1.4 510(K) Summary

510(K) Summary

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.

510(k) Number ______________________ Date Prepared: May 13, 2003

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<tr>
<th>Submitter</th>
<th>Contact Person</th>
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<tbody>
<tr>
<td>Beckman Coulter, Inc</td>
<td>Lynn Weist</td>
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<tr>
<td>1000 Lake Hazeltine Drive</td>
<td>Staff Regulatory Affairs Specialist</td>
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<td>Phone: 952-368-1271</td>
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<td>Fax: 952-368-7710</td>
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General Information

<table>
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<tr>
<th>Proprietary Name</th>
<th>Access® Immunoassay System Toxo IgM II Assay</th>
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<tr>
<td>Classification Name</td>
<td>Toxoplasma gondii serological reagents</td>
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<td>Device Class</td>
<td>Class II</td>
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<tr>
<td>Legally Marketed (Unmodified) Device</td>
<td>Access Toxo IgM II Reagents for use on the Access Immunoassay System (K003259, cleared 6/13/01)</td>
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Device Description

The Access Toxo IgM II reagents consist of reagent packs, controls, QC, substrate and wash buffer.

Intended Use

The Access Toxo IgM II assay is a paramagnetic-particle, chemiluminescent immunoassay for the qualitative determination of Toxoplasma gondii-specific IgM antibody in adult human serum and plasma, using the Access Immunoassay Systems. The Access Toxo IgM II assay is presumptive for the diagnosis of acute, recent or reactivated Toxoplasma gondii infections in males and pregnant or non-pregnant females. It is recommended this assay be performed in conjunction with a Toxoplasma gondii-specific IgG antibody assay.
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Description of the Modification to the Legally Marketed Device

The modification to the Access Toxo IgM II reagents is to add a new instrument platform, the Beckman Coulter UniCel™ Dxl 800 Access® Immunoassay System, to the family of Access Immunoassay Systems. The Dxl System is a new model within the same model series of Access Immunoassay Systems manufactured and distributed by Beckman Coulter, Inc. The Dxl System was cleared for marketing by FDA on January 28, 2003, (K023764).

The Dxl uses the same Access Toxo IgM II reagents, controls and QC, packaged the same as for the Access 2 System. The formulations of the substrate and wash buffer used with the Access Toxo IgM II assay are unchanged. There are no changes to the intended uses, technical specifications or final performance specifications and claims for the assay.

Supporting Data

In order to demonstrate that the Access Toxo IgM II assay on the Dxl System is substantially equivalent to the Access Toxo IgM II assay on the Access 2 System, reproducibility and concordance studies were conducted. The Access Toxo IgM II assay met the established acceptance criteria for reproducibility and concordance. Method comparison (linear regression) using the concordance study data was completed and showed good correlation between the Dxl and Access 2 Systems.

Conclusion

The information provided in this submission supports a substantial equivalence determination, and therefore, 510(k) premarket notification clearance of the Access Toxo IgM II Reagents on the UniCel Dxl 800 Access Immunoassay System.
Ms. Lynn Weist  
Staff Regulatory Affairs Specialist  
Beckman Coulter, Inc.  
1000 Lake Hazeltine Drive  
Chaska, MN  55318-1084  

Re:  k031506  
Trade/Device Name:  Access® Toxo IgM II Reagents for use on the Access® Immunoassay Systems  
Regulation Number:  21 CFR 866.3780  
Regulation Name:  Toxoplasma Gondii Serological Reagents  
Regulatory Class:  Class II  
Product Code:  LGD  
Dated:  May 13, 2003  
Received:  May 14, 2003

Dear Ms. Weist:

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). Other general information on your responsibilities under the Act may be obtained 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
1.3 Indications for Use Statement

510(k) Number (if known): KD31506

Device Name: Access® Toxo IgM II Reagents for use on the Access® Immunoassay Systems

Indications for Use:

The Access Toxo IgM II assay is a paramagnetic-particle, chemiluminescent immunoassay for the qualitative determination of Toxoplasma gondii-specific IgM antibody in adult human serum and plasma, using the Access Immunoassay Systems. The Access Toxo IgM II assay is presumptive for the diagnosis of acute, recent, or reactivated Toxoplasma gondii infections in males and pregnant or non-pregnant females. It is recommended this assay be performed in conjunction with a Toxoplasma gondii-specific IgG antibody assay.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✔ OR Over-the-Counter Use (per 21 CFR 801.109)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) KD31506