR 801.109)

OR

Over-the-Counter Use   
Optional Format 1-2-96