K994277

JAN 14 2000

Summary of Safety & Effectiveness
Access Ostase QC

1.0 **Submitted By:**

Mara Caler
Regulatory Specialist, Product Submissions
Beckman Coulter, Inc.
7330 Carroll Road
P.O. Box 269006
San Diego, CA 92196-9006
Telephone: (619) 621-4583
FAX: (619) 621-4752

2.0 **Date Submitted:**

December 15, 1999

3.0 **Device Name(s):**

3.1 **Proprietary Names**

Access Ostase QC

3.2 **Classification Name**

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

3.3 **Device Classification**

Class I (low risk)

4.0 **Predicate Device(s):**

BECKMAN COULTER Reagent	Predicate	Predicate Company	Docket Number
Access Ostase QC	Access AFP QC	Beckman Coulter Inc.	K 981864

5.0 **Description:**

The Access Ostase QC are bi-level ready-to-use defined protein-based liquid controls manufactured by Beckman Coulter, Inc. Each kit contains 1 X 4 mL bottles for each level of control.

6.0 **Intended Use:**

Beckman Coulter's Access Ostase QC is intended for use in monitoring the reliability and overall performance of the Access Ostase Immunoassay system in the clinical laboratory. The use of control materials allow the laboratorian to monitor linearity along with analytical error and imprecision.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 14 2000

Ms. Mara Caler
Regulatory Specialist
Beckman Coulter, Inc.
P.O. Box 269006
7330 Carroll Road
San Diego, California 92196-9006

Re: K994277
Trade Name: Access® Ostase® QC
Regulatory Class: I reserved
Product Code: JJX
Dated: December 15, 1999
Received: December 20, 1999

Dear Ms. Caler:

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 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). 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.

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/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

510(k) Number (if known): ~~Not yet assigned~~ K994277

Device Name: **Access® Ostase® QC**

Indications for Use:

Beckman Coulter's Access Ostase QC is intended for use in monitoring the reliability and overall performance of the Access Ostase Immunoassay system in the clinical laboratory. The use of control materials allow the laboratorian to monitor 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)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K994277

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