

JAN 18 2000

K994200

510(k) Summary

Prepared January 14, 2000

Applicant's Name and Address

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

Contact Person: Michele S. Gust

Device Name

Trade Name - Access® Hybritech® PSA QC on the Access® Immunoassay System
Common Name - Access® Hybritech® PSA QC
Classification name - Quality control material (assayed and unassayed)

Device Description

The Access Hybritech PSA QC are controls intended for monitoring system performance of immunoenzymatic procedures for the quantitative measurement of Prostate Specific Antigen (PSA) using the Access Immunoassay systems.

The Access Hybritech PSA QC are ready to use tri-level control material consisting of human PSA in a buffered bovine serum albumin (BSA) matrix with preservatives. The controls are targeted to cover the assay range of approximately 0.008 - 150 ng/mL at three levels of approximate PSA concentrations of 1 ng/mL, 15 ng/mL, and 90 ng/mL.

Intended Use

Access Hybritech PSA QC are tri-level controls intended for monitoring system performance of immunoenzymatic procedures for the quantitative measurement of total Prostate Specific Antigen (PSA) using the Access Immunoassay Systems.

Comparison of Technological Characteristics

The Access Hybritech PSA QC and the predicate device are both ready to use quality control materials intended to monitor assay performance.

Summary of Studies**Precision:**

Within-run, between-run, and total imprecision of all three levels of the Access Hybritech PSA QC were less than 5% CV.

Conclusion

These data demonstrate the Access Hybritech PSA QC tri-level controls give reproducible results when used as quality control materials with the Access Immunoassay Systems for the quantitative determination of PSA levels. Based on similarity of features and the reproducibility of results, the Access Hybritech PSA QC is substantially equivalent to the predicate device for the monitoring of system performance of the Access Hybritech total PSA immunoassay.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 18 2000

Ms. Michele Gust
Senior Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

Re: K994200
Trade Name: Access® Hybritech® PSA QC on the Access® Immunoassay System
Regulatory Class: I
Product Code: JJX
Dated: December 10, 1999
Received: December 13, 1999

Dear Ms. Gust:

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.

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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" (21CFR 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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):

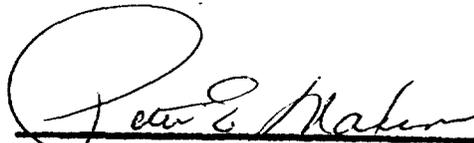
Device Name: Access® Hybritech® PSA QC

Indications For Use:

The ACCESS® Hybritech® PSA QC are tri-level controls intended for monitoring system performance of immunoenzymatic procedures for the quantitative measurement of total PSA using the Access® Immunoassay Systems.

(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 _____

K99/ESU

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

(Optional Format 1-2-96)