OCT 5 - 2004

K042651

Access Free T3 Calibrator
510(k) Summary

1.0 Submitted By:

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Chaska, MN 55318
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2.0 Date Submitted

September 27, 2004

3.0 Device Name(s):

3.1 Proprietary Names

Access® Free T3 Calibrators

3.2 Classification Names

Calibrator (21 CFR § 862.1150)

4.0 Legally Marketed Device

The Access Free T3 Calibrators claim substantial equivalence to the Beckman Coulter Access Ultrasensitive hGH Calibrators currently in commercial distribution, FDA 510(k) Number K003098.

5.0 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.

6.0 Intended Use

The Access Free T3 Calibrators are intended to calibrate the Access Free T3 assay for the quantitative determination of free triiodothyronine levels in human serum and plasma using the Access Immunoassay Systems.

7.0 Comparison to the Predicate

The Access Free T3 Calibrators and the predicate calibrator utilize the same test methodology specific to Access Immunoassay Systems. Each calibrator is intended for use in a different analyte test system. The Access Free T3 calibrators and the predicate calibrator are provided in a stabilized bovine serum albumin matrix. The predicate device contains somatropin (human growth hormone) while the Access Free T3 calibrator contains 3′, 3, 5-triiodothyronine. The Access Free T3 Calibrators are liquid stable while the predicate calibrator is lyophilized and requires preparation.

8.0 Summary of Performance Data

The Access Free T3 Calibrators have been demonstrated to be equivalent to the predicate product. Based on the results of the performance characteristics testing, these calibrator materials meet product claims and specifications.

Performance data from validation testing supports a finding of substantial equivalence to the Beckman Coulter Access Ultrasensitive hGH Calibrators already in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 5 - 2004

Ms. Valynda Machen
Senior Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Re: k042651
Trade/Device Name: Free T3 Calibrators on the Access Immunoassay System
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: September 27, 2004
Received: September 28, 2004

Dear Ms. Machen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042651

Device Name: Free T3 Calibrators on the Access Immunoassay Systems

Indications 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.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042651