

K993210

JAN - 5 2000

510(k) Summary

Prepared September 16, 1999

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

Device Description

The Access Hybritech free PSA QC are controls intended for use in monitoring system performance of immunoenzymatic procedures for the quantitative measurement of free PSA using the Access Immunoassay systems.

The Access Hybritech free PSA QC are ready to use bi-level control material consisting of human free PSA in a buffered bovine serum albumin (BSA) matrix with preservatives. The controls are targeted to cover the assay range of approximately 0.005 – 20 ng/ml at two levels of approximate concentrations of 1ng/mL and 13 ng/mL.

Intended Use

Access Hybritech free PSA QC are bi-level controls intended for use in monitoring system performance of immunoenzymatic procedures for the quantitative measurement of free PSA using the Access Immunoassay Systems.

Comparison of Technological Characteristics

The Access Hybritech free PSA QC and the predicate devices are ready to use quality control materials intended to monitor the system performance of immunoassays on Access Immunoassay Systems.

Summary of Studies

Precision:

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

Conclusion

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



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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

Re: K993210
Trade Name: Access® Hybritech® free PSA QC on the Access® Immunoassay Analyzer
Regulatory Class: I
Product Code: JJX
Dated: December 3, 1999
Received: December 7, 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.

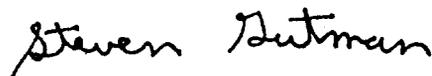
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 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): K 993210

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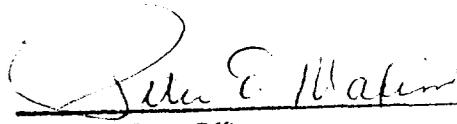
Device Name: Access® Hybritech® free PSA QC

Indications For Use:

The ACCESS® Hybritech® free PSA QC are bi-level controls intended for use in monitoring system performance of immunoenzymatic procedures for the quantitative measurement of free 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 K993210
510(k) Number _____

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

(Optional Format 1-2-96)