

JUL 6 1998

Summary of Safety & Effectiveness
Beckman VIGIL™ HbA1c Controls

1.0 **Submitted By:**

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2.0 **Date Submitted:**

8 June 1998

3.0 **Device Name(s):**

3.1 **Proprietary Names**

VIGIL™ Hemoglobin A1c Controls

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™ HbA1c Controls	Boehringer Mannheim Tina-quant® Hemoglobin A1c assay	Boehringer Mannheim	K934070

5.0 Description:

The Vigil HbA1c Controls are a two level lyophilized control set made from hemolyzed human and ovine blood. Each kit contains 3 X 1 mL bottles of each specific level of control. The levels are identified as Vigil HbA1c Control Level 1, and Vigil HbA1c Control Level 2. The products require reconstitution with exactly 1.0 mL of distilled water prior to use. The lyophilized products must be stored at +2°C to +8°C when not in use. The reconstituted controls are stable for 1 week at +2°C to +8°C, 8 hours at +20°C to +25°C, and 3 months when stored frozen between -15°C to -20°C.

6.0 Intended Use:

The Vigil™ HbA1c Controls are designed for monitoring the overall reliability of HbA1c assays on SYNCHRON CX® and LX™ Systems.

7.0 Comparison to Predicate(s):

Boehringer Mannheim Corporation manufactures the Vigil™ HbA1c controls for Beckman Coulter, Inc. Boehringer Mannheim has clearance to market these products under the names Precinorm® HbA1c and Precipath® HbA1c. Beckman Coulter, Inc. labels are placed on the product and Beckman assigns SYNCHRON® Systems values to the product.

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 HbA1c Controls to the Boehringer Mannheim Precinorm® and Precipath®. Stress stability studies of the lyophilized Vigil HbA1c Controls support the Beckman stability claim of 24 months.

**Vigil HbA1c Controls
Stability Study Summary**

Stress Temperature	Duration of Incubation	Beckman Stability Claim*
25°C	65 Days	24 Months
32°C	30 Days	24 Months
37°C	18 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.



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Lucinda Stockert
Staff Regulatory Specialist
Beckman Coulter, Inc.
200 S. Kraemer Boulevard, M/S W-104
P.O. Box 800
Brea, California 92822-8000

Re: K982022
VIGIL™ HbA1c Controls
Regulatory Class: I
Product Code: JJX
Dated: June 8, 1998
Received: June 9, 1998

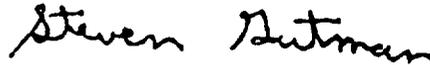
Dear Ms. Stockert:

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 (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 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™ HbA1c Controls**

Indications for Use:

The Beckman Vigil Hemoglobin A1c (HbA1c) Controls are designed for monitoring the reliability and overall performance of Beckman Hemoglobin A1c (HbA1c) test systems in the clinical laboratory. The use of two levels of control allows the laboratorian to monitor analytical error and imprecision.

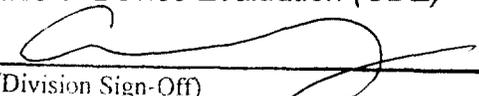
21 CFR 862.1660 Quality Control Material (assayed and unassayed)

(a) Identification. A quality control material (assayed and unassayed) 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 analytical instrument variation. A quality control material (assayed and unassayed) may be used for proficiency testing 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 12982022

Prescription Use ✓
(per 21 CFR 801.109)

OR

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