APPENDIX 4: Summary of Safety and Effectiveness Information

1. **General Information**

Device Generic Name:	Enzyme Immunoassay, Free T4
Device Trade Name:	ACCESS® Free T4 assay
Applicant's Name and Address:	Beckman Coulter, Inc. 1000 Lake Hazeltine Drive Chaska, MN 55318

2. **Predicate Device**
IMx® Free T4 Assay
Abbott Laboratories
Diagnostics Division
Abbott Park, IL 60064

3. **Device Description**
The ACCESS® Free T4 reagents and the ACCESS® Immunoassay Analyzer comprise the ACCESS® Immunoassay System for the quantitative determination of free thyroxine in human serum or plasma (heparin).

4. **Indications for Use**
The ACCESS® Free T4 assay is a paramagnetic particle chemiluminescent immunoassay for the quantitative determination of free thyroxine levels in human serum or plasma (heparin) using the ACCESS® Immunoassay System.

5. **Comparison of Technological Characteristics**
Both the ACCESS® Free T4 assay and the Abbott IMx® Free T4 assay measure free thyroxine levels in human serum or plasma (heparin). The ACCESS® Free T4 assay and the Abbott IMx® Free T4 assay are competitive binding immunoassays, utilize particle technology and use a sequential format. Both assays use a T3 alkaline phosphatase conjugate which binds to unoccupied/vacant anti-T4 binding sites. Both assays utilize a four parameter logistic curve (4PLC) data reduction method to generate the curve. Both calibrator sets are prepared in human serum, use a six point calibration, provided in liquid form, and range from 0 - 6 ng/dl. The ACCESS® Free T4 assay binds streptavidin to paramagnetic particles where as the Abbott IMx® Free T4 assay binds anti-T4 to microparticles. The ACCESS® Free T4 assay measures light (photon) production from a chemiluminescent reaction while the Abbott IMx® Free T4 assay measures fluorescence. The ACCESS® Free T4 assay separates the solid phase magnetic particles in a magnetic field during the washing, while the Abbott IMx® Free T4 assay separates the solid phase microparticles by irreversible binding to a glass fiber matrix. The ACCESS®Free T4 assay utilizes a T4 antibody produced in mice while the Abbott IMx® Free T4 assay utilizes a T4 antibody produced in sheep.

6. **Summary of Studies**
Precision studies: Within run precision ranges from 3.11% CV (high control) to 4.13% CV (low control). Total imprecision ranges from 4.56% CV (high control) to 7.42% CV (low control).
Correlation: A comparison of Free T4 values from 327 samples run in both the ACCESS® Free T4 assay and the Abbott IMx® Free T4 assay gives the following statistical data using Deming calculations: $r = 0.940$, $y = 1.16x - 0.275$.
Analytical Sensitivity: The lowest detectable level of free T4 distinguishable from zero (ACCESS® Free T4 Calibrator S0) with 95% confidence is 0.15 ng/dl.

7. **Conclusion**
The ACCESS® Free T4 reagents when used with the ACCESS® Immunoassay Analyzer are substantially equivalent to another test for the measurement of free T4 currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 14 1998

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

Re: K982250
ACCESS® Free T4 Assay on the ACCESS® Immunoassay Analyzer
Regulatory Class: II
Product Code: CEC, JIS
Dated: June 24, 1998
Received: June 26, 1998

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 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/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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: ACCESS® Free T4 Reagents on the ACCESS® Immunoassay Analyzer

Indications For Use:

The ACCESS® Free T4 Assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of free thyroxine levels in human or plasma (heparin) using the ACCESS® Immunoassay System.

A free thyroxine test system is a device intended to measure free (not protein bound) thyroxine (thyroid hormone) in human serum or plasma (heparin). Levels of free thyroxine in plasma are thought to reflect the amount of thyroxine hormone available to the cells and may therefore determine the clinical metabolic status of thyroxine. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(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 K982250

Prescription Use ✓ OR Over-The Counter Use_____
(Per 21 CFR 801.109)