APPENDIX 4: Summary of Safety and Effectiveness Information

K973966

OCT 31 1997

1. General Information

Device Generic Name:	Enzyme Immunoassay, Total T3
Device Trade Name:	ACCESS® Total T3 assay
Applicant's Name and Address:	Beckman Instruments, Inc. 1000 Lake Hazeltine Drive Chaska, MN 55318

2. Predicate Device

Ciba Corning ACS™ T3
Ciba Corning Diagnostics Corp.
Medfield, MA 02052

3. Device Description

The ACCESS® Total T3 reagents and the ACCESS® Immunoassay Analyzer comprise the ACCESS® Immunoassay System for the quantitative determination of triiodothyronine in human serum.

4. Indications for Use

The ACCESS® Total T3 assay is a paramagnetic particle chemiluminescent immunoassay for the quantitative determination of triiodothyronine levels in human serum using the ACCESS® Immunoassay System.

5. Comparison of Technological Characteristics

Both the ACCESS® Total T3 assay and the Ciba Corning ACS™ T3 assay measure triiodothyronine in human serum. The ACCESS® Total T3 assay and the Ciba Corning ACS™ T3 assay are competitive binding immunoassays. Both assays utilize microparticle technology. The ACCESS® Total T3 binds streptavidin to paramagnetic particles and Ciba Corning ACS™ T3 binds T3 analogue to paramagnetic particles. Both assays use light generated from a chemiluminescent reaction which is measured in a luminometer. Both assays use a T3 analogue and an alkaline phosphatase conjugated monoclonal anti-T3 antibody. The ACCESS® Total T3 assay uses a monoclonal anti-T3 antibody conjugated to alkaline phosphatase which acts on a dioxetane based chemiluminescent substrate to produce light. The Ciba Corning ACS™ T3 assay uses a monoclonal anti-T3 antibody conjugated to acridinium ester which when activated by hydrogen peroxide and weak sodium peroxide produces light. The ACCESS® Total T3 assay uses a six point calibration while the Ciba Corning ACS™ T3 assay uses a two point calibration. The ACCESS® Total T3 assay utilizes a T3 analogue coupled to biotin while the Ciba Corning ACS™ utilizes a T3 analogue coupled to particles.

6. Summary of Studies

Precision studies: Within run precision ranges from 3.22% CV (high control) to 5.22% CV (low control). Total imprecision ranges from 4.74% CV (high control) to 9.12% CV (low control).
Accuracy: Dilution recovery studies performed by diluting two patient samples containing Total T3 with Total T3 Calibrator S0 range from 85.6% to 107.7% recovery. Spiking recovery studies performed by adding T3 to two patient samples containing low levels of T3 range from 87.7% to 112.1 % recovery.
Correlation: A comparison of Total T3 values from 153 samples run in both the ACCESS® Total T3 assay and the Ciba Corning ACS™ T3 assay gives the following statistical data using deming calculations: $r = 0.978$, $y = 1.020x + 0.077$.
Analytical Sensitivity: The lowest detectable level of total T3 distinguishable from zero (Total T3 Calibrator S0) with 95% confidence is 0.1 ng/ml.

7. Conclusion

The ACCESS® Total T3 reagents when used with the ACCESS® Immunoassay Analyzer are substantially equivalent to another test for the measurement of Total T3 currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 31 1997

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

Re: K973966
Enzyme Immunoassay, Total T3 ACCESS® Total T3 Assay
Regulatory Class: II
Product Code: CDP, JIS
Dated: October 16, 1997
Received: October 17, 1997

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): K973966

Device Name: ACCESS® Total T3 Reagents on the ACCESS® Immunoassay Analyzer

Indications For Use:

The ACCESS® Total T3 Assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of triiodothyronine levels in human serum, using the ACCESS® Immunoassay System.

The clinical importance of total serum T3 determination is in the diagnosis of thyroid disorders. Elevated concentrations of T3 can be found in Grave's disease, and most other classical causes of hyperthyroidism. Decreased concentrations occur in primary hypothyroid diseases such as Hashimoto's thyroiditis and neonatal hypothyroidism or secondary hypothyroidism due to defects at the hypothalamo-hypophyseal level.

(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 k973966

✓ Prescription Use