510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k042651

B. Purpose for Submission:
New Device

C. Analyte:
Calibrator for Free T3

D. Type of Test:
Quantitative and Semi-quantitative / Chemiluminescent Magnetic partial detection

E. Applicant:
BECKMAN COULTER, INC.

F. Proprietary and Established Names:
FREE T3 CALIBRATORS ON THE ACCESS IMMUNOASSAY SYSTEMS

G. Regulatory Information:

1. Regulation section:
   21CFR §862.1150 -Calibrator.
2. Classification:
   Class II
3. Product Code:
   JIT
4. Panel:
   Chemistry (75)

H. Intended Use:

1. Indication(s) for use:
   The Access Free T3 Calibrator set is a device intended for medical purposes for use in the Access Immunoassay Systems to establish points of reference that are used in the determination of values in the measurement of free T3 levels in human serum and plasma.

2. Special condition for use statement(s):
   Not Applicable

3. Special instrument Requirements:
   -Access Immunoanalyzer, k922823; August 5, 1992
   -Access 2 Immunoassay Analyzer, k922823/A007; July 2, 2001

-Synchron LXi 725 Clinical System, k023049; October 4, 2002
-UniCel DxI 800 Access Immunoassay System, k023764; January 28, 2003

I. Device Description:

The Access Free T3 Calibrators are designed for use with the Access Free T3 Reagent for generation of the Free T3 assay calibration curve on Beckman Coulter's Access Immunoassay Systems. The Access Free T3 Calibrator kit contains 6 x 2.5 mL bottles, one for each of six calibrator levels. The Access Immunoassay Systems utilize a competitive binding immunoenzymatic method for quantitative analyte measurement.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   BECKMAN COULTER, INC., ACCESS ULTRASENSITIVE HGH CALIBRATORS
2. Predicate K number(s):
   K003098
3. Comparison with predicate:
   The Access Ultrasensitive hGH Calibrators are intended to calibrate the Access Ultrasensitive hGH assay for the quantitative determination of hGH levels in human serum and plasma using the Access Immunoassay Systems.

Similarities
-Both calibrators are intended for use with the Access Immunoassay Systems. -Both calibrators are provided in a stabilized bovine serum albumin matrix.
Differences
-The Access Free T3 Calibrators and the Access hGH Calibrators are intended to test for different analytes. -The Access Free T3 Calibrators contains 3', 3, 5-triiodothyronine, while the Access hGH Calibrators contains somatropin (human growth hormone). -The Access Free T3 Calibrators are liquid stable ready to use, while the Access hGH Calibrators are lyophilized and require preparation prior to use.

K. Standard/Guidance Document Referenced (if applicable):

Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators

L. Test Principle

Access Free T3 Calibrators are used with the Access Free T3 assay, which is a competitive binding immunoenzymatic assay. A sample is added to a reaction vessel with an anti-T3 monoclonal antibody conjugated to alkaline phosphatase. During the incubation, free T3 in the sample reacts with the anti-T3 antibody. Particles coated with streptavidin and biotinylated T3 analog are then added to the mixture. Unoccupied binding sites on the anti-T3 are bridged to the particle through the T3 analog. After incubation in a reaction vessel, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate Lumi-Phos 530 is added to the vessel and light generated

by the reaction is measured with a luminometer. The light production is inversely proportional to the concentration of free T3 in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
Not Applicable

b. Linearity/assay reportable range:
Not Applicable

c. Traceability (controls, calibrators, or method):

Calibration Curve Stability
To verify the 28 day stability for the stored calibration curve, four quality control samples were assayed in replicates of five at multiple time points between day 0 and day 28 after the establishment of a new six point calibration curve. The mean value for each control level at each time period was compared to the mean value of that control on day zero and compared to the expected range. Each mean value fell within the expected range for all days tested in the 28 day period. Conclusion: The Access Free T3 immunoassay calibration curve is valid for 28 days.

Calibrator Open Vial Stability
To verify the open vial stability for the calibrators at the recommended storage conditions (2-10 °C), four quality control samples are assayed at five time points, time zero, 1, 2, 3, and 4 months. The mean value for each control level at each time period is compared to the mean value of that control on day zero and compared to the expected range. Control values fell into the assigned range. The data supports calibrator open vial stability of four months.

Calibrator Shelf Life Stability
To verify the stability for the calibrators at the recommended storage conditions (2-10 °C), four quality control samples are assayed at various time points, including time zero, 1, 2, 3, and 4 months. The mean value for each control level at each time period is compared to the mean value of that control on day zero and compared to the expected range. Control values fell into the assigned range. Calibrator stability is projected to be greater than or equal to 12 months. At the time of submission, stability study data meets specifications through the 4 month time point. Stability studies are continuing at this time.

Calibrator Composition
Access Free T3 Calibrators are intended to calibrate the Access Free T3 assay. The calibrators are provided as liquid materials, consisting of 3′, 3, 5-triiodothyronine (T3) antigen in a buffer with bovine serum albumin, <0.1% sodium azide, and 0.5% ProClin 300. The calibrators are provided at zero and approximately 1, 2, 5, 10, and 30 pg/mL. There are no human source materials in the Access Free T3 calibrators. The calibrators contain sodium azide and ProClin 300 as preservatives. Complete instructions, warnings and precautions are contained in the labeling.

Value Assignment
The commercial calibrators are value assigned using the secondary reference calibrators and the resulting calibrator values are provided to the customers on a card, which can be bar coded directly into the Access immunoassay analyzers. Individual commercial calibrators are prepared from T3 antigen stock and buffered BSA based matrix. Assays are performed which include the secondary reference calibrators, the newly manufactured commercial calibrators, controls and QC patient samples. Values for the newly manufactured commercial calibrators are determined from the secondary reference curves. Dose values for commercial calibrators must fall within quality control ranges. Control and QC patient samples are recalculated from the new assigned commercial calibrators and must meet QC specifications.

Traceability
The primary reference calibrator sets were prepared as follows. T3 antigen was prepared to a target value. Individual calibrators were then prepared from the T3 antigen stock and BSA based matrix and preservatives added as indicated in the labeling. The calibrators were given a preliminary value based on the target value and used to run patient samples. The same patient samples were also run on the Bayer Centaur Free T3 assay. The Access primary reference calibrator values were then adjusted so that the two assays gave equivalent results. The primary reference calibrator set is stored in an ultra-cold freezer and used in the value assignment of the secondary reference calibrator sets.

d. Detection limit:
Not Applicable

e. Analytical specificity:
Not Applicable

f. Assay cut-off:
Not Applicable

2. Comparison studies:
    a. *Method comparison with predicate device:*
    Not Applicable
    b. *Matrix comparison:*
    Not Applicable

3. Clinical studies:
    a. *Clinical sensitivity:*
    Not Applicable
    b. *Clinical specificity:*
    Not Applicable
    c. *Other clinical supportive data (when a and b are not applicable):*
    Not Applicable

4. Clinical cut-off:
    Not Applicable

5. Expected values/Reference range:
    Not Applicable

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.