

510(k) Summary of Safety and Effectiveness for the JUN - 2 2011

ADVIA Centaur® Calibrator 80

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

A. 510(k) Number: k103548

B. Date of Preparation: May 11, 2011

C. Proprietary and Established Names:
ADVIA Centaur® Calibrator 80

D. Applicant

Contact: Sandra D. White, MS, RAC
Sr. Regulatory Technical Specialist

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333 Coney Street
East Walpole, MA 02032

Phone: (508) 660-4553
(508) 660-4591 (fax)

E. Regulatory Information:

1. Regulation section:
21 CFR §862.1150 Calibrator, Secondary
2. Classification:
Class II
3. Product Code:
JIT
4. Panel:
75 – Clinical Chemistry

F. Predicate Device:

1. Device Name:
Siemens Healthcare Diagnostics (formerly Ciba Corning Diagnostics Corp.) ACS Calibrator B
2. Common Name:
Calibrator B
3. 510(k) Number:
k920372
4. Manufacturer:
Siemens Healthcare Diagnostics (formerly Ciba Corning Diagnostics Corp.)

G. Intended Use:

For *in vitro* diagnostic use in calibrating the ADVIA Centaur® Total IgE (tIgE) quantitative assay on the ADVIA Centaur system.

H. Device Description:

The ADVIA Centaur® Calibrator 80 is a 2 level human IgE in equine serum containing detergents and preservatives. All human source materials used in the manufacture of this product was tested by FDA-approved methods and found nonreactive for hepatitis B surface antigen (HBsAg), antibody to hepatitis C (HCV), and antibody to HIV-1/2. The Total IgE Calibrators have expected values of 35 and 1825 IU/mL.

The Calibrator 80 (2.0 mL/vial) is lyophilized. Storage for the lyophilized calibrators is at 2 - 8°C until expiration date specified on label, the reconstituted calibrator storage is at 2 - 8°C up to 60 days, and on board is up to 8 hours.

I. Substantial Equivalence Information:

1. Predicate device name: Siemens Healthcare Diagnostics (formerly Ciba Corning Diagnostics Corp.) Calibrator B
2. Predicate K number: k920372
3. Comparison with predicate:

Similarities		
Item	ADVIA Centaur® Calibrator 80 (New Device)	ADVIA Centaur® Calibrator B (Predicate Device)
Number of Levels	2	Same
Form	Lyophilized	Same
Matrix	Equine serum	Same
Total IgE Target Concentrations	Low Calibrator = 35 IU/mL High Calibrator = 1825 IU/mL	Same
Storage Temperature	2 - 8°C	Same
Differences		
Item	ADVIA Centaur® Calibrator 80 (New Device)	ADVIA Centaur® Calibrator B (Predicate Device)
Analytes	Single Analyte: Total IgE (tIgE)	Multi Analyte: Digoxin, FSH, Total IgE, LH LH2, Prolactin, Total hCG, TSH
Ingredients	After reconstitution, low or high levels of human IgE in equine serum, detergents and preservatives	After reconstitution, low or high levels of the analytes listed in <i>Intended Use</i> in equine serum with preservatives and protein stabilizers
Stability	Unopened – until expiration date on the vial label Reconstituted - 60 days On-board - 8 hours	Unopened – until expiration date on the vial label Reconstituted - 28 days On-board - 4 hours
Fill Volume	2 mL/vial	5 mL/vial

J. Performance Characteristics:

The traceability, value assignment, and stability of the ADVIA Centaur® Calibrator 80 have been validated following procedures of Siemens Healthcare Diagnostics.

K. Conclusion:

The ADVIA Centaur® Calibrator 80 is substantially equivalent to other products in commercial distribution intended for similar use. Most notably, it is substantially equivalent to the currently marketed Siemens Healthcare Diagnostics (formerly Ciba Corning Diagnostics Corp.) ACS Calibrator B (k920372).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Siemens Healthcare Diagnostics, Inc.
c/o Ms. Sandra D. White
Manager Regulatory Affairs
333 Coney Street
East Walpole, MA 02032

JUN 02 2011

Re: k103548
Trade/Device Name: ADVIA Centaur® Calibrator 80
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: April 25, 2011
Received: April 28, 2011

Dear Ms. White:

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 class II (Special Controls), 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice

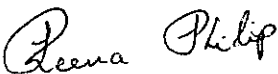
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requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of 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 advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


for Maria M. Chan, Ph.D.

Director

Division of Immunology and Hematology Devices

Office of *In Vitro* Diagnostic Device Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): k103548

Device Name: ADVIA Centaur® Calibrator 80

Indication for Use:

For *in vitro* diagnostic use in calibrating the ADVIA Centaur® Total IgE (tIgE) quantitative assay on the ADVIA Centaur system.

Prescription Use X

And/Or

Over the Counter Use _____

(21 CFR Part 801 Subpart D)

(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Deena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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