

K974452

Summary of Safety & Effectiveness
Beckman VIGIL™ Lipid Controls

DEC 17 1997

1.0 **Submitted By:**

Richard T. Ross
Staff Regulatory Specialist, Product Submissions
Beckman Instruments, Inc.
200 S. Kraemer Blvd., W-104
Brea, California 92822-8000
Telephone: (714) 961-4912
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2.0 **Date Submitted:**

21 November 1997

3.0 **Device Name(s):**

3.1 **Proprietary Names**

VIGIL™ Lipid Control

3.2 **Classification Name**

Quality Control Material (assayed and unassayed) (21 CFR § 862.1660)

4.0 **Predicate Device(s):**

BECKMAN Reagent	Predicate	Predicate Company	Docket Number
VIGIL™ Lipid Controls	VIGIL PR _x ™ Controls	Beckman Instruments, Inc.	K936184

5.0 **Description:**

The VIGIL™ Lipid Controls are four level ready-to-use human serum-based liquid controls manufactured by Beckman Instruments, Inc. Each kit contains 4 X 4 mL bottles of a single level of control.

6.0 **Intended Use:**

Beckman's Vigil Lipid Control is intended for use in monitoring the reliability of automated *in vitro* diagnostic assays of total cholesterol, HDL cholesterol (HDLc), triglycerides, apolipoprotein A-1 and apolipoprotein B in the clinical laboratory. The use of three or more levels of control allows the laboratorian to monitor change in calibration linearity 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 Lipid Control	Intended use	Same as the predicate
	Value Assignment	Same process as the predicate
	Storage Temperature	Same as predicate at -15 °C to -20°C

DIFFERENCES from the PREDICATE

Reagent	Aspect/Characteristic	Comments
Vigil Lipid Control	Formulation	Vigil Lipid: stabilized by storage at -15°C to -20°C Vigil PR _x : stabilized with ethylene glycol and storage at -15°C to -20°C
	Levels of analyte	Vigil Lipid: 4 levels Vigil PR _x : 3 levels
	Analytes	Vigil Lipid: Contains: cholesterol, HDL cholesterol, triglycerides, apolipoprotein A-1 and apolipoprotein B fortified to attain various levels. Vigil PR _x : Contains: apolipoprotein A-1, apolipoprotein B and endogenous cholesterol, HDL cholesterol and triglycerides.

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 Lipid Controls to the Vigil PR_x. Stress stability studies of the Vigil Lipid Controls support the Beckman stability claim of 24 months.

**Vigil Lipid Controls
 Shelf Life Stability Study Summary**

Stress Temperature	Duration of Incubation	Beckman Stability Claim*
25°C	42 Days	24 months
32°C	45 Days	24 months
37°C	27 Days	24 months
41°C	20 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

DEC 17 1997

Richard T. Ross
Staff Regulatory Specialist
Beckman Instruments, Inc.
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P.O. Box 8000
Brea, California 92822-8000

Re: K974452
VIGIL™ Lipid Controls
Regulatory Class: I
Product Code: JJY
Dated: November 21, 1997
Received: November 25, 1997

Dear Mr. Ross:

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.

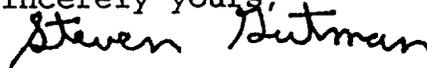
Page 2

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

K974452

page ___ of ___

510(k) Number (if known): Not yet assigned

Device Name: VIGIL™ Lipid Control

Indications for Use:

Beckman's Vigil Lipid Control is intended for use in monitoring the reliability of automated *in vitro* diagnostic assays of total cholesterol, HDL cholesterol (HDLc), triglycerides, apolipoprotein A-1 and apolipoprotein B in the clinical laboratory. The use of three or more levels of control allows the laboratorian to monitor change in calibration linearity along with analytical error and imprecision.

21 CFR 862.1660 Quality Control Material (assayed and unassayed)

(a) *Identification.* A quality control material (assayed and unassayed) for clinical chemistry is a device intended for medical purposes for use in a test system to estimate test precision and to detect systematic analytical deviations that may arise from reagent or analytical instrument variation. A quality control material (assayed and unassayed) may be used for proficiency studies in interlaboratory surveys. This generic type of device includes controls (assayed and unassayed) for blood gases, electrolytes, enzymes, multianalytes (all kinds), single (specified) analytes, or urinalysis controls.

(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

K974452

Prescription Use (per 21 CFR 801.109)

OR

Over-the-Counter Use

Optional Format 1-2-96