JUL 9 1998

K982224



Summary of Safety & Effectiveness
Beckman Coulter Vigil™ Protein Controls

1.0 **Submitted By:**

Richard T. Ross
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Beckman Coulter, Inc.
200 South Kraemer Blvd., W-104
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2.0 **Date Submitted:**

22 June 1998

3.0 **Device Name(s):**

3.1 **Proprietary Names**

Vigil™ Protein Control

3.2 **Classification Name**

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

4.0 **Predicate Device(s):**

| BECKMAN COULTER Reagent | Predicate | Predicate Company | Docket Number |
|---|---|---|---|
| Vigil™ Protein Controls | Vigil $PR_X$™ Controls | Beckman Instruments, Inc. | K936184 |

5.0 **Description:**

The Vigil™ Protein Controls are three level ready-to-use human serum-based liquid controls manufactured by Beckman Coulter, Inc. Each kit contains 4 X 5 mL bottles of a single level of control.

6.0 **Intended Use:**

Beckman Coulter's Protein Control is intended for use in monitoring the reliability and overall performance of specific protein tests systems in the clinical laboratory. The use of three levels of control allows the laboratorian to monitor change in calibration linearity along with analytical error and imprecision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 9 1998

Richard T. Ross
Staff Regulatory Specialist
Beckman Coulter, Inc.
200 S. Kramer Boulevard, M/S W-104
P.O. Box 8000
Brea, California 92822-8000

Re: K982224
Vigil™ Protein Controls
Regulatory Class: I
Product Code: JJY
Dated: June 22, 1998
Received: June 24, 1998

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.

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 "dsmo@fdadr.cdrh.fda.gov".

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

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

Device Name: **Vigil™ Protein Control**

Indications for Use:

**Beckman Coulter's Protein Control is intended for use in monitoring the reliability and overall performance of specific protein tests systems in the clinical laboratory. The use of three 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)*

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) Optional Format 1-2-96

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K98 224